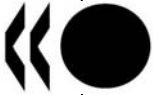


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NUCLEAR ENERGY AGENCY

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**Committee on the Safety of Nuclear Installations
Working Group on Fuel Cycle Safety**

**USE AND IMPLEMENTATION OF SAFETY CASES BY REGULATORS AND NUCLEAR SITE
OPERATORS ON FUEL CYCLE FACILITIES IN NEA MEMBER COUNTRIES**

JT00197316

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CSNI GROUP ON FUEL CYCLE SAFETY

The Group on Fuel Cycle Safety was created by the Committee on the Safety of Nuclear Installation in 1976. This is a joint regulator and industry organisation devoted to nuclear fuel cycle safety in the international community. The group has broad wide ranging interests covering topics which encompass the full scope of fuel cycle activities, including but not restricted to; safety assessments, nuclear criticality safety, probabilistic safety assessment, safety management, decommissioning and site remediation, fire protection and human factors as well as other wide ranging topics.

The main mission of Working Group on Fuel Cycle Safety (FCS) is to advance the understanding of relevant aspects of nuclear fuel cycle safety in Member countries. In pursuing this goal, the Working Group shall:

- meet to exchange information on relevant matters including licensing systems, safety philosophy and safety standards to improve mutual understanding,
- maintain a database on incidents involving fuel cycle facilities (FINAS),
- indicate where further research is needed,
- review and prioritise safety issues,
- prepare state-of-the-art fuel cycle safety reports, and
- collaborate with other groups as necessary.

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ABSTRACT

This report provides a usable collation of responses to the questionnaire. It provides information on the regulatory requirements for safety cases, and how regulators and operators address these requirements in the relevant Member Countries.

1. INTRODUCTION

The Workshop in Japan on “Safety in the Nuclear Fuel Cycle (1-2 October 2002)” identified differences in the requirements for, in the structure of, and the implementation of safety cases for fuel cycle facilities in a number of Member Countries. A proposal was developed, and accepted by CSNI, to identify and better understand the safety case requirements for fuel cycle facilities in Member Countries, to clarify any differences for the benefit of the fuel cycle community and to learn from the different approaches in the use of safety cases. A questionnaire was prepared as the means to collect the necessary information on safety cases.

The questionnaire was sent out to NEA Member Countries in 2004. Responses have been received from the following Member Countries, with contributions from the following individuals whose time and care in completing the questionnaire is very much appreciated:

Belgium:	Henri Drymael
France:	Gerard Fraize, Dorothee Conte and Jacques Aguilar
Germany	Karl Gelpke
Japan	Yoshinori Ueda
Spain	Jose Manuel Martín Calvarro; Fernando Zamora Martín
UK	Alec Bounds, Andy Buchan, Kenneth Percival, Peter Watson
USA	Robert C. Pierson

Further details of the respondents are given in Appendix 4. This state-of-the-art report has been collated from the above responses by Alec Bounds, BNFL, UK.

2. QUESTIONNAIRE

The purpose of the questionnaire was defined in the separate introduction to the questionnaire, which is reproduced in Section 4. In summary the purpose was:

- to better understand how safety cases impact on the management of safety on nuclear fuel cycle facilities;
- to collate information on the regulations in Member Countries and the requirements for safety cases;
- to collate information on the structure and implementation of safety cases in the different Member Countries

3. THIS STATE-OF-THE-ART REPORT

The purpose of this state-of-the-art report is to provide a usable collation of responses to the questionnaire. It provides a comparison of the regulatory requirements for safety cases, and how regulators and operators address these requirements in the relevant Member Countries.

- Appendix 1 presents the responses to Part 1 of the questionnaire on the operator
- Appendix 2 presents the responses to Part 2 of the questionnaire on legislation
- Appendix 3 presents the responses to Part 3 of the questionnaire on the regulatory body
- Appendix 4 presents the responses to Part 4 of the questionnaire, giving the details of respondents

This report neither makes a judgement on the adequacy of the relevant regulations on safety cases nor on the implementation of the requirements in the responding Member Countries.

Each individual completed questionnaire is available on request, if anyone wishes to read through an individual Member Country's completed questionnaire from start to finish. However, all the information in the completed questionnaires has been reproduced throughout the Appendices.

In addition to collating the actual responses, the collator has summarised the responses to each question. These *collator's comments* are reproduced in Table 2, which provides a five-page summary of responses to Parts 1-3 of the questionnaire.

Conclusions

The provision of safety cases is clearly a key feature of safety management systems in all responding countries. Section 5 provides a relatively brief summary of the questions and responses received. More useful detail on individual questions is given in the Appendices to this report.

The questionnaire has successfully met its purpose as defined in Section 2.

4. QUESTIONNAIRE

The Workshop in Japan on “Safety in the Nuclear Fuel Cycle (1-2 October 2002)” identified differences in the requirements for, in the structure of, and the implementation of safety cases for fuel cycle facilities in a number of Member States. Also from our discussions there was some confusion as to what “safety cases” are, their purpose and when they are required. A proposal was developed, and accepted by CSNI, to identify and better understand the safety case requirements for fuel cycle facilities in Member States, to clarify any differences for the benefit of the fuel cycle community and to learn from the different approaches in the use of safety cases. This Questionnaire has been prepared as the means to collect the necessary information on safety cases.

The term “safety case” may not be universally used or understood but is intended to encompass “the totality of documented information and arguments that substantiate the safety of the plant, activity, operation or modification in question. It provides a **written** demonstration that the proposed activity is adequately safe, that relevant standards have been met and that risks have been reduced to an acceptable level. In some regulatory systems of Member States there may be a specific definition as to what the “acceptable” level is. However this proposal was developed not to examine the technical content of safety cases but the processes that required the preparation and implementation of safety cases for fuel cycle facilities.

This Questionnaire has been developed as a means to exchange information between Members of the WGOE/FCS so that differences and similarities can be collated, enabling Member States to learn from current experience and make informed decisions as to the role safety cases should have in their own countries. The Questionnaire is about the safety case and associated processes; it is not about the detailed technical safety criteria or methods used within the safety case.

The objectives of the Questionnaire are:

- To better understand how safety cases impact on the management of safety on nuclear fuel cycle facilities;
- To collate information on the regulations in Member States and the requirements for safety cases;
- To collate information on the structure and implementation of safety cases in the different Member States;

Safety cases are fundamental to the safety of nuclear installations and “state of the art” information collated as part of a Workshop or in a published document would be invaluable to both regulators and operators. The approach to “safety justification” in Member States may be different and the aim of the proposal is to record these different approaches and to hopefully learn from this exchange of information. If there are differences in terminology that describe “safety cases, safety documentation etc”, hopefully these will be identified in the responses to the Questionnaire.

5. QUESTIONNAIRE AND SUMMARY OF RESPONSES

Questionnaire Questions and Summary of Responses

1. Operator

- 1.1. Are safety cases prepared for nuclear fuel cycle facilities? If not, go straight to Section 4.
- Collator's comment: All responding countries answered 'yes'.
- 1.2. Is the operator of nuclear fuel cycle facilities responsible for preparing safety cases for operations on the site? If yes, who are the operators?
- Collator's comment: The answer to the first question is 'yes' in every case. For the second question, see individual responses.
- 1.3. Does the operator prepare safety cases to its own pre-determined structure or to a structure prescribed by the regulatory requirements or the regulatory body?
- Collator's comment: In most responding countries, regulatory requirements are placed on safety case structure, either directly or indirectly through technical requirements. However, Belgium and the UK have stated that the operator typically has their own structure.
- 1.4. Where is the structure for safety cases prescribed?
- Collator's comment: Highly varied responses – see individual responses.
- 1.5. At what stages in a facility's life is a safety case required? If it is required, please enter whether the designer or operator is responsible.
- Collator's comment: There is significant variety in practices between responding countries. A safety case for option selection is not required by most responding countries, or for de-licensing. Most responding countries require a safety case at the design stage. All responding countries require safety cases at the following stages: operations, significant modifications to plant/equipment during operations, periodic review during operations and decommissioning.
- 1.6. What are the responsibilities for ownership, management and maintenance of safety cases?
- Collator's comment: Most responding countries stated that the operator is responsible. Germany emphasised the role of the 'supervisory authority'.

- 1.7. Does the operator have a process for obtaining approval of the safety documentation by the regulatory body? If so, what is the process? Does this approval have to be given prior to the activity being carried out?
- Collator's comment: All responding countries have an approval process, though not for the safety case itself – the project that the safety case supports is approved. For all responding countries, the approval does have to be given prior to the activity being carried out, but responding countries differ on which are the key stages at which this approval is required (see Question 1.5 response).
- 1.8. Does the operator have to carry out independent review of the safety case before the documents are submitted to the regulatory body?
- Collator's comment: Practice varies between responding countries on this issue – see individual responses.
- 1.9. What are the main features of a safety case prepared by the operators?
- Collator's comment: This question has generated a variety of answers. Belgium focussed on completeness of hazards; France focussed on justifications and on providing an input to technical specifications; Germany and Japan focussed on precautions/safety measures, Spain, the UK and the USA focussed on safety case structure.
- 1.10. What balance is given to probabilistic and deterministic safety arguments within the safety cases?
- Collator's comment: Most responding countries have safety cases which are mainly deterministic. Probabilistic safety assessment is used more for external hazards. There is also a development in Spain towards probabilistic safety assessment.
- 1.11. If periodic review is required during operations, at what frequency are reviews required? Are new safety case standards/methods fully applied at each periodic review?
- Collator's comment: 10 years is a common period for review/reassessment, but the content of the review differs between responding countries (see individual responses). In addition, the 10 year review is not in every country an absolute requirement of regulations or of the regulator.
- 1.12. Do safety cases for nuclear fuel cycle facilities address not only radiological and criticality issues, but also other safety issues such as chemotoxic and conventional safety?
- Collator's comment: In some responding countries the safety case only considers radiological and criticality issues (other safety issues being addressed via other legislation), but in other responding countries safety cases have a wider scope.

1.13. Does the safety case prescribe limits or constraints on operation? If so, how is the safety case implemented (how are these limits/constraints translated into real operations)?

- Collator's comment: While all responding countries have operator instructions containing limits/constraints from the safety case, some responding countries also use dedicated safety case documents, such as technical specifications, to help translate the limits/constraints from the safety case into real operations.

2. Legislation

2.1. Under what legislation is the safety of the nuclear fuel cycle regulated?

- Collator's comment: As expected, the responses are specific to each country – see individual responses.

2.2. Does the legislation require safety cases to be prepared? If so, what is the requirement? If not, go straight to Section 3 (Regulatory Body).

- Collator's comment: In most responding countries the legislation does not directly require the preparation of safety cases. However, the end result of the legislation in all responding countries is the preparation of safety cases, usually through the establishment of regulatory bodies which require safety cases.

2.3. Does the legislation specify which organisation is responsible for preparing safety cases?

- Collator's comment: For most responding countries, the responsible organisation is solely the operator; in Germany a wider range of organisations are responsible.

2.4. Does the legislation clearly identify at what stage during the lifetime of a facility the safety cases have to be prepared? If so what are the stages?

- Collator's comment: Requirements in most responding countries are for a few or several specific stages (see individual responses); in the UK the requirement applies to all stages.

2.5. Does the legislation require the regulatory body to approve safety cases before the activity being justified can be implemented?

- Collator's comment: In most responding countries, the answer is 'Yes'. The UK regulator clarified that it only approves safety cases for the more safety-significant projects.

2.6. Does the legislation require periodic review of the safety cases during the lifetime of the facility?

- Collator's comment: In some responding countries the requirement for periodic review is part of the legislation, usually ten years; in other responding countries the requirement is regulatory although it does not necessarily apply to all fuel cycle facilities. Two responding countries emphasised the requirement to keep the safety case live throughout the ten years.

2.7. Does the legislation identify the structure of safety cases? If so, what is the structure? If not, how is the structure specified?

- Collator's comment: For most responding countries the structure of the safety case is not identified in the legislation. In these cases the regulator and/or operators identify the structure.

2.8. Does the legislation require the regulatory body to approve or otherwise agree to safety cases submitted by operators of fuel cycle facilities? If so, what is the regulatory requirement?

- Collator's comment: Regulatory requirements vary – see individual responses.

3. **Regulatory Body**

3.1. Which organisation is responsible for regulating the safety of nuclear fuel cycle facilities?

- Collator's comment: As expected, the responses are specific to individual countries.

3.2. By what means does the regulatory body identify to the operator that safety documentation is required?

- Collator's comment: In general the answer for most responding countries is by rules, regulations, guidance documents and official letters.

3.3. If a licensing system is in place, does this licence identify the requirement for safety cases? If so, what is this requirement?

- Collator's comment: In some responding countries the requirement is within the licence; in other responding countries the licence is the means by which requirements elsewhere (e.g. regulations) are enforced.

3.4. Has the regulatory body prepared and issued any guidance on the purpose of a safety case? If so, what is the defined purpose?

- Collator's comment: Some responding countries have issued guidance on the purpose of safety cases which is publicly available.

3.5. Has the regulatory body prepared and issued any guidance on the structure of safety cases? If so, what is it?

- Collator's comment: Some responding countries have issued guidance on the structure of safety cases which is publicly available.

3.6. Has the regulatory body prepared and issued any guidance on quality standards for safety cases? If so, what are they?

- Collator's comment: Most responding countries have issued guidance – see individual responses.

- 3.7. Does the regulatory body carry out any technical assessment of the safety claims made in safety cases submitted by the operator? If so, give a brief description of the resources available and the scope of work carried out.
- Collator's comment: Regulatory (or associated) bodies do carry out this technical assessment in all responding countries – see individual responses for resources available.
- 3.8. Does the regulatory body use the safety cases to inform its decisions with respect to compliance with legal requirements? If so, how is this done?
- Collator's comment: Most responding countries answered 'yes' to the first question – see individual responses. The UK additionally noted a link between safety cases and the inspection regime.
- 3.9. How much technical resource within the regulatory body is available to carry out compared to regulatory site inspection activities?
- Collator's comment: Only a few responding countries provided a comparison between technical resource and site inspection – see individual responses.
- 3.10. Does the regulatory body use external independent technical reviewers to carry out the technical review of safety cases submitted by the operators of nuclear fuel cycle facilities?
- Collator's comment: Most responding countries do use external independent technical reviewers.

APPENDIX 1: RESPONSES TO QUESTIONNAIRE SECTION 1: OPERATOR

1.1 Are safety cases prepared for nuclear fuel cycle facilities? If not, go straight to Section 4.

Collator's comment: All responding countries answered 'yes'.

Belgium: Yes.

France: Yes

Germany: Yes

Japan: Yes. The safety of uranium fabrication facilities (including uranium enrichment facilities), MOX fuel fabrication facilities and reprocessing facilities is ensured by safety regulation at each stage from facility planning to facility decommissioning. The details of safety cases at each stage are shown in section 1.5. This framework is laid down by legislation.

The other answers in this document, i.e. from section 1 to 3, are also for uranium fabrication facilities (including uranium enrichment facilities), MOX fuel fabrication facilities and reprocessing facilities.

Spain: Yes, safety cases are considered. We are referring mainly to the next Spanish nuclear cycle facilities:

- Juzbado fuel element Plant
- Quercus mining decommissioning plant
- El Cabril storage intermediate radwaste plant

United Kingdom:

The UK offered a pre-amble before answering the first question. The two main operators of fuel cycle facilities in the UK are:

- British Nuclear Fuels plc (BNFL)
- United Kingdom Atomic Energy Authority (UKAEA)

Both operators have responded to Part 1 of the questionnaire. [Their separate responses are preserved in the following questions.]

BNFL: Yes

UKAEA: Yes, in common with any other nuclear operational/facility governed by the Nuclear Installations Act

United States: Yes, safety cases are prepared for nuclear fuel cycle facilities. These safety cases form the basis for the issuance of licenses to construct and operate these facilities. The requirement for a license is contained in the Atomic Energy Act and the implementing regulations of that act. These regulations are the Series 10 United States Code of Federal Regulations (CFR). The principal chapters within 10 CFR which relate to the safety case for fuel cycle facilities are:

Part 2 - Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders

Part 20 - Standards for Protection against Radiation

Part 40 - Domestic Licensing of Source Material

Part 70 - Domestic Licensing of Special Nuclear Material

Part 73 - Physical Protection of Plants and Materials

Part 74 - Material Control and Accounting of Special Nuclear Material

Part 76 - Certification of Gaseous Diffusion Plants

1.2 Is the operator of nuclear fuel cycle facilities responsible for preparing safety cases for operations on the site? If yes, who are the operators?

Collator's comment: The answer to the first question is 'yes' in every case. For the second question, see individual responses.

Belgium: Yes

Operators are: Belgonucléaire, FBFC, Belgoprocess.

France: Safety cases are needed before (see question 1.5) granting authorization of creation, active commissioning and shutdown of any nuclear fuel cycle facility.

During operation, dedicated safety cases have to be prepared by the operator prior to changes in operation conditions that could impact the approved safety parameter or technical specification. Typical circumstances are:

- Modification of feed materials characteristics (burn-up, enrichment, type or specific activity of waste, etc),
- Modification of operating conditions (significant modification in the process, throughput increase, effluent or waste management techniques),
- Corrective maintenance (e.g. specific intervention on a process equipment which is not mentioned in the initial safety documentation and that could impact the plant safety or radioprotection),

Similar procedures are also applied when:

- Operating experience shows that the observed characteristics do not comply with the limits resulting from the initial safety case. (Concentration, activity, dose rate, etc.)
- Operating experience derived from incidental situations illustrate significant deficiencies or inaccurate parameters in the initial safety cases,
- Facility shut-down requires specific process or equipment implementation for draining, rinsing, cleaning, decontaminating or removing parts of the facility.

Such safety cases are submitted to the regulator for expert review and approval. The corresponding process is presented in item 1.7

For minor modifications or interventions, “internal” safety cases are prepared and approved in compliance with operator’s internal procedures. The regulator periodically inspects the corresponding internal procedures, lists and content of such safety cases.

In France, all the nuclear operators are submitted to the same regulations, the different categories of operating entities are:

- National agencies (e.g. Atomic Energy Commission, national laboratories, National Agency for waste management),
- State-owned industrial entities such as AREVA or EDF,
- Private entities, (which operate irradiators for example.)

The regulatory framework for nuclear fuel activities is independent on the type and size of the responsible entity (operator). It only depends on the involved level of nuclear radioactivity.

The different categories of facilities and the corresponding regulations are commented in question 1.5.

Germany: Yes

- URENCO – Gronau (fuel enrichment, 1800 MSWU/year)
- ANF – Lingen (fuel fabrication, 500 tHM/year)
- WAK – Karlsruhe (reprocessing plant in decommissioning)
- Several stores for spent fuel and radioactive waste

Japan: Yes. According to the legislation, the responsibility for preparing safety cases lies in the operator. The license holder of a facility is the operator of the facility.

Spain: Yes, in every installation there is a qualified staffs. This is the people who can prepare or modify safety cases. Some of them have licences granted by the regulatory body, these kinds of licences are essential to operate the installations.

The operator of our facilities are:

- ENUSA Industrias Avanzadas, SA for Juzbado and Quercus.
- ENRESA for El Cabril.

United Kingdom:

BNFL: Yes. See Question 1.1

UKAEA: It is the Licensee who is responsible. This is the organisation that holds the Nuclear Site Licence. The Licensee is invariably the Operator. The Site Licence requires suitable arrangements for the production of safety cases.

United States: The operators are responsible for preparing the safety case for operations on the site. Our current fuel cycle facility operators, or applicants to conduct operations, under 10 CFR Part 70 unless otherwise noted, include the following:

Uranium fuel fabrication facilities

1. BWX Technologies, Lynchburg, VA
2. Nuclear Fuel Services, Inc., Erwin, TN
3. Framatome Fuels, Lynchburg, VA
4. Framatome ANP Richland, Inc., Richland, WA
5. Global Nuclear Fuel Americas, LLC, Wilmington, NC
6. Westinghouse Electric Co, LLC, Columbia, SC

Uranium Hexafluoride Production Facility (Licensed under 10 CFR Part 40)

Honeywell International Inc., Metropolis, IL

Gaseous Diffusion Enrichment Facilities (which are certified under 10 CFR Part 76)

1. U. S. Enrichment Corporation, Paducah, KY
2. U. S. Enrichment Corporation, Portsmouth, OH

Proposed Mixed Oxide Fuel Fabrication Facility

Duke Cogema Stone & Webster, Aiken, SC

Proposed Gas Centrifuge Enrichment Facilities

1. LES, Eunice NM
2. USEC, Piketon, OH

1.3 Does the operator prepare safety cases to its own pre-determined structure or to a structure prescribed by the regulatory requirements or the regulatory body?

Collator's comment: In most responding countries, regulatory requirements are placed on safety case structure, either directly or indirectly through technical requirements. However, Belgium and the UK have stated that the operator typically has their own structure.

Belgium: Own structure, not prescribed by regulatory requirements but agreed by the regulatory body.

France: The applicable general regulations do not prescribe any detailed structure for the documentation. Nevertheless, they precisely describe the different steps of the project that are submitted to authorization and the type of information to be provided for each of them. (Impact study, Safety report, test reports, etc.). They also prescribe that all the risks involved in the construction and operation of the planned facility must be listed and assessed, prevention and mitigation dispositions must be described and potential consequences must be presented.

More detailed technical regulations such as "Basic Safety Rules" provide, for the different risks (criticality, earthquake, fire, etc), general safety objectives, implementation guidelines for design and operation.

The safety cases address the identified internal and external risks (fire, earthquake, aircraft crash, flooding, criticality, personal exposure to radiation, containment rupture, human and organizational factors, etc) in reference to the defence in depth principle and the corresponding BSR. The level of detail is of course depending on the project stage. (See 1.5)

In addition, the project has to take into account the regulations related to conventional industrial security (electrical standards, workers security, etc.).

Furthermore, the regulator has issued guidelines for the contents of the safety documents (Safety reports, General Operating Rules, Emergency plans, etc.)

For example, the standard practice is to divide the final SAR in three parts:

- Volume A: Description of the facility (layouts, Process and Instrumentation Diagram, etc.),
- Volume B: Safety assessment for the relevant risks,
- Volume C: (issued after a period of active operation) presents a complete view of the operation experience feedback including: process performances, active test results, observed workers doses, observed incidents, observed releases and waste generation, etc.

Detailed documentation has to be submitted to independent expert technical review. The review processes at the different stages generate technical observations and recommendations, so the further safety cases have to address these raised issues. (See 1.5)

Germany: The rough structure is given by requirements of the legislation.

Japan: The structure of establishment license (business designation) application documents, application documents for approval of design and construction methods and safety operational rules are described in the respective sets of business rules (Rules for Spent Fuel Reprocessing Business, Rules for Nuclear Fuel Material Processing Business, etc.) under the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors, and therefore these are applied.

Because governmental examination of the establishment license (business designation) applications is carried out based on the Safety Examination Guidelines, the details in application documents draw on the Guideline in many cases.

Spain: The most of the safety cases are prepared following the Spanish nuclear legislation and regulatory body requirements.

Nevertheless it is possible to find safety cases following a own pre-determine structure from the operator.

United Kingdom:

BNFL: BNFL has its own pre-determined structure, which was developed in consultation with the regulatory body, but remains BNFL's.

UKAEA: All UK Licensees have their own format for the various types of safety cases. Most are very similar in form due to Regulator (NII) expectations and cross industry comparisons.

United States: The operator prepares safety cases as required by the regulations as delineated above. The regulatory body, the NRC, also has available a Standard Review Plan which describes the contents or requirements for an acceptable method of meeting the safety case. If the operator, or licensee, chooses to provide an alternative structure for the safety case, which meets the regulation, but which does not adhere to the guidance described in the standard review plan, then the operator must provide the technical justification for this alternative approach.

1.4 Where is the structure for safety cases prescribed?

Collator's comment: Highly varied responses – see individual responses.

Belgium: Not prescribed.

France: As detailed in item 1.3, the general content of the safety cases is prescribed in the general regulations, more detailed guidelines related to both structure and technical issues are issued by the Safety Authority.

Germany: For the Safety Report in the „Nuclear Licensing Procedure Ordinance“ (Verordnung über das Verfahren bei der Genehmigung von Anlagen nach §7 des Atomgesetzes - AtVfV).

Japan: As described in section 1.3, the structures for safety cases are prescribed in the document on business rules (the legislation they fall under is the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors and the Enforcement Ordinance of the Law). The structures for safety cases can also draw on the Safety Examination Guidelines.

Spain:

In Legislation

- The main standard Spanish rule is the Basic law about nuclear energy issued in 1964, which after is developed in several rules and regulations.
- In the Spanish legislation, the government grants permissions to operate this installation. To obtain this permission or licence the operator has to present the safety case.
- For these permissions CSN establishes the conditions which's must follow the different installations.
- In addition to the licence CSN may issue Instructions and Resolutions, which affect the fuel cycle facilities.
- CSN can issue Complementary Technical Instructions during the operation life of facility due to new rules, deviations, findings during inspections practices, and so on.

United Kingdom:

BNFL: BNFL prescribes the structure within its UK Environmental Health & Safety Manual.

UKAEA: In UKAEA Corporate Procedures.

United States; The regulatory requirement which is the general safety standard to be met is contained in the regulations listed above. The principle safety regulation for fuel cycle facilities, 10 CFR Part 70, has the following Standard Review Plan guidance available for implementing the regulation.

NUREG -1520, AStandard Review Plan for the Review of a License Application for a Fuel Cycle Facility≅

NUREG- 1718, AStandard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility≅

1.5 At what stages in a facility's life is a safety case required? If it is required, please enter whether the designer or operator is responsible:

Collator's comment: This question basically consisted of several sub-questions, so the responses have been divided into each plant life stage.

As an overall comment, there is significant variety in practices between responding countries. A safety case for option selection is not required by most responding countries, or for de-licensing. Most responding countries require a safety case at the design stage. All responding countries require safety cases at the following stages: operations, significant modifications to plant/equipment during operations, periodic review during operations and decommissioning.

1.5.1 Safety Case for Option Selection

France: The corresponding safety document is optional. The major operators generally prepare such a document as it allows an early discussion on the main safety options to be taken into account for the project.

The document is based on Preliminary design studies and provides:

- The general features of the planned project, the major safety objectives, (doses limits considered for design, site characteristics and impact of the project, etc.),
- The considered safety principles (e.g. number of containment barriers).
- Methodologies to be applied for demonstrating the safety of the plant in reference to the design stage, applicable regulations, and standards.
- Design basis for safety principles implementation: detailed list of considered risks and associated parameters, implementing conditions of the corresponding BSR, major safety parameters to be considered in the further safety cases,
- Preliminary but sufficient information on the design which demonstrate that the safety objectives can be met by the project.

Spain: None

United Kingdom:

BNFL: Designer, but operator retains overall responsibility

UKAEA: Preliminary Safety Report

1.5.2 Safety Case at Design Stage

Belgium: Yes

France: The creation of a new facility (BNI) requires a specific decree. The operator's request is based on technical documents that provide a description of the project based on Detailed Design studies:

- 1) A Preliminary Safety Assessment Report (PSAR); which presents:
 - A description of the project (process steps, throughputs, layouts, buffer and final storage capacities, effluents and waste estimates and management option, Process and Instrumentation Diagrams)
 - Detailed methodologies to be applied for demonstrating the safety of the plant in reference to defence in depth principle, the detailed list of the risk and the different process units' design.
 - Design basis for safety principles implementation: Safety parameters and acceptance criteria to be considered in the further safety cases, construction and QA standards to be applied to the different equipment (mechanical, electrical, software) in reference to their significance for safety.
- 2) Documents to be submitted to a public inquiry and an expert review:
 - An Environmental Impact Statement (EIS),
 - A "Risk assessment" report ("Etude de dangers"), which describes the risks, involved in the project, the potential consequences and the protection and mitigation arrangements.
- 3) A detailed QA plan

These documents are reviewed by the TSO and submitted to an expert the Standing Group, which provides the regulator with technical advices and recommendations.

The regulator endorses the recommendations and submits the creation decree to the signature of the three ministers of Industry, Environment and Health.

The decree stipulates the major safety related data such as, authorized releases limits, type and characteristics of the feed products, capacities and other specific obligations.

Japan: Establishment license (business designation) application shall be approved. The operator is responsible for it.

Application of design and construction methods shall be approved. The operator is responsible for it.

Spain: The operator

United Kingdom: BNFL: Designer, but operator retains overall responsibility

1.5.3 Safety Case for Pre-construction

France: No specific document is required at this stage. Construction of equipment, final design studies and qualification or test activities are audited and inspected

Japan: Application of design and construction methods shall be approved. The operator is responsible for it.

Spain: The operator

United Kingdom:

BNFL: Designer, but operator retains overall responsibility

UKAEA: Pre Construction Safety Report

1.5.4 Safety Case for Construction

France: No specific document is required at this stage. Construction of equipment, final design studies and qualification or test activities are audited and inspected

Germany: Designer

Japan: Application of design and construction methods shall be approved. The operator is responsible for it.

About welding inspection; normally the work executor of welding requests it and gets the approval.

The operator cannot use the part of the facility, which includes the welding portions to be inspected, without the approval of welding inspection.

Spain: Operator

United Kingdom: BNFL: Designer, but operator retains overall responsibility

United States: The facility must have approved an operating license or a construction authorization in order to commence construction. These approvals are the responsibility of the operator.

1.5.5 Safety Case for Manufacture of plant/equipment

France: No specific document is required at this stage. Construction of equipment, final design studies and qualification or test activities are audited and inspected

Germany: Designer

Japan: Application of design and construction methods shall be approved. The operator is responsible for it.

Spain: the operator (process included in Construction)

United States: A license or safety case is not required unless prescribed by the operator's safety case, in which case the provisions implemented by the manufacturer would be commitments in the operator's application/license and these commitments would be inspected by the regulator. An example would be a commitment to a certain quality assurance program for construction of some safety related equipment.

1.5.6 Safety Case for Installation of plant/equipment

France: No specific document is required at this stage. Construction of equipment, final design studies and qualification or test activities are audited and inspected

Germany: Designer/operator

Japan: Application of design and construction methods shall be approved. The operator is responsible for it.

Spain: the operator (process included in Construction or Modifications)

United Kingdom: BNFL: Designer, but operator retains overall responsibility

United States: Typically special provisions are not required and when required are normally contained in the operating license or construction authorization although in some cases additional installation specific commitments may be made, as an example the installation of a barrier or shield to protect against the introduction of moderator within the process area.

1.5.7 Safety Case for Inactive commissioning

France: There is no specific authorization procedure for granting inactive commissioning.

In parallel to inactive commissioning, the operator has to provide the regulator with information based on the "as build" documentation:

A Provisional Safety Report, which presents all the detailed safety justifications as specified in the PSAR and address the still pending questions raised during the previous project phases,

- A Complete documentation on QA implementation during the construction phase,
- The operator's emergency plans,

- The General Operating Rules.
- These documents support the authorization request for active commissioning.

Germany: Designer/operator

Japan: Application of pre-service inspection shall be approved before starting use of the facility. The operator is responsible for it.

Spain: The operator

United Kingdom:

BNFL: Designer, but operator retains overall responsibility

UKAEA: Pre-commissioning safety report

1.5.8 Safety Case for Active commissioning involving radioactive material

Belgium: Yes

France: The Technical Support Organization performs complete and detailed reviews of the above-mentioned documentation.

In addition, the operator has to provide the regulator with the inactive test results.

The technical remarks and recommendations derived from these reviews are submitted to the Standing group, which gives a final advise before the regulator's decision about the active commissioning.

Germany: Operator

Japan: Application of pre-service inspection shall be approved before starting use of the facility. The operator is responsible for it.

Application of safety operational rules (for items related to active commissioning) shall be approved. The operator is responsible for it.

Spain: The operator

United Kingdom: BNFL: Operator

United States: Granted with the operating license. Additional inspection measures if required are placed as conditions within the license.

1.5.9 Safety Case for Operation

Belgium: Yes

France: After some years of active operation, updates of the General Operating Rules, Safety Assessment Report and Emergency plans are transmitted to the regulator and reviewed. These updates present the operating experience and demonstrate that the safety related parameters derived from the safety cases are correctly implemented and that the operating experience is consistent with them.

These updated documents (including Appendix C see 1.3) are reviewed for granting the definitive authorization for operation.

Germany: Operator

Japan: Application of safety operational rules shall be approved. The operator is responsible for it.

Spain: the operator

United Kingdom: BNFL: Operator; UKAEA: Operational Safety Report

United States: Operating license is submitted by the operator and approved by the regulator.

1.5.10 Safety case for Modifications to plant/equipment during operations

Belgium: Yes

France: See question 1.2

Germany: Operator

Japan: When items of modification are those approved in an establishment license application or a design and construction methods, before the implementation of modification, changes of establishment license application or design and construction methods shall be approved. Also, changes of safety operational rules due to the modification shall be approved.

The operator is responsible for them.

Spain: the operator

United Kingdom: BNFL: Operator; UKAEA: Plant modifications

United States: If a modification affects the safety basis of the license then the safety case for the modification must be approved by the regulator.

1.5.11 Safety Case for Periodic review during operations

Belgium: Yes

France: See question 1.11

Germany: Operator

Japan: See question 1.11

Spain: the operator

United Kingdom: BNFL: Operator; UKAEA: 10 year periodic reviews

United States: licenses issued must be renewed every 10 years.

1.5.12 Safety Case for Shutdown prior to decommissioning

Belgium: Yes

France: Prior to final shutdown, the operator must provide the Regulator with a detailed D&D plan including:

- Technical descriptions of the different D&D phases (the level of detail of course depends on the phase schedule),
- The estimated schedules of D&D,
- The impact of the planned operation on the applicable safety cases and the subsequent additional safety cases. Specific attention is of course paid to the waste management and radioprotection issues.
- Surveillance plans adapted to the different phases of the D&D
- The subsequent emergency plans.

The D&D program is considered as a project; so, specific a decree is required. It involves the same procedures as for construction including public inquiries.

Germany: Operator

Japan: Application of safety operational rules shall be approved if necessary.

The operator is responsible for it.

Spain: the operator

United Kingdom: BNFL: Operator

1.5.13 Safety Case for Decommissioning

Belgium: Yes

France: Specific operations or unexpected events can give raise to dedicated safety cases and authorizations.

Germany: Operator

Japan: The plan related to de-licensing activities (decommissioning, de-contamination, and disposal of contaminated materials, etc.) shall be approved. The operator is responsible for it.

Spain: the operator

United Kingdom: BNFL: Operator; UKAEA: Decommissioning Safety Report

United States: A decommissioning plan must be approved by the regulator.

1.5.14 Safety Case for De-licensing

France: If the operator has chosen a complete D&D and does not plan any re-use of some part of the facility. The complete decontamination is performed and reviewed and the facility can be de-licensed.

Japan: When planned de-licensing activities are completed, it shall be approved that the result conforms to the standard defined in the ministerial ordinance. The operator is responsible for it.

Spain: None

United Kingdom: BNFL: Operator

1.5.15 Other comments on this question

France:

- 1) There are several categories of nuclear facilities. The above items describes applicable procedures for BNI (“Basic Nuclear Installation”), this category includes all the main facilities involved in the fuel cycle. If the considered radioactivity is below a defined threshold, the facility is called “ICPE” (handling of depleted uranium, small sources, etc) and depends on specific regulations.
- 2) The operator is fully responsible for all the mentioned documents and the corresponding activities. In case of sub contract for part of the activities involved in a nuclear project, the operator’s obligation is to provide its subcontractors (designer, engineering, construction, etc) with relevant requirements on all the safety and QA related aspects (e.g. design code qualification). The regulator can perform checks and audits of all the contracts and exchanged documentation (QA plans, internal procedures, etc) and of the sub contractors practices.

United Kingdom: BNFL: Design team is part of BNFL, and may contract out work packages to contractors, while retaining overall responsibility for the design. Design team may help operator to prepare the safety case for major modifications and decommissioning.

1.6 What are the responsibilities for ownership, management and maintenance of safety cases?

Collator’s comment: Most responding countries stated that the operator is responsible. Germany emphasised the role of the ‘supervisory authority’.

Belgium: The operator is responsible for all aspects.

France: The operator is fully responsible for the preparation and submission of all the documentation. Moreover, it is fully responsible of the safety of its facilities. The regulator defines the major safety objectives (typically doses to the public and the workers) and control that the operator acts in consistency with these regulations and the commitments mentioned and approved in the safety documentation. The regulator is supported by an independent technical entity in charge of expertise in safety and radioprotection.

Germany: From the start of construction to the end of decommissioning with the corresponding licenses and safety cases, nuclear installations are subject to continuous regulatory supervision in accordance with

the Atomic Energy Act and related nuclear ordinances. In particular, it is the duty of the supervisory authority to monitor the safety cases to correspondence with:

- the provisions, obligations and ancillary provisions imposed by the licensing notices,
- the nuclear ordinances and other nuclear safety standards and guidelines, and
- the performance of in-service inspection of systems important to safety.

Japan: The operator is responsible for owning, managing and maintaining safety cases and obeying them.

Spain: The operator is responsible for those activities. The operator has to develop a Quality Assurance Programs that considers for every installation:

- how safety cases must be controlled and kept in the installations,
- how this operational official documents must be distributed,
- how this documents can be modified.

United Kingdom: BNFL: The operator is responsible for ownership, management and maintenance of safety cases. Within each operational facility, a safety case owner is appointed, who is responsible for management and maintenance of the safety case.

UKAEA: It differs between Licensees. Most UK Licensee's have a Safety Department who produce safety cases in conjunction with operations or projects. Operators are responsible for compliance with the limits and conditions of a safety case.

United States: Most licensees or operators of fuel cycle facilities have a licensing department which is responsible for ensuring that the safety case is maintained. The regulator also routinely inspects the facility against the license to ensure that the safety case is current and valid.

1.7 Does the operator have a process for obtaining approval of the safety documentation by the regulatory body? If so, what is the process? Does this approval have to be given prior to the activity being carried out?

Collator's comment: All responding countries have an approval process, though not for the safety case itself – the project that the safety case supports is approved. For all responding countries, the approval does have to be given prior to the activity being carried out, but responding countries differ on which are the key stages at which this approval is required (see Question 1.5 response).

Belgium: Yes, there is a process.

The approval has to be given prior to the activity being carried on.

Safety documentation is established by the operator or its technical support organisation.

This documentation is reviewed by the authorized inspection organisation (like AVN) which transmits a report to the Scientific Committee of the Federal Agency for Nuclear Control (FANC). The positive advice of this Scientific Committee permits the FANC to give authorisation to the operator to carry out the activity.

France: For the main milestones of the project such as design, construction, commissioning, safety re-assessment, final shut down, dismantling; the operators have to provide the regulator with safety related documentation. An expert Technical Support Organization (IRSN) reviews these documents. The Standing Group that provides the regulator with a set of technical recommendations assesses the conclusions of these reviews. Based on this information, the regulator gives instructions to the operator (authorization, additional information requirements or modifications of the project).

The review procedure that involves the Standing Group is implemented for the major milestones of the project such as creation decree, active commissioning, major modifications and shutdown. Safety documentations related to minor modifications, operation reporting and incidental situations are transmitted to the regulator and to the TSO and reviewed by the TSO upon regulator's request.

The regulatory framework also prescribes audits and inspections.

The operator can initiate the design and pre-construction without any formal authorization. Construction is authorized after the signature of the creation decree. Active commissioning requires an authorization from the regulator. This authorization is given after approval of all the safety documentation and a dedicated meeting of the Standing Group that assess the effective implementation of the recommendations. (See 1.5)

Germany: For all activity should be carry out the safety documentation has to be described from the operator before he get the approval from the regulatory body to start the work.

Japan: There is a legislation-based process in each stage (stage-specific safety regulations). (For details of each stage, see question 1.5.) The operator shall obtain approval before proceeding to the next stage.

Spain: The regulatory body don't approve the safety case itself . It approves different processes (construction, operation, modifications, decommissioning, etc..) which have to be supported by a safety case.

Independently of the regulatory approval process the operator will have implemented procedures for approving the safety cases in advance to be submitted to the regulatory body. In addition any modifications in whatever documentation or procedure related with nuclear safety or radiological protection must by analysed and approved by internals committees at the installation.

Some minor modifications in this documents can be done by the operator itself, nevertheless a new approval by CSN and in some occasion by the regulatory body is required for the majority of the modifications on safety documentation, prior they to be implemented.

United Kingdom: BNFL: The regulatory body requires safety cases to be approved prior to key stages such as construction, active commissioning, and operation and for major changes to operational facilities. BNFL has processes to align with this regulatory requirement, to ensure that adequate time is given for regulatory scrutiny of the safety case, to ensure as far as possible that project delays are minimised.

UKAEA: Plants are categorised re safety significance. Category 1 and 2 are regulated internally and by the Regulator (NII). Lower Categories 3 are regulated by the Licensee.

United States: Yes the operator submits a request for approval to operate a new facility or modify an existing facility (where the modification affects the safety basis or introduces a new process) and provides with that request sufficient basis to demonstrate the safety case to the regulator. The regulator then reviews the submitted request and independently confirms that the safety case has been met. The regulator then issues a Safety Evaluation Report and license amendment to allow the operator to make the change. The approval for the change must be made prior to the activity being carried out.

1.8 Does the operator have to carry out independent review of the safety case before the documents are submitted to the regulatory body?

Collator's comment: Practice varies between responding countries on this issue – see individual responses:

Belgium: Yes, a review has to be done by the “Health Physics Department” of the operator or by the authorized inspection organisation.

France: Yes; Prior to the transmission to the regulator, the documentation is prepared in accordance with operator's internal procedures. These procedures are also applicable for internal (that do not require any review and approval) documentation such as routine operation procedures.

The operator's internal procedures and organization must comply with the general regulations related to QA and safety (10 August 1984 decree). They have to be presented to the regulator in the first phases of the project. They are submitted to audit and inspections.

This decree prescribes that independent internal reviews must be achieved.

More specifically, these regulations clearly stipulate the need for entities in charge of safety and QA for design control, internal reviews dedicated procedures for safety documentation preparation. Specific attention is paid to the exclusive use of qualified computer codes for all the safety cases.

The operator's procedures and practices related to the relations with sub contractors must also be defined in accordance with the regulation. They must implement the operator's general obligations for application of the relevant QA standards to the sub-contracted activities

For the operation phase, these regulations stipulate the need for entities in charge of safety control and radioprotection in the organization.

Germany: If the designer and operator have the special know how it is not necessary. An independent review of the safety cases mostly will be commissioned from the regulatory body. These expert organisations prepare reports outlining whether or not the requirements regarding nuclear safety and radiation protection have been met; but they do not have decision-making authority.

Japan: There are no legal requirements of the independent review. The operator carries it out voluntarily.

Spain: This review it is not required.

United Kingdom: BNFL: Yes, Independent Nuclear Safety Assessment is a fundamental part of the safety case production process. In addition, a Management Safety Committee considers the safety case.

UKAEA: Yes we have internal requirements for document verification and approval. In addition, depending on Category, safety cases are submitted to a Safety Working Party or the Nuclear Safety Committee; both have external members.

United States: The operator has to ensure that the submittal is accurate and factual. There is no specific requirement that operators conduct an independent review of the safety case prior to submittal to the regulatory body.

1.9 What are the main features of a safety case prepared by the operators?

Collator's comment: This question has generated a variety of answers. Belgium focussed on completeness of hazards; France focussed on justifications and on providing an input to technical specifications; Germany and Japan focussed on precautions/safety measures, Spain, the UK and the USA focussed on safety case structure.

Belgium: Features of safety cases depend on the installation/operator.

Safety cases should cover internal events (incidents or accidents which depend on the type of the installations) and external events (earthquake, airplane crash, ...).

France: During the design phase, safety cases generally aim at:

- Providing a complete justification that the proposed design comply, for each of the selected risks with the defence in depth principle, the corresponding BSR and the safety objectives defined and approved during the early stages of the project.
- Providing a consistent set of parameters and requirements to be used as a basis for the elaboration of the technical specifications of the facility.

Safety cases are based on deterministic approaches. The considered event is postulated and characterized by a set of bounding assumptions (earthquake intensity, maximal mass, maximal concentrations, flammable materials quantities, etc). The robustness of the design is assessed in reference to approved technical acceptance criteria. (See question 1.10).

The case can be made on generic design standards if the facility contains a lot of similar type of equipment; if so, the bounding assumptions are more conservative and the final assessment of the concerned process units must ensure that the assumptions are satisfied.

The case also requires auxiliary assumptions (response time, component resistance, etc.). The correspondence between these assumptions and the applied construction standards is reviewed.

Operating technical specifications (General Operating Rules) for operation, maintenance or training are derived from these results including appropriate margins

The emergency plans are based on major accidents studies.

Germany: Precautions against damage caused by the erection and operation of the facility in accordance with the state of the art in science and technology, including an explanation of the measures taken to prevent or mitigate the consequences of accidents not covered by the design of the facility and their tasks.

Japan: A main feature is that the measures to secure safety are stipulated in a stage-specific manner. (On details of each stage, see question 1.5.)

Spain: It follows a structure determined into the regulation. In general the basic components of the safety case are:

Safety Analysis.

Technical Specifications.

Operating Rules.

Radiation Protection Manual.

Quality Assurance Program.

Fire Protection Manual.

Inside Emergency Plan

Normally each safety case has a specific treatment by the CSN and by the regulatory body.

United Kingdom:

BNFL: The main headings in a BNFL safety report are typically:

- A Introduction
- B Process and plant description and safety philosophy
- C Operational safety prediction(/review)
- D Safety assessment summary
- E Engineering substantiation
- F Overall ALARP (As Low As Reasonably Practicable)
- G Conclusions

The safety report is typically a document less than 200 pages long, which summarises a wider safety case typically thousands of pages long.

Safety assessments and engineering substantiation are carried out by departments in BNFL independent of the operating unit.

UKAEA:

Introduction, summary of limits and conditions, summary of safety case.

Plant Description

Management of Safety

Operational Review

Safety Assessment

Engineering Substantiation

ALARP Review and documentation

United States: In most cases the safety case will follow the guidelines specified in the Standard Review Plan. The Standard Review Plan guidelines suggest that the following areas be addressed:

- Facility and Process Description
- Institutional Information
- Site Description
- Organization and Administration of the Facility conducting the operations
- Integrated Safety Analysis
- Radiation Protection
- Nuclear Criticality Safety
- Chemical Process Safety
- Fire Safety
- Emergency Management
- Environmental Protection
- Decommissioning
- Management Measures

1.10 What balance is given to probabilistic and deterministic safety arguments within the safety cases?

Collator's comment: Most responding countries have safety cases which are mainly deterministic. Probabilistic safety assessment is used more for external hazards. There is also a development in Spain towards probabilistic safety assessment.

Belgium: Mainly deterministic.

Probabilistic safety arguments are used for example in the case of external accidents (airplane crash).

France: The justification of safety is based on deterministic approach.

There is no use of any systematic approach based on probability/consequences graphs. Each risk is considered separately; a defined set of combination of risks is also considered (e.g. earthquake and electric shutdown).

For the considered risks, the safety cases must demonstrate that acceptance criteria are satisfied. The acceptance criteria are generally technical criteria and not calculated consequences. The selection of these acceptance criteria including appropriate margins limits the impact of uncertainties on consequences evaluations and provides adequate overall safety margins.

For example; the safety case of a fission product storage cooling system demonstrate that the design ensures the temperatures of the containment materials are kept below a defined value even under Design Basis Accidental circumstances (earthquake, equipment failure, etc). The calculations are based on conservative and bounding parameters. Critical redundant systems are assessed using reliability assessments based on probabilistic calculations.

Estimates of released fractions are made for Design Basis scenarios in order to validate the relevance of the design.

However, some safety cases related to specific risks include some probabilistic features (e.g. risk of external flooding). The corresponding situations are categorized based on their occurrence frequencies. The higher frequencies, as defined in the BSR, are taken into account as design basis accidents, they are then considered in the safety cases.

For such risks, the BSR states that the probability of accident must not exceed $1E-E7$.

Unlikely and highly unlikely scenarios are considered as Beyond Design Scenarios.

Germany: Mostly deterministic.

Japan: Quantitative probabilistic safety arguments are not required in the safety cases.

Spain: Until now deterministic safety arguments are only considered in safety cases.

Juzbado fuel facility has been required very recently to do an Integrated Safety Analysis (ISA) within the Safety Periodic Revision plant.

ISA methodology considers the probabilistic ones.

United Kingdom: BNFL: There is a strong preference for deterministic safety, but this is not fully achieved. Where significant consequences are not ruled out deterministically, analysis of defence in depth is carried out, as well as a qualitative analysis of risk. Where the risk is judged to be potentially high, a quantitative probabilistic safety assessment is carried out.

UKAEA: The main thrust of the safety case is deterministic. This is supported by PSA, for design basis accidents and where judged appropriate. The emphasis is on demonstrating engineering and procedural barriers to faults.

United States: The applicable regulation is a performance based risk informed regulation. Either probabilistic or deterministic safety arguments can be used to support a safety basis.

1.11 If periodic review are required during operations, at what frequency are reviews required? Are new safety case standards/methods fully applied at each periodic review?

Collator's comment: 10 years is a common period for review/reassessment, but the content of the review differs between responding countries (see individual responses). In addition, the 10 year review is not in every country an absolute requirement of regulations or of the regulator.

Belgium: Periodic review (frequency 10 years) are (or will be) required. Regulation is yet under evolution to require periodic review.

New safety case standards/methods could be applied at each periodic review.

France: Yes;

- Continuously during audits and inspections, which check that operation is made in accordance with the operating specifications (General Operating Rules) and that ALARA principle is effectively implemented for radioprotection.

- The yearly report provides the regulators with detailed information related to the process performances, safety and radioprotections records, minor incidents and modifications, etc.
- Assessment of operator proposed modifications takes into account the lessons learned from operation. The corresponding reviews encompass all the safety aspects of the facility. The corresponding cases can lead to consideration of revised parameters and, if needed new approaches (codes for examples). No major changes in the methodology or safety objectives are considered under such assessments.
- A periodic safety re assessment is performed periodically (typically every 10 years). The observed level of safety is assessed and compared to the up-dated state of the art and not only to the initial assumptions. So, the comparison takes into account the lessons learned from operating period, the progress in relevant R&D and the safety standards that would be applied to a new project. On case-by-case basis, facility upgrades can be requested to the operator.

This set of control procedures corresponds to a permanent improvement approach of safety.

Germany: The frequency of periodic review are different in the fabrication and storage facilities, they should be not more than 10 years.

New safety case standards only will be applied if there is a change in the fabrication process or if the nuclear installation poses a hazard endangering the persons engaged at the plant or the general public.

Japan: The legislation stipulates that an assessment of (1) how safety preservation is being put into practice and (2) how most recent technical knowledge is being put into safety preservation activities shall be carried out at intervals not exceeding 10 years. The legislation also stipulates that a technical assessment of aging shall be carried out before 20 years have passed from commencement of business.

Spain: A Safety Periodic Revision is required for every installation each 10 years.

The objective of this study is to verify that after an operating experience period, considering the modifications carried out by the installation and taken into account the new rules and recommendations, the installation has not been reduced their approval threshold safety level.

United Kingdom: BNFL: Periodic reviews are carried out every 10 years.

New safety case standards/methods are considered at the periodic review, and if there is a significant gap between the standards used in the existing safety case and the current standards, this gap will be filled, either by supplementary analysis, or by re-work. For some operational facilities, complete re-writes of safety cases have been carried out at the periodic review. In either case, the requirement for risk to be As Low As Reasonably Practicable (ALARP) is the key factor.

UKAEA: Every 10 years in line with guidance from UK Regulator, the NII. Yes the review is conducted against current safety and engineering standards, but with ALARP being the determinant of acceptability.

United States: Presently operators are issued a license for 10 years. Following this 10 year interval the operator must resubmit the safety case for the facility operation highlighting any changes since the last license was reviewed and issued.

1.12 Do safety cases for nuclear fuel cycle facilities address not only radiological and criticality issues, but also other safety issues such as chemotoxic and conventional safety?

Collator's comment: In some responding countries the safety case only considers radiological and criticality issues (other safety issues being addressed via other legislation), but in other responding countries safety cases have a wider scope.

Belgium: Other safety issues such as chemotoxic and conventional safety are regulated by other laws/regulations, and do not fall within the competence of the FANC.

France: Chemo toxic risks are considered for:

- Induced risks to nuclear safety such as ignition, and explosion hazards,
- Impact on the workers,
- Impacts on the environment due to normal and accidental releases.

The safety Report and Environmental Impact Statement address the corresponding questions.

Germany: Yes:, they also addresses chemotoxic and conventional safety and furthermore the assessment of environmental impacts and the consideration of other licensing requirements e.g. non-radioactive emissions into the air or discharges into water.

Japan: There is no direct mention of other safety issues such as chemotoxic and conventional safety in the establishment license (business designation) application document, design and construction approval (approval of design and construction methods) document or the safety operational rules. Nevertheless, there is the responsibility for obeying other laws and ordinances (laws concerning handling of hazardous materials, etc.). The specific laws and ordinances to be obeyed are shown in the establishment license (business designation) application document.

Spain: There is only a safety case considering radiological and criticality issues. . Nevertheless the installation must comply with other Spanish legislation and normally has others safety cases aimed to safety issues such as chemotoxic and conventional safety.

United Kingdom: BNFL: Chemotoxic safety is being introduced into safety cases, as it affects workers, the public and the environment.

Conventional safety is also addressed in safety cases, but not to the same depth as radiological and criticality safety.

UKAEA: Yes chemotoxic and conventional safety is addressed. The main way in which conventional safety is reviewed in operations is through formal risk assessment of operating procedures. Safety cases can only identify conventional hazards at a fairly high level.

United States: Yes, please see the response to question 1.9 for the areas addressed. Conventional safety is not regulated by the nuclear regulating agency. It is regulated by a separate agency and is not a part of the fuel facility operating license.

1.13 Does the safety case prescribe limits or constraints on operation? If so, how is the safety case implemented (how are these limits/constraints translated into real operations)?

Collator's comment: While all responding countries have operator instructions containing limits/constraints from the safety case, some responding countries also use dedicated safety case documents, such as technical specifications, to help translate the limits/constraints from the safety case into real operations.

Belgium: The safety case may prescribe limits or constraints on operation. These limits are quoted in the authorisation or in associated documents (Safety Report, Technical Specifications).

If necessary, procedures contain information related to those limits/constraints.

France: Operation limits are justified by the Safety Reports. They are gathered in a dedicated document (General Operating Rules). The content of this document takes into account the results of the safety cases with appropriate margins for the identified parameters.

These GOR are reviewed and approved by the regulator.

Germany: The limits prescribed in the safety cases came from the safety regulations like General Administrative Regulations, Recommendations of the Reactor Safety Commission (RSK) and Commission on Radiological Protection (SSK), KTA Rules and DIN Standards. The limits are described in the license and the operator has to translate them into the work instructions of the operating manual.

Japan: In the establishment license (business designation) application document, the important limit values (such as nuclear, thermal and chemical limits) for preventing criticality, fire or explosion are given. In the safety operational rules, safety-related limit values (or control target values) necessary for operation to prevent such events are given.

Spain: Yes, there are prescribed limits in relation with radiological and nuclear safety in both normal and accidental conditions.

The main limits are defined in the Technical Specifications, which are a part of the safety case.

To implement these limits the installation have develop procedures and protocols and a Quality Assurance Programme to confirm that the procedures and limits are fulfilled.

United Kingdom: BNFL: Yes, the safety case identifies equipment which has to be tested and maintained, and procedures which have to be followed. Safety functions are clearly defined for each safety-significant item of equipment and procedure. These are summarised in a Clearance Certificate, which is a key document for the operating unit. Operating and maintenance instructions have to incorporate the requirements of the Clearance Certificate.

If a change is desired to operation or maintenance, the change is checked to ensure that compliance with the Clearance Certificate is retained. If the change would contravene the Clearance Certificate, it cannot take place until the safety case itself has been changed, which allows a change in the Clearance Certificate. If no justification can be made for changing the safety case requirement, then the desired change to operation or maintenance cannot take place.

Another key document for safety case implementation is the Plant Maintenance Schedule, which defines the frequency of examination, inspection, maintenance and/or testing of safety-significant equipment.

If safety case requirements are ever not met, there is an event/incident reporting system in place, irrespective of whether there is an actual release of radioactive material or not.

UKAEA: Yes these are the principal output from a safety case. Limits arise on engineering plant and procedures. Procedural limits are embedded in the plants operating instructions and engineering requirements are included in the Plant Maintenance Schedule.

United States: The safety case does bound the allowed operations for the facility. These limits are translated into license requirements by specifying in the license, parameters such as operating limits, mass limits, construction or configuration specifications.

APPENDIX 2: RESPONSES TO QUESTIONNAIRE SECTION 2: LEGISLATION

2.1 Under what legislation is the safety of the nuclear fuel cycle regulated?

Collator's comment: As expected, the responses are specific to each country – see individual responses.

Belgium: Law of 15 April 1994 and Royal Decree of 20 July 2001.

France: The major specific legislative texts that regulate the licensing and operation control of the fuel cycle facilities (BNI) are:

- The 11 December 1963 decree that clarifies the responsibilities of the operating entity and defines the main guidelines of the licensing procedures as defined in question 1.5
- Specific decrees are related to the public inquiries procedures (involved entities, type of documentation, implementing conditions)
- The 10 August 1984 defines the basis for QA standards for all the tasks and activities related to the safety of nuclear facilities design and operation
- The 4 May 1995 decree regulates the licensing procedures for natural water intakes and releases

DGSNR has issued (or confirmed) the Basic Safety Rules, which are periodically updated.

Germany: Overall, German nuclear safety regulations may be hierarchically structured in form of a pyramid.

- Atomic Energy Act - Ordinances
- General Administrative Regulations - Guidelines
- Recommendations of RSK, SSK and KTA Rules, BMU Safety Requirements
- DIN Standards, international technical Standardisation

Japan: Under the scope of the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors at the top, specific regulatory terms are stipulated in the Ordinance for the Enforcement for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors and the business rules for each case.

In the examination of establishment license (business designation) application document by the regulatory agency, the safety examination guidelines (the governmental examination guidelines for establishment license (business designation) application), which are available to the public, are used. Therefore, information is also taken from them when preparing the application document.

Spain: Firstly Spanish rules:

- Nuclear Energy Law issued in 1964.
- Regulations on Nuclear and Radioactive Installations, last issued in 1999 (**the requirements of the safety case are specified here**).
- Rules for Protection Health against Ionising Radiation, last issued in 2001.
- Rules to cover Nuclear Risk, issued in 1967, and modified in 1968 and 1987.
- Law for arrangement of the electrical field, issued in 1999.

And in the case of the Juzbado fuel facility, also are taken into account rules from their native country plant (USA).

United Kingdom: Relevant statutory provisions of the Nuclear Installations (as amended) Act 1965.

A corporate body has to have a nuclear site licence for prescribed facilities and conditions can be attached to the licence in the interests of safety.

United States: The Energy Reorganization Act of 1974 created the Nuclear Regulatory Commission as an independent regulatory agency. This act along with the Atomic Energy Act of 1954, as amended, provides the foundation for regulation of the Nation's commercial nuclear power industry including the nuclear fuel cycle.

2.2 Does the legislation require safety cases to be prepared? If so, what is the requirement? If not, go straight to Section 3 (Regulatory Body).

Collator's comment: In most responding countries the legislation does not directly require the preparation of safety cases. However, the end result of the legislation in all responding countries is the preparation of safety cases, usually through the establishment of regulatory bodies which require safety cases.

Belgium: Safety principles (including design basis accidents) are to be included in the Safety Report introduced to obtain the authorisation for construction and operation.

France: The 11 December 1963 Decree is the basis of the licensing and authorization procedures presented in section 1. It stipulates that:

“For supporting the authorization request, the operator submit to the regulator a safety documentation that includes the overall description of the facility, the list of the involved risks and an analysis of the dispositions aiming at prevention and mitigation of accidents”

Germany: The requirement for the safety cases of nuclear fuel cycle facilities are formulated in parts of the Recommendations of RSK, SSK, KTA Rules and BMU Safety Requirements. Most of these standards refer to nuclear power plants, although some parts apply analogously to nuclear fuel cycle facilities.

Japan: The legislation stipulates that, at the basic design stage, at the pre-construction stage and at the pre-service stage of the facility, an establishment license (business designation) application document, an application document for approval of design and construction methods and safety operational rules shall be prepared and approval shall be obtained from the regulatory body for each of them. The legislation also stipulates that the plan related to de-licensing activities (decommissioning, de-contamination, and disposal

of contaminated materials, etc.) shall be prepared and approval shall be obtained from the regulatory body. (See Question 1.5.)

The requirements are given in the legislation and the safety examination guideline (the governmental examination guidelines for establishment license (business designation) applications).

Spain: Yes it is required in the Regulations on Nuclear and Radioactive Installations, which establishes that a safety case have to support the application for the licence to construct, operate, modify, etc, an installation.

United Kingdom:

Not directly but safety documentation is required under conditions attached to the nuclear site licence. The operator has to make arrangements to satisfy the requirements of the licence conditions.

Currently thirty-six licence conditions are in place including those for the preparation and review of safety documentation including safety cases.

Relevant licence conditions which make reference to safety documentation are: -

- 14 – Safety Documentation
- 15 – Periodic Review
- 19 – Construction or Installation of New Plant
- 20 – Modification to Design of Plant Under Construction
- 21 – Commissioning
- 22 – Modification or Experiment on Existing Plant
- 23 – Operating Rules
- 35 – Decommissioning
- 36 – Control of Organisational Change

The full details of each of the licence conditions can be found on the Nuclear Safety Directorate website - <http://www.hse.gov/nsd/nsdhome.htm>

United States:

For most applications the legislation does not specifically require that a safety case be prepared, but does establish the regulatory body and stipulates that the regulatory body develop a basis or process to utilize nuclear materials and issue licenses. The regulatory body, the NRC uses this as the basis for requiring a safety case to issue licenses to use nuclear materials. The legislation does require that for certain licenses, such as for uranium enrichment facilities, the issuance of the license is considered a major federal action and therefore an Environmental Impact Statement must be performed and as another example legislation requires that the regulatory body recertify for safe operation the gaseous diffusion plants every five years.

2.3 Does the legislation specify which organisation is responsible for preparing safety cases?

Collator's comment: For most responding countries, the responsible organisation is solely the operator; in Germany a wider range of organisations are responsible.

Belgium: No, but the operator is responsible for presenting safety cases to the regulatory body.

France: Yes; The entire regulating framework designate the operator as fully responsible for preparing safety cases and for all the activities related to the construction and operation of the fuel cycle facilities.

The operating entity is mentioned in the creation decree; so a additional licensing procedure is in case of new operating entity.

Germany: Yes: -Designer/operator

- Independent expert organisations
- Regulatory body

Japan: The legislation stipulates that the operator (the license holder) shall be responsible.

Spain: Always the operator.

United Kingdom: The nuclear site licensee is responsible for the safety of installations on the site and for documentation, including safety cases, justifying the safety of the facilities.

USA: The legislation requires that for any person in the United States to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export any utilization or production facility that person must have a license issued by the Commission (the regulatory body). The person wishing to do these activities is responsible for preparing the safety case to do the activity.

2.4 Does the legislation clearly identify at what stage during the lifetime of a facility the safety cases have to be prepared? If so what are the stages?

Collator's comment: Requirements in most responding countries are for a few or several specific stages (see individual responses); in the UK the requirement applies to all stages.

Belgium: Safety cases are to be prepared:

- during the design stage, in order to obtain the authorisation for construction and operation,
- during operation, if modifications to the installations may affect safety and are to be authorised by the regulatory body or the authorised inspection organisation,
- before decommissioning (specific authorisation to be obtained).

France: Yes, see question 1.5

The main stages that require safety cases are specified in the 11 December 1963.

The authorization decree generally does not specify any lifetime duration for the concerned facilities. Current practice is to re-assess the safety of the facilities on a decade basis. The widely media reported

Cadarache MOX facility example illustrate the possible consequences of such a safety re-assessment. (The reassessment has lead to halt any industrial production)

Germany: The important stages during the lifetime of a facility need a separate license with special safety cases:

- Construction, Installation of plant equipment
- Active commissioning involving radioactive material
- Decommissioning

Japan: It is stipulated that an establishment license (business designation) application document shall be prepared at the basic design stage, an application document for approval of design and construction methods shall be prepared at the pre-service stage, and safety operational rules shall be established at the pre-service stage. If a change is made to the facility, it is stipulated that the each of the above documents regarding the change shall be prepared. It is also stipulated that the plan related to de-licensing activities (decommissioning, de-contamination, and disposal of contaminated materials, etc.) shall be prepared. (See Question 1.5.)

Spain: Yes in our Regulations on Nuclear and Radioactive Installations (Reglamento de Instalaciones Nucleares y Radiactivas) usually known by their acronymic RINR, it is specified which kind of studies must be done by the operator and in which time this must be sent to government in order to get the license.

Construction, Inactive commissioning, Active commissioning involving radioactive material, Operations, Modifications to plant/equipment during operations, Periodic review during operations, Shutdown prior to decommissioning and Decommissioning.

United Kingdom: Safety cases are required for all stages of the lifetime of the facility as identified in conditions attached to the nuclear site licence from design through construction, commissioning, operations to decommissioning.

United States: Yes as an example the Environmental Impact Statement for a uranium enrichment facility must be performed before the hearing on the issuance of a license for the construction and operation of the facility.

2.5 Does the legislation require the regulatory body to approve safety cases before the activity being justified can be implemented?

Collator's comment: In most responding countries, the answer is 'Yes'. The UK regulator clarified that it only approves safety cases for the more safety-significant projects.

Belgium: Yes.

France: Yes, see section 1

Germany: Yes

Japan: Yes. Approval for safety cases by the regulatory body is required.

Spain: Yes it does.

United Kingdom: The nuclear site licensee prepares arrangements to satisfy the requirements of the site licence conditions and the regulator has the discretion to approve any the arrangements, as it considers necessary in the interests of safety.

The regulator can specify when it may wish to approve safety cases under primary powers or the approval/consent process may be contained within the arrangements made under the licence conditions.

The regulator expects the arrangements made by the licensee to categorise safety cases and modifications to existing plant and equipment, and apply a higher level of justification for those which have higher safety significance. In the UK the regulator does not approve all safety cases but has the discretion to be involved and uses, for example, the categorisation process to decide on whether to be involved or not.

United States: Yes, typically for fuel cycle facilities the issuance of a license for the construction and operation of the facility is required prior to construction of the facility.

2.6 Does the legislation require periodic review of the safety cases during the lifetime of the facility?

Collator's comment: In some responding countries the requirement for periodic review is part of the legislation, usually ten years; in other responding countries the requirement is regulatory although it does not necessarily apply to all fuel cycle facilities. Two responding countries emphasised the requirement to keep the safety case live throughout the ten years.

Belgium: Not explicitly, but it may be a subject for the periodic (decennial) review.

France: This periodic safety re-assessment is not part of the legislation itself but part of the implementing practices and procedures defined and managed by the regulator.

Safety re-assessment can also be performed on ministers request.

Germany: The supervisory activities of the "Länder" under nuclear legislation include the performance of safety assessment on a continuous as well as discontinuous and periodic basis. These continuous supervisory activities assure an intensive assessment of plant safety. Additionally a periodic review (10 year) of more general safety aspects with analysis of national and international operating experience and a specific safety reviews is assumed.

Japan: Yes. The legislation stipulates that an assessment of (1) how safety preservation is being put into practice and (2) how most recent technical knowledge is being put into safety preservation activities shall be carried out at intervals not exceeding 10 years. The legislation also stipulates that a technical assessment of aging shall be carried out before 20 years have passed from commencement of business.

Spain: A Safety Periodic Revision it is required to the installation each 10 years. This leads to a revision of the main features of the safety cases, as much as the procedures and most of the documentation of the facility.

United Kingdom: Yes, as a condition attached to the nuclear site licence, and in general the period of review is ten yearly although it is expected that the safety case is maintained "live" through this period and for the life of the facility.

United States: In some cases yes, as an example, legislation requires that the regulatory body recertify for safe operation the gaseous diffusion plants every five years.

2.7 Does the legislation identify the structure of safety cases? If so, what is the structure? If not, how is the structure specified?

Collator's comment: For most responding countries the structure of the safety case is not identified in the legislation. In these cases the regulator and/or operators identify the structure.

Belgium: No. There is no structure defined by the regulatory body, but the regulatory body must agree on the structure of the presented safety cases.

France: No; See section 1

Germany: Not at detail

Japan: Yes. The structure of safety cases is based upon the content and structure of the legislation and safety examination guidelines (the Governmental examination guidelines for establishment license (business designation) applications).

Spain: Yes the RINR specifies how it must be structured and what their content must be (See 1.9)

United Kingdom: The structure of the safety documentation is a matter for the licensee (see the answer to question 1.9) but the safety regulator has issued guidance on what it expects to see in the safety case. This guidance is available in the public domain (Nuclear Safety Directorate - TECHNICAL ASSESSMENT GUIDE T/AST/051 - GUIDANCE ON THE PURPOSE, SCOPE AND CONTENT OF NUCLEAR SAFETY CASES)

United States: The legislation does not identify the structure of the safety case. This is done in the implementing regulations required by the legislation.

2.8 Does the legislation require the regulatory body to approve or otherwise agree to safety cases submitted by operators of fuel cycle facilities? If so, what is the regulatory requirement?

Collator's comment: Regulatory requirements vary – see individual responses.

Belgium: Yes.

Authorisation is given by FANC if the Safety Analysis Report (including safety cases) has been approved by its Scientific Committee. The advice of the Scientific Committee is based on the review made by the authorised inspection organisation.

France: All the safety related documentation has to be approved by the regulator.

The approval procedure involve independent expert reviews

Any active commissioning requires a specific authorization that is granted after approval of all the safety related data and cases.

Any changes in the operating modes, feed products, process design etc. require a full approval of the corresponding safety cases before being implemented.

Final shutdown and D&D activities require specific licensing.

Germany: The regulatory body together with his independent expert organisation have to prepare reports outlining whether or not the requirements formulated in the recommendations of RSK, SSK, KTA Rules and BMU Safety Requirements have been met.

Japan: Yes. The legislation stipulates that a safety case shall be prepared by the operator at each stage of the facility and shall be approved by the regulatory body. The main focus of the requirements is disaster prevention.

Spain: See 2.2.

Safety cases are assessed by CSN. During the assessment process CSN may normally establish requirements, suggestions and recommendations and in which manner safety cases must be modified, prior to get necessary agreement in order their approval.

United Kingdom: The legislation is so structured that the regulator may approve safety cases at its discretion by specifying when a consent or approval may be required to allow certain operations or under the arrangements made by the licensee to satisfy the site licence conditions (see also the response to question 2.5).

The specific requirements are contained within the conditions attached to the nuclear site licence and further developed in the arrangements made by the licensee to satisfy these conditions.

United States: No specific legislation requires that the regulatory body approve or otherwise agree to safety cases submitted by operators of fuel cycle facilities; however legislation does require that the regulatory body have a basis for issuing a license to an operator and implicit in this requirement is that the regulatory body approve or otherwise agree to safety cases submitted by operators.

APPENDIX 3: RESPONSES TO QUESTIONNAIRE SECTION 3: REGULATORY BODY

3.1 Which organisation is responsible for regulating the safety of nuclear fuel cycle facilities?

Collator's comment: As expected, the responses are specific to individual countries.

Belgium: Federal Agency for Nuclear Control (FANC).

Some tasks of the FANC may be delegated to authorised inspection organisations (like AVN).

France: DGSNR (General Directorate for Nuclear Safety and Radioprotection) is in charge of regulating all the nuclear activities in France for both safety and radioprotection.

The three ministers of Industry, Environment and Health supervise DGSNR.

IRSN is an independent research and expertise institute in charge of the technical support of the DGSNR. IRSN has been created in 2002 as the national TSO by gathering the former IPSN with radioprotection experts from the Health minister.

Germany: The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) is responsible for the German Atomic Energy Act and therefore for the safety of all NPP and nuclear fuel cycle facilities.

According to Article 87 of the Basic Law, the execution of the administrative tasks is performed by the Federal States (Länder), as agents of the Federal Government. That means that in executing the Atomic Energy Act and its associated ordinances, the *Länder* are under the supervision of the Federal Government with regard to the lawfulness and expediency of their actions.

Japan: For uranium fabrication facilities (including uranium enrichment facilities), MOX fuel fabrication facilities and reprocessing facilities, the Nuclear and Industrial Safety Agency (NISA), which is under the Ministry of Economy, Trade and Industry (METI), takes charge of the safety regulation.

Spain: The Spanish regulatory body is the Ministry of Industry, who issues the licence and authorisation to the installations, in base to the report emitted by the CSN, which is the only one responsible for nuclear safety and radiological protection aspects in Spain.

CSN proposes to regulatory body rules and regulations and carry out specific assessments of the safety cases and other operator documentation.

After these assessments CSN reports to the regulatory body the limits and conditions under which the licence can be granted to the operator.

In the CSN there is an area or project manager responsible for each installation; who coordinates all the subjects relates to each specific installation.

United Kingdom: The Health and Safety Executive's Nuclear Installations Inspectorate (HSE/NII) as part of the Nuclear Safety Directorate

United States: The U. S. Nuclear Regulatory Commission is responsible for regulating the safety of nuclear fuel cycle facilities.

3.2 By what means does the regulatory body identify to the operator that safety documentation is required?

Collator's comment: In general the answer for most responding countries is by rules, regulations, guidance documents and official letters.

Belgium: Safety documentation is required by the regulation (Royal Decree of 20 July 2001).

The regulatory body may ask additional documentation, by letter for example.

France: The national legislation is applicable to any nuclear project or facility construction or operation.

Germany: The requirement of the safety documentation in general is assigned in the Atomic Energy Act and in detail fixed in the instructions of the operating manual (Betriebshandbuch-BHB) which has to be agreed by the Länder Ministry in charge of licensing, supervision and inspection of the nuclear facility.

Japan: The regulatory body enacts and enforces laws and ordinances such as the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors and specifies the documents that must be submitted by the operator to the regulatory body in the licensing procedure.

Spain: By rules and regulations, Guidance documents and by official letters.

Apart from rules, guidance and official letters the CSN uses a more fluently and kindly relation with the operator, ; so, meetings at the facility headquarter or at the CSN headquarter, video-phone calls, inspections, phone calls and E-mails, are used very frequently.

United Kingdom: Within conditions attached to the nuclear site licence.

United States: NRC regulations are issued under the United States Code of Federal Regulations (CFR), Title 10, Chapter 1. These regulations provide the requirements to be met for operators of fuel cycle facilities. Guidance for how these requirements can be met are contained in the following Standard Review Plans

NUREG -1520, AStandard Review Plan for the Review of a License Application for a Fuel Cycle Facility≅

NUREG- 1718, AStandard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility≅

3.3 If a licensing system is in place, does this licence identify the requirement for safety cases? If so, what is this requirement?

Collator's comment: In some responding countries the requirement is within the licence; in other responding countries the licence is the means by which requirements elsewhere (e.g. regulations) are enforced.

Belgium: Safety principles (including design basis accidents) are to be included in the Safety Report introduced to obtain the authorisation for construction and operation.

Additional requirements concerning safety cases may be included in the licence (for example, additional studies to be presented within a given delay).

France: Yes, see section 1

Germany: The requirement for the safety cases of nuclear fuel cycle facilities are formulated in parts of the Recommendations of RSK, SSK, KTA Rules and BMU Safety Requirements. Most of these standards refer to nuclear power plants, although some parts apply analogously to nuclear fuel cycle facilities.

In the licence these requirements are formulated.

Japan: Yes. The legislation stipulates the items to be detailed in safety cases in each stage of the facility. The main focus of the requirements is disaster prevention. See section 1 on detailed matters.

Spain: See 2.2.

United Kingdom: Yes. See the answer to 3.2.

United States: The requirement for the safety case is in the regulations governing the operations; the license provides the basis for how the operator meets these regulations.

3.4 Has the regulatory body prepared and issued any guidance on the purpose of a safety case? If so, what is the defined purpose?

Collator's comment: Some responding countries have issued guidance on the purpose of safety cases which is publicly available.

Belgium: No guidance.

France: Yes, see section 1

The applicable legislation is available on the regulator's web site (<http://www.asn.gouv.fr/index.asp>) part of the site is available in English.

Some BSR are available on the web site.

The inspections follow-up letters are disclosed on line on this web site.

The safety reports and cases are not public documents as they content proprietary information.

EIS and public inquiry documentation is made available to the public.

Germany: A number of ordinances have been promulgated in the field of nuclear energy on the basis of the Atomic Energy Act relating to the management of spent nuclear fuel and the radioactive wastes. The most important ones pertain to:

- radiation protection (Radiation Protection Ordinance) (StrlSchV)
- the licensing procedure (Nuclear Licensing Procedure Ordinance) (AtVfV)

- the reporting of notifiable events (Ordinance on the Nuclear Safety Officer and Reporting of Accidents and other Events) (AtSMV)
- the Guideline on the Monitoring of Emissions and Immissions Resulting from Nuclear facilities
- the Guide to Decommissioning Nuclear Facilities

The purpose of the safety cases is to protect life, health and property against the hazards of nuclear energy and the detrimental effects of ionising radiation.

Japan: Yes. The structure of safety cases at each stage are shown in the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors.

The Purpose of the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors is to ensure that the utilization of nuclear source material, nuclear fuel material, and reactors are limited to peaceful purposes, and carried out in a planned manner, and to ensure safety of the public by preventing the hazards due to these utilization and providing physical protection of nuclear fuel material.

Spain: No the regulatory body, although CSN have several guidance about subjects related to safety cases, but none of those issued have that specific denomination.

Most of these guides have been specifically developed to Nuclear Power Plant but are very useful for fuel cycle facilities.

United Kingdom: The regulatory body has prepared guidance on safety cases and placed this guidance on safety cases i.e. Nuclear Safety Directorate T/AST/051 - TECHNICAL ASSESSMENT GUIDE - GUIDANCE ON THE PURPOSE, SCOPE AND CONTENT OF NUCLEAR SAFETY CASES on the public domain.

The purpose of this guide is to provide generic guidance to NII inspectors on what is required by NII from licensees in their safety cases for licensed nuclear installations. The guide sets out the purpose of nuclear safety cases, their overall qualities, how they may be structured and what information they may contain, noting that the actual content of safety cases is a matter for licensees to decide. There is also coverage of how safety cases may be managed and maintained. The guidance is all set into the context of the requirements of the nuclear site licence.

The guide embodies NII's expectations of safety cases for nuclear plants, notably reactors and process plants handling radioactive materials. It is recognised however that under occasional circumstances, or in specialist plant, additional factors will need to be considered and addressed in the safety case. Licensees may choose to address environmental and non-nuclear safety issues in their safety cases but these are not within the scope of this guide.

The scope of the guide covers whole plant safety cases over the full life cycle. It also encompasses safety cases, and revisions to safety cases, for part of a plant, a plant modification or a specific topic.

Although the guide has been developed for NII's own use, it indicates to licensees and other stakeholders the standards that the NII expects. It is expected that this guide will influence the issues which should be addressed in safety cases during the various stages of the life of a nuclear plant or facility. The guide does not prescribe the detail or the depth that needs to be addressed; these remain the responsibility of the licensee and will be dependent upon the specifics of each safety case.

United States:

Yes, the Standard Review Plans provide guidance on the purpose of and method for developing the safety case. The purpose of the safety case is to provide the health, safety and environmental protection basis for possession and use of nuclear materials. For fuel cycle facilities the principle standard review plans are: NUREG -1520, AStandard Review Plan for the Review of a License Application for a Fuel Cycle Facility and NUREG- 1718, AStandard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility.

3.5 Has the regulatory body prepared and issued any guidance on the structure of safety cases? If so, what is it?

Collator's comment: Some responding countries have issued guidance on the structure of safety cases which is publicly available.

Belgium: No guidance.

France: Guidelines for the content of the safety documents are provided by DGSNR.

The regulations mainly define the safety objectives and the authorization procedures. Operators are fully responsible of the implementation methodologies and technologies. They are also fully responsible for providing the regulators with relevant technical data that demonstrate the safety of the proposed activities.

Germany: Not at detail.

Japan: Yes. In the legislations, e.g. the Rules for Reprocessing Business of Spent Fuels, the Rules for Fabrication Business of Nuclear Fuel Materials, the content of each application document is given.

The Safety Examination Guidelines has been stipulated and made public by the Nuclear Safety Commission as a means of giving guidance concerning the content of establishment license (business designation) application documents.

(Please refer to the section 3.10 about the Nuclear Safety Commission)

The safety examination guidelines for nuclear fuel cycle facilities include:

- Basic Guidelines for Safety Examination of Nuclear Fuel Facilities
- Safety Examination Guidelines for Uranium Fabrication Facilities
- Safety Examination Guidelines for Specified Uranium Fabrication Facilities
- Safety Examination Guidelines for Mixed Uranium-Plutonium Oxide Fuel Fabrication Facilities.
- Safety Examination Guidelines for Reprocessing Facilities

Spain: Same answer that for 3.4.

United Kingdom: See the answer to Question 3.4

United States: Yes, this guidance on the structure of a safety case is contained in the Standard Review Plan. This guidance for implementing the fuel cycle facility regulatory requirements are: NUREG -1520, A Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility and NUREG-1718, A Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility.

3.6 Has the regulatory body prepared and issued any guidance on quality standards for safety cases? If so, what are they?

Collator's comment: Most responding countries have issued guidance – see individual responses.

Belgium: No guidance.

France: The 10 August 1984 decree stipulates that all the activities related to the safety of the nuclear facilities must be performed in accordance with relevant QA standards.

Namely, the preparation and validation procedures of the safety cases are submitted to stringent QA standards.

Operator's internal procedures and associated QA are part of the safety documentation. Their effective implementation is checked during the review of cases (consistency control of the assumptions, revisions, code qualification, etc) and during specific audits

Germany: The requirements of KTA Nuclear Safety Standard 1401 regarding quality assurance are applied, wherever relevant. These include the principle of operational organisation, planning and design, production and construction including quality control, specified normal operation and accidents, documentation and archiving, as well as auditing of the quality assurance system itself. The applicant or licensee is responsible for the planning, performance and control of the effectiveness of quality assurance. In this respect, an essential requirement of KTA Nuclear Safety Standard 1401 is the technical knowledge and qualification of the personnel.

Japan: The judgment criteria for safety cases are described in legislation, e.g. the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors, the Rules for Reprocessing Business of Spent Fuels, the Rules for Technical Standards of Design and Construction Methods of Reprocessing Facilities, the Rules for Technical Standards of Welding in Fabrication Facilities, Reprocessing Facilities and Designated Waste Management Facilities.

The Safety Examination Guidelines issued by the Nuclear Safety Commission are used for the examination of establishment license (business designation) application.

(Note: The phrase "quality standard" is taken to mean "judgment criterion" in this reply.)

Spain: Same answer that for 3.4.

United Kingdom: See the answer to Question 3.4

United States: Safety cases are required to be factual. The content of these cases and the methodology for assuring that the information provided accurately depicts the processes is contained in the above referenced standard review plans.

3.7 Does the regulatory body carry out any technical assessment of the safety claims made in safety cases submitted by the operator? If so, give a brief description of the resources available and the scope of work carried out:

Collator's comment: Regulatory (or associated) bodies do carry out this technical assessment in all responding countries – see individual responses for resources available.

Belgium: The regulatory body (FANC) and the authorised inspection organisation (AVN) carry out technical assessment of the safety claims made in safety cases.

Scope for AVN is all aspects of nuclear safety and radiation protection. About 50 experts work by AVN.

France: Safety cases are reviewed by the Technical Support Organization (IRSN) and conclusions and recommendations are elaborated by the Standing Group meetings ("Permanent Group").

IRSN groups 1500 experts in various disciplines such as nuclear engineering, medicine, environment monitoring, experimental research and technical reviewing.

The division in charge of fuel cycle, transport and waste facilities involve 200 persons working in close cooperation with the remaining entities of the Institute.

IRSN is involved in many international Research programs and co-operations including expertise for facilities from eastern countries.

Germany: The regulatory body in co-operation with his commissioned experts in various disciplines such as nuclear engineering, radiological protection, criticality safety etc. carry out technical assessments of the safety claims made in safety cases submitted by the operator.

Japan: The regulatory body carries out the technical assessments for each safety case. In the technical assessment the regulatory body reflects the views of experts of sub committees.

For the examination of establishment license (business designation) application documents, the Nuclear Safety Commission checks about the technical capability and disaster prevention, and the Atomic Energy Commission checked about the planned implementation and financial foundation, and that the use is for peaceful means. (Please refer to the section 3.10 on the Nuclear Safety Commission and the Atomic Energy Commission.)

Spain: The CSN makes the technical assessment of the safety cases submitted by the operator, and establishes the limits and conditions under which the permission is granted.

In the CSN the Unit responsible of the installation and, in particular the project manager, receives the safety case and co-ordinates the technical assessment of the different experts Units: mechanical, thermal, criticality, radiological protection, quality assurance, etc. . These experts make a report that will be a part of the final assessment report emitted by the project manager.

United Kingdom: NII has inspection, technical assessment, project and strategy resources supported by administrative groups. About one third (60) of the inspector grades are employed on technical assessment split almost equally between reactor (30) and fuel cycle (30) assessment. Areas of expertise include engineering (including structural integrity), scientific, including radiation protection, fault studies and reactor physics, and Human Factors/QA.

The assessment resource is predominantly used to judge the adequacy of the technical and safety claims made in the safety documentation.

United States: The regulatory body, the Nuclear Regulatory Commission, performs technical assessments and documents this assessment of the safety claims made in the safety cases submitted by the operator in a Safety Evaluation Report which is provided to the licensee and provides the technical basis for approving the safety claim or license amendment. In most cases these safety evaluations are publicly available. The NRC has approximately 50 persons available to perform this technical assessment of safety claims work. The reviews are typically conducted in accordance with the standard review plan described above.

3.8 Does the regulatory body use the safety cases to inform its decisions with respect to compliance with legal requirements? If so, how is this done?

Collator's comment: Most responding countries answered 'yes' to the first question – see individual responses. The UK additionally noted a link between safety cases and the inspection regime.

Belgium: Yes, by notification in the authorisation if necessary.

France: The operator prepares the safety cases at the different stages of the project including operation. These cases are reviewed by the technical support organization (IRSN), which provides the regulator with technical advices. These advices refer to the content of the cases, to the past experience of the facility or of similar facilities, to the operator's commitment derived from former stages safety documentation (see section 1) and to the state of art in the considered disciplines.

The advices aim at providing the regulator with the technical basis for the decision.

For the major steps of the projects, the technical advice is reviewed by the Standing Group. The operator attends to this review. The Group provides the regulator with proposed conclusions including technical recommendations.

Germany: The regulatory body together with his independent expert organisation have to ensure that the safety cases are in compliance with the requirements formulated in the recommendations of RSK, SSK, KTA Rules and BMU Safety Requirements.

Japan: The regulatory body informs the operator of whether there is compliance with the legislation by means of licensing (approval).

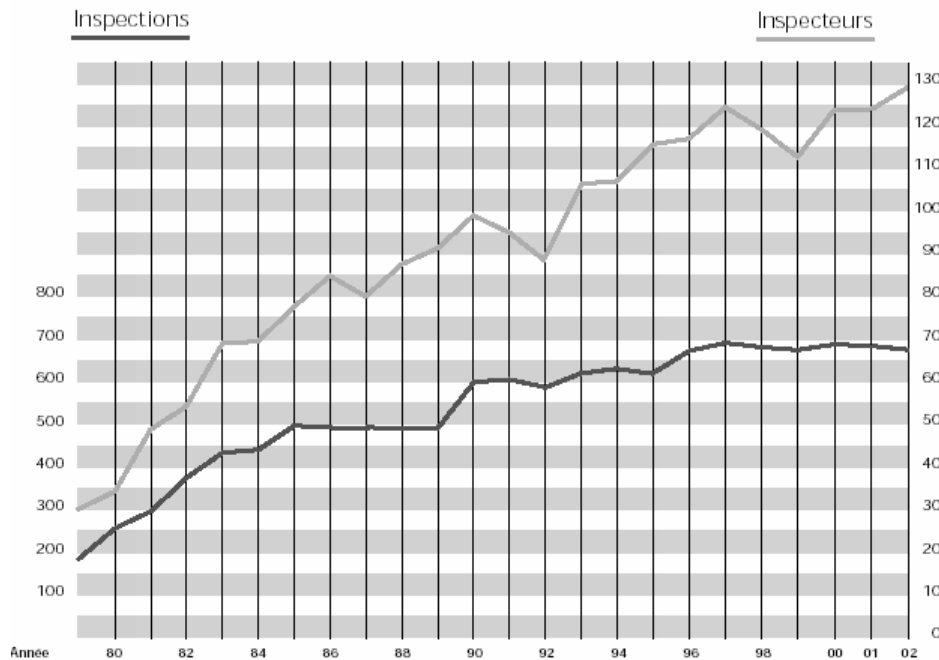
Spain: No, it is conducted through the licence or particular instructions emitted by the regulatory body or the CSN.

United Kingdom: The safety case is required to justify the safety of operations and identify the features, both engineered and administrative, that are required in the interests of safety. NII inspects to ensure that these features are in place as part of its interactions on the sites. NII has the facility to ensure improvements are made to ensure the requirements of the safety case are met.

The safety case has to demonstrate that the licensee is doing all that is reasonably practicable to minimise the risk to workers and others. The regulator has to judge whether the claims made meet this level of legal compliance.

United States: The regulatory body uses the safety cases to provide the basis for its regulatory decision with respect to compliance with legal requirements. This is done by ensuring that the safety case has been demonstrated through application of the standard review plan. If the safety case does not adhere to the

standard review plan a comparable level of safety must be demonstrated and approved by the regulatory body.



3.9 How much technical resource within the regulatory body is available to carry out compared to regulatory site inspection activities?

Collator's comment: Only a few responding countries provided a comparison between technical resource and site inspection – see individual responses.

Belgium: Same order of magnitude.

France: The above graphic illustrate the inspection activity of the DGSNR and its evolution:

At the end of 2002, the regulator's total workforces were 260 persons including 130 inspectors (50% at national level and 50% at regional level).

In 2002, more than 650 inspections have been carried out.

The inspection follow-up letters are disclosed on the regulator's web site.

Germany: For the ANF fuel manufacturing facility the inspection activity from the regulatory body on site, within independent expert organisations, is about 82 (person x day) per year.

Japan: Note: It is difficult to define the "technical resource," and it is hard to distinguish a technical resource for "regulatory site inspection activities" from "other activities" quantitatively. Therefore, followings show just the 'approximate' staff numbers relating the regulatory activities (including site inspections) on July 2004 as the reference.

The number of staffs in the Nuclear Fuel Cycle Regulation Division (that is regulating uranium fabrication facilities, MOX fuel fabrication facilities and reprocessing facilities under the NISA) is as follows:

- 22 at the Tokyo head office,
- 24 at onsite as the resident inspectors (for 4 sites).
- The number of staffs relating the inspection activities of the nuclear fuel facilities in the Japan Nuclear Energy Safety Organization, an incorporated administrative agency, is as follows:
- 9 at the Rokkasho office as the inspectors (not only for Rokkasho site but also for other site in Japan).
- The number of staffs relating the technical analysis and evaluations etc. of the nuclear fuel facilities (except above direct inspection activities) in the Japan Nuclear Energy Safety Organization, an incorporated administrative agency, is as follows:
- 12 at the Tokyo head office.

Spain: The CSN is the responsible of this activity. The CSN define a Basic Inspection Program for each installation. This programme establishes the areas to be inspected and the frequency of the inspections.

The inspections are carry out by the Units specialised in the different safety areas.

The fulfilment of the Programme is co-ordinated by the Installation Project Manager

More than ten inspections are performed every year in each facility, besides more not planed inspections are conducted if required.

In the regulatory body headquarter there is not limit in how many people can be involve in a determined assessment.

United Kingdom: See the answer to 3.7

United States: 52 persons are available to carry out the technical review work and an additional 23 persons perform the inspection activities.

3.10 Does the regulatory body use external independent technical reviewers to carry out the technical review of safety cases submitted by the operators of nuclear fuel cycle facilities?

Collator's comment: Most responding countries do use external independent technical reviewers.

Belgium: Yes, it is one of the roles of the authorised inspection organisations like AVN.

France: The safety Authority (DGSNR) mainly uses IRSN as TSO.

Germany: For many supervisory and inspection programmes independent experts are assigned by the *Länder* authorities for examination of reports, reported events, calculations, technical specifications, safety assessments for modifications and for conducting or assessing in-service inspections

Japan: As described in the reply to question 3.7, establishment license (business designation) application documents are referred to the Nuclear Safety Commission and the Atomic Energy Commission for review.

The Nuclear Safety Commission is the commission established within the Cabinet Office as an independent agency to play the main role in nuclear safety administration. The Atomic Energy Commission is also the commission established within the Cabinet Office as an independent agency to play the main role in deliberating long term program of research, development and utilization of atomic energy, checking the progress along the program and making advice.

For some of the technical analysis in safety cases, the Nuclear and Industrial Safety Agency requests the Japan Nuclear Energy Safety Organization, an incorporated administrative agency, to make a review (called a cross check).

Spain: Neither in the regulatory body nor in the CSN it is usual, but in the CSN and in relation with very specific questions or lack of time to their civil servant staffs, can be required the use of external independent technical reviewers.

United Kingdom: NII has the facility to use external resources to support its regulatory activities, including technical assessment, if the need arises. Such a facility has been used, and continues to be used, in a number of technical areas.

United States: No, external independent technical reviewers are not used to carry out the technical review of safety cases submitted by the operators of nuclear fuel cycle facilities.

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