



IAEA

International Atomic Energy Agency

**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
- REDUCED SCOPE -**

TO

The United Kingdom

Liverpool

26 March – 4 April 2006

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICES

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish standards of safety for protection of health and minimization of danger to life and property in the civil development and application of nuclear energy and to provide for the application of these standards to peaceful activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. The Agency also provides Safety Services, at the request of Member States, which are directly based on the IAEA Safety Standards and Security Guidance.

In the thematic area of Legal and Governmental Infrastructure (LGI) the Agency offers several peer review services:

- ✓ The ***International Regulatory Review Team (IRRT)*** programme provides advice and assistance to Member States to strengthen and enhance the effectiveness of the legal and governmental infrastructure for nuclear safety;
- ✓ The ***Radiation Safety and Security Infrastructure Appraisal (RaSSIA)*** assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources.
- ✓ The ***Transport Safety Appraisal Service (TranSAS)*** has for objective to assess the implementation of the Agency's Transport Regulations;
- ✓ The ***International Nuclear Security Advisory Service (INSServ)*** assists Member States in the identification of the best means by which to strengthen their nuclear security;
- ✓ The ***Emergency Preparedness Review (EPREV)*** is conducted to review both the preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

In addition, to ensure and enhance the safety of operating research reactors, the *International Safety Assessment of Research Reactors* (INSARR) is being offered to Member States. In this area, in the context of LGI, another instrument that needs to be considered is the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in March 2004.

The importance of peer review and enhancing the regulatory body self-assessment capabilities to identify strengths and weaknesses as well as indicate areas for improvement of the necessary legislative and regulatory frameworks had been underlined during the 3rd Review Meeting of the contracting parties to the International Convention on Nuclear Safety (CNS) in April 2005. Peer reviews are now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. They are neither an inspection nor an audit but are a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, and that contributes to ensuring a strong nuclear safety.

Moreover, considering that the five peer reviews listed above have areas in common, the IAEA Department of Safety and Security has initiated the development of an integrated approach to review missions on Legal and Governmental Infrastructure. The new service is structured in modules, which cover general requirements, regulatory activities and management systems for Nuclear Installation Safety (Nuclear Power Plants, Fuel Cycle Facilities, and Research Reactors), Radiation Safety, Waste Safety, Transport Safety, Emergency Preparedness and Response and Security. The objectives are to make the IAEA services related to LGI more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of IAEA Safety Standards. The modular structure also enables tailoring the service to meet the need and priority of the Member State.

The missions will also be used as the most effective feedback for the improvement of existing standards and guidance, the development of new ones, and to establish a knowledge base in the context of an integrated safety approach.

Global Nuclear Safety and Security Regimes have emerged over the last ten years, with international legal instruments such as Conventions and Code of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA Safety Standards and Security Guidance. The IAEA will continue to support the promotion of the Conventions and Codes of Conduct, as well as the application of the IAEA Safety Standards and Security Guidance in order to prevent serious accidents and continuously improve the global levels of safety and security. Through its Integrated Regulatory Review Service (IRRS), the IAEA assist Member States in strengthening their national safety and security infrastructure. This would contribute towards achieving a strong and sustainable global safety and security regime.

REPORT

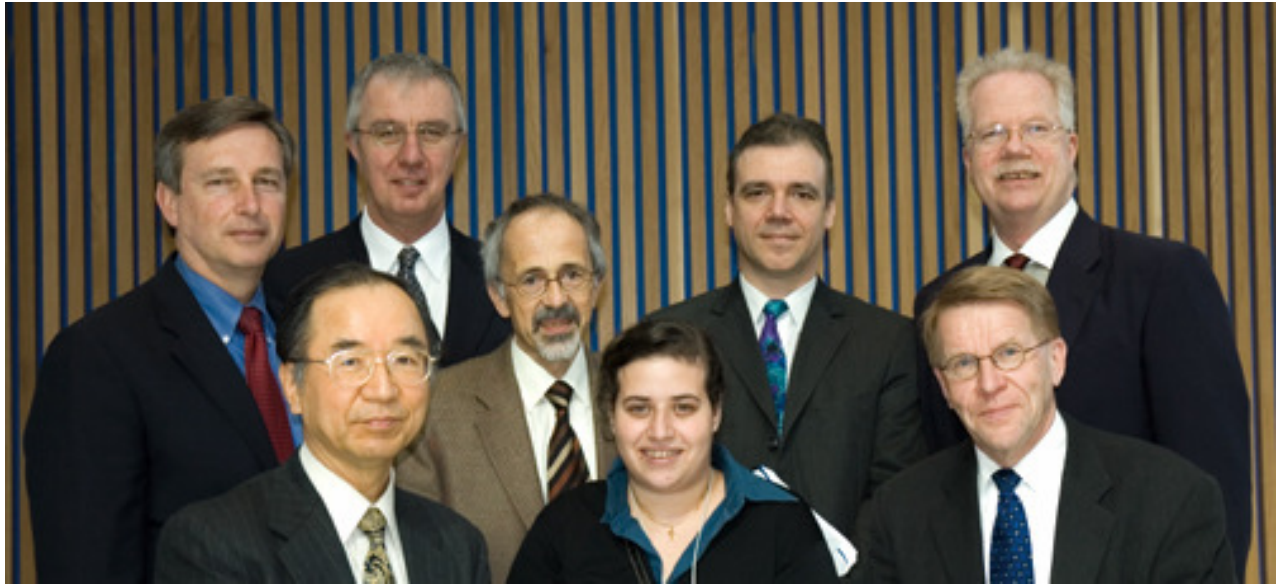
INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

- REDUCED SCOPE -

REPORT TO THE GOVERNMENT OF THE UNITED KINGDOM

Liverpool, United Kingdom
26 March – 4 April 2006





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Liverpool, United Kingdom
26 March – 4 April 2006

Mission date: 26 March – 3 April 2006

Regulatory Body: Health and Safety Executive (HSE)

Location: HSE Headquarters, Liverpool, United Kingdom

Regulated Facilities: Nuclear Power Plants

Organized by: IAEA

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IRRT

FOREWORD

by the

Director General

The IAEA International Regulatory Review Team (IRRT) programme assists Member States to enhance the organization and performance of their nuclear safety regulatory body. Such a regulatory body must work within the framework of its national legal system, which in turn should ensure both the independence and the legal powers available to the regulatory body. Additionally the national administrative and legislative system should ensure that the regulatory body has sufficient funding and resources to carry out its functions of reviewing and assessing safety submissions; licensing or authorizing nuclear safety activities, establishing regulations and criteria; inspecting nuclear facilities and enforcing national legislation. The regulatory body should be resourced and staffed by capable and experienced people to a level commensurate with the national nuclear programme. IRRT missions focus on all these aspects in assessing the regulatory body's safety effectiveness. Comparisons with successful practices in other countries are made and ideas for improving safety are exchanged at the working level.

An IRRT mission is made only at the request of a Member State. It is not an inspection to determine compliance with national legislation, rather an objective review of nuclear regulatory practices with respect to international guidelines. The evaluation can complement national efforts by providing an independent, international assessment of work processes that may identify areas for improvement. Through the IRRT programme, the IAEA facilitates the exchange of knowledge and experience between international experts and regulatory body personnel. Such advice and assistance will enhance nuclear safety in all nuclear countries. An IRRT mission is also a good training ground for observers from newly formed regulatory bodies in developing countries who follow the evaluation process. This approach, based on voluntary co-operation, contributes to the attainment of international standards of excellence in nuclear safety at the regulatory body level.

Essential features of the work of the IRRT experts and their regulatory body counterparts are the comparisons of regulatory practices with international guidelines and best practices, and a joint search for areas where practices can be enhanced. The implementation of any recommendations or suggestions, after consideration by the regulatory body, is entirely voluntary.

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government authorities of the United Kingdom, an IAEA team of six experts visited the UK Health and Safety Executive (HSE), Nuclear Safety Directorate (NSD), in March 2006 to conduct an Integrated Regulatory Review Service (IRRS) mission with reduced scope. The request for the mission was made in the context of the energy policy review that has been announced in the UK. The Secretary of State at the Department of Trade and Industry (DTI) asked HSE to contribute an expert report that includes an assessment of the risks associated with the new generation of NPPs and the potential role of pre-licensing assessments of the candidate designs.

The purpose of the mission was to evaluate the effectiveness of both the current HSE/NSD regulation of existing nuclear power plants and its preparedness to regulate and licence any new reactor designs. The team reviewed the effectiveness of the HSE/NSD and exchanged information and experience in the regulation of nuclear safety in selected predetermined areas that were considered by the IRRS. The selected areas were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; and review and assessment; development of regulations and guides and the management system.

The team was provided with the NSD's response to the questionnaires mainly on the basis of self-assessment carried out by NSD to identify any areas of non-compliance with the IAEA safety standards and the most relevant regulatory documentation. The outcome of the team's review is presented as findings as represented by recommendations, suggestions and good practices noted.

In the review the team recognized that HSE/NSD has taken a number of initiatives to ensure that NSD moves forwards seeking regulatory excellence by applying international best practices and by improving its effectiveness and efficiency while meeting a number of new challenges.

The team considers that it is important to mention the NSD's efforts in ensuring greater consistency with the IAEA safety standards; for example, the 'Safety Assessment Principles for Nuclear Facilities' document proposed for public consultation, which was benchmarked against both the most recent IAEA safety standards and the WENRA harmonization work, is a valuable high quality document for decision making in the authorization process.

Additional strengths identified in particular were:

- The mature and transparent regulatory system and the advanced review process.
- Highly trained, expert and experienced staff.
- A flexible regulatory regime that sets clear expectations for the licensees and permits the NSD to make decisions on well justified technical grounds rather than being restricted by predetermined rules which may not apply well to all decision making situations.
- The use of risk insights as one aspect for practically all types of regulatory decision making.
- Regulatory review meetings that involve site inspectors and assessors to share experience and set priorities.
- An active international role, particularly at the IAEA.

The report also includes recommendations or suggestions of where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for nuclear safety.

The team believes that consideration of the following items should be given high priority because they were identified in several review areas or because the experts consider that they will significantly contribute to the enhancement of the overall performance of the regulatory system:

- Establish an appropriate budget and staffing levels to accomplish all assigned work;
- The need for improvement in the independent capability for safety analysis in specific areas;
- Clarification of the authorization process for ‘new build’, including stepwise licensing and guidance for the potential applicant, including the activities, responsibilities, inputs and outputs.
- The need for improvement in the assessment of operating experience feedback and follow-up of the corrective actions; and
- Continued development of the business manual system.

The team also considers that the NSD, in the event of its receiving an application for a new nuclear power plant, will have to acquire significant additional resources in order to be able to meet its current responsibilities and to meet this new challenge.

In addition to the above mentioned findings, the experts’ opinion on new build, and in particular concerning the planning and execution of new build activities, are outlined in Appendix I.

The mission team’s findings are summarized in Appendix V.

HSE/NSD staff put a significant effort into the preparation of the mission. In the review the administrative and logistical support was excellent and the team was extended full co-operation in technical discussions with HSE/NSD personnel. HSE/NSD counterparts were enthusiastic and were interested in obtaining further advice relating to the way they conduct their work and on their plans for further development.

I. INTRODUCTION

At the request of the UK Government Authorities, an IAEA team of six experts visited the Health & Safety Executive (HSE), Nuclear Safety Directorate (NSD), in March 2006 to conduct an Integrated Regulatory Review Service (IRRS) with reduced scope. On January 2006 a preparatory mission was carried out in HSE offices, St Peter's House, to discuss the objective/purpose of the review in connection with the readiness to regulate and licence any new reactor designs in advance of any specific proposals for building a new nuclear power plant in UK considering the Energy Policy review announced by UK Prime Minister and the Secretary of State for Trade and Industry (DTI) in 2005.

Therefore, the purpose of the mission was to conduct a review of how HSE intends to go about the appraisal of reactor designs in advance of specific proposals for a new build, to review the effectiveness of the HSE/NSD and to exchange information and experience in the regulation of nuclear safety in selected predetermined areas considered on IRRS. The selected areas are: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; authorization process; review and assessment; development of regulations and guides and the management system.

The IAEA has expanded its previous International Regulatory Review Team (IRRT) mission to address the complete gamut of regulatory activities associated with the safe utilization of nuclear technology – in this regard, it is now known as an Integrated Regulatory Review Service (IRRS). The peer review team mission proposed, in this instance, did not consider additional topical areas included in the IRRS. This is the reason of the named –reduced scope.

The review was conducted from 26th, March to 3rd April 2006. Before the mission, the HSE/NSD made available a collection of Advance Reference Material (ARM) for the team to review. This material comprised of a large number of legal, regulatory and internal documents, in particular the report of NSD IRRT Self-Assessment. During the mission the team performed a systematic review of the predetermined topic areas using the Self-Assessment in response to the IAEA questionnaire, the ARM, interviews with HSE/NSD staff and direct observation of their working practices. Most of the IRRS activities took place at the new HSE/NSD offices at Redgrave Court in Bootle, Merseyside. In addition, the members of the team participated on a technical visit at the Wylfa Nuclear Power Plant in Wales.

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS to review the effectiveness of the UK regulatory body and to exchange information and experience in the nuclear safety regulation (see Introduction). During the review the team recognized that the review had to include in its scope the regulatory effectiveness of both the current HSE/NSD regulation of existing nuclear power plants and its readiness to regulate and licence any new reactor designs.

IRRS missions are tailored to address the specific needs or activities of the regulatory body, or to review a situation where the scope of regulatory responsibility is changing.

The key objectives of an IRRS mission are to enhance nuclear safety by:

- Providing the host country (regulatory body and governmental authorities) with an objective peer review of their nuclear regulatory practices with respect to international safety standards;
- Providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance falls short of internationally accepted standards;
- Providing key staff at the host regulatory body with an opportunity to discuss their practices with experts who have experience of other practices in the same field;
- Providing all Member States with information regarding good practices identified in the course of the review; and
- Providing experts from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.

In addition in preparing for the mission the IRRS:

Provides the host country (regulatory body and governmental authorities) through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against International Standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work was carried out by G. Caruso, NSNI/ IAEA staff member, acting as the Team Leader of the mission. In accordance with the request from HSE, and taking into account the scope as above indicated, it was agreed that the IAEA review team was comprised of 5 external experts: Mr. R. W. Borchardt (United States of America), Mr. J. Laaksonen (Finland), Mr. U. Schmocker (Switzerland), Mr. K. Soda (Japan), Mr. P. Webster (Canada).

The working areas and the HSE counterparts were distributed according to Appendix IV.

During the preparatory period the electronic files of the documents were sent by HSE/NSD and distributed to the experts. All details and organizational aspects were defined with the nominated HSE/NSD Counterpart, acting as Liaison Officer Mr. Peter Addison, HM Principal Inspector, Nuclear Installations Inspectorate.

B) REFERENCES FOR THE REVIEW

The main reference documents provided by HSE/NSD for the review mission are indicated in Appendix VI part A. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VI part B.

C) CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted for all the review areas, with the objective to provide recommendations, suggestions and good practices (findings of the review) to advise HSE/NSD. The review was conducted through meetings and visits to the different areas and buildings of the written material, interviewing the HSE/NSD personnel and through observations regarding the national practices and activities.

The team performed its activities based on the Mission Programme stated in Appendix III.

The entrance meeting was held on Monday, 27th March with the participation of HSE/NSD authorities. Opening remarks were held by Mr. M. Weightman, HM Chief Inspector Nuclear Installations and Director Nuclear Safety Directorate, Commissioner Ms. M. Burns, and Mr. T. Taniguchi, Deputy Director General, Department of Nuclear Safety and Security, IAEA.

The Exit meeting was held on Monday, 3rd April, with the HSE/NSD authorities, Mr. Mike Weightman, HM Chief Inspector Nuclear Installations and Director Nuclear Safety Directorate, Division Heads, Section Heads, Technical and support staff, as well as Mr. Kenneth E. Brockman, Director, Division of Nuclear Installation Safety and the IRRS Review Team. The draft technical notes were handed over to HSE/NSD at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

The Health and Safety Commission (HSC) is responsible to “make arrangements to secure the health, safety and welfare of persons at work, and the public, in the way undertakings are conducted.” The HSC reports to the Secretary of State for Work and Pensions, but also provides advice to other Secretaries of State including the Secretary of State for Trade and Industry. The Health and Safety Executive (HSE) reports to the HSC on matters of industrial safety. HSE develops health and safety policy, performs inspection and enforcement activities, and conducts investigations. The Nuclear Safety Directorate (NSD) is a free standing directorate within HSE, its operational arm is HM Nuclear Installations Inspectorate. The authority for UK Regulators to carry out assigned responsibilities is provided by the following legislation:

The Health and Safety at Work Act 1974 (HSWA74) requires employers to ensure, so far as is reasonably practicable, the health and safety at work of their employees and also of affected members of the general public. This act also defines two regulatory bodies, the Health and Safety Executive (HSE) and the Health and Safety Commission (HSC).

The Nuclear Installations Act 1965 etc. (Repeals and Modifications) Regulations 1974 made HSE the nuclear licensing authority for nuclear sites. Under the NI Act, the provision applicable to HSE is that the Act requires the licensing of sites, which are to be used for the operation of nuclear reactors and certain other classes of nuclear installations, which may be prescribed. In addition, section 24A enables HSE to impose fees on nuclear licensees and applicants. The authority to grant a nuclear site licence is delegated to Her Majesty’s Chief Inspector of Nuclear Installations, who is also the Director of HSE's Nuclear Safety Directorate (NSD), which administers this licensing function on HSE’s behalf.

Ionizing Radiation Regulations, IRR99 provides for the protection of all workers and members of the public, whether on licensed sites or elsewhere, from ionising radiation. IRR99 implements aspects of the European Council Directive establishing Basic Safety Standards and includes the setting of radiation dose limits for employees and members of the public for all activities involving ionising radiation.

The Electricity Act 1989 requires that a generating station with a capacity greater than 50 megawatts be granted a consent by the Secretary of State for Trade and Industry (for England and Wales) or the Secretary of State for Scotland under section 36 of the Electricity Act 1989 before being constructed, extended or operated.

The Radioactive Substances Act 1993 (RSA93) requires the operator of a nuclear licensed site to obtain prior authorisation to dispose of radioactive waste.

The Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 implement the requirement for an environmental impact assessment for decommissioning nuclear power stations and nuclear reactors.

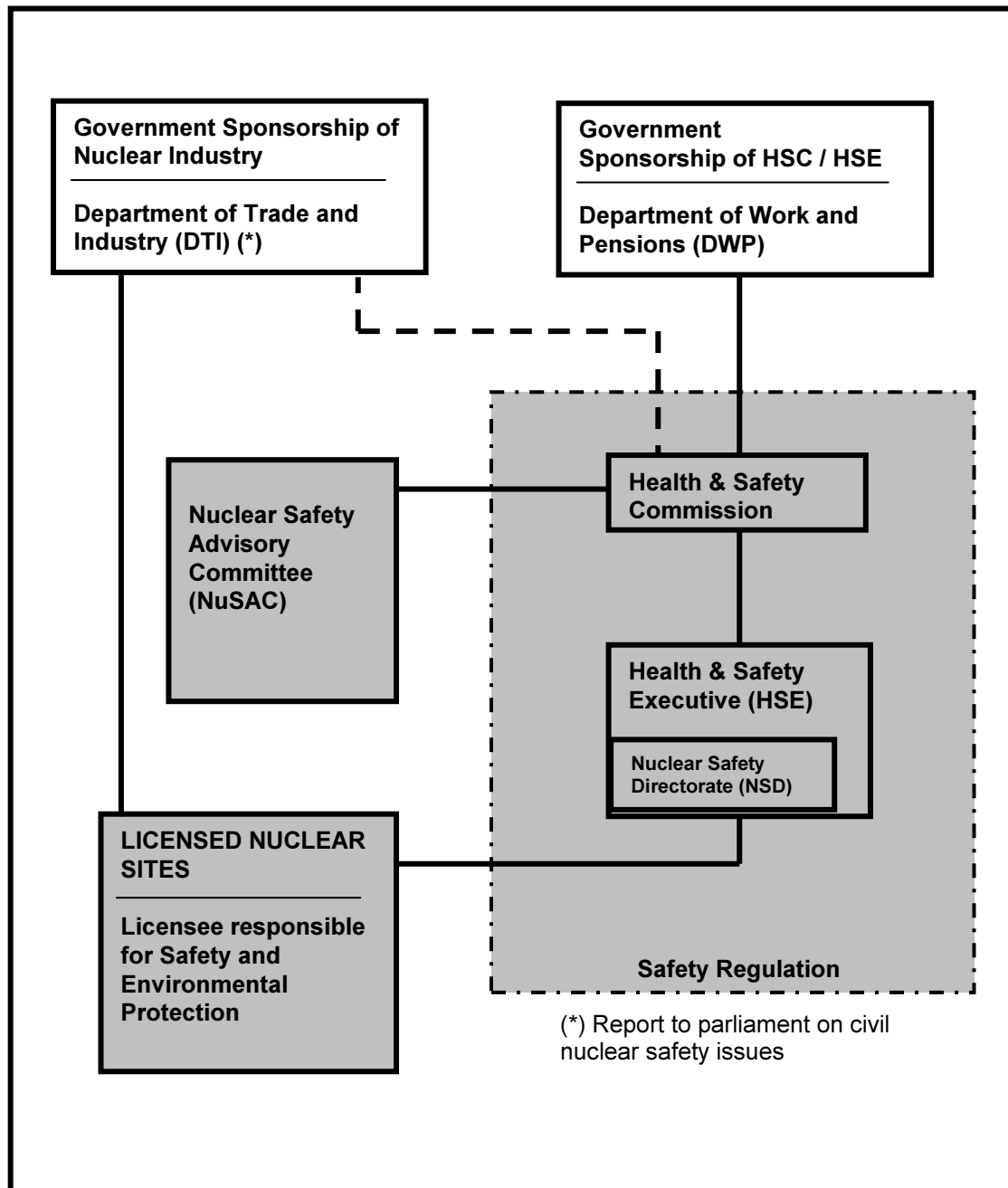
The Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR) implements the articles on intervention in cases of radiation emergency in European Council Directive 96/29/Euratom.

1.1.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 2.4 (5) states that the legislation “*shall arrange for adequate funding of the regulatory body.*”
- S1) **Suggestions:** *HSE should make arrangements to charge fees for pre-licence application work.*
- (2) **BASIS:** Section 2.4 (7) states that the legislation “*shall establish a procedure for review of, and appeal against, regulatory decisions (without compromising safety).*”
- R1) **Recommendation:** *HSE should review and document the legislative authority that allows the appeal and review of technical basis for regulatory decisions in addition to the procedural review that is currently allowed, and take appropriate actions. (S1 of section 2.1.1. addresses the NSD internal practices and procedures related to this recommendation.)*
- (3) **BASIS:** Section 2.4 (16) states that the legislation “*shall define how the public and other bodies are involved in the regulatory process.*”
- S2) **Suggestion:** *HSE should initiate actions to establish and document the role of the public in the regulatory process.*

1.2 POSITION AND RESOURCES OF THE REGULATORY BODY

HSE is given direct responsibility for the enforcement of the nuclear safety regulatory system and its independence as a regulator is ensured by HSWA74. There are also governmental mechanisms in place to maintain regulatory independence. HSE is sponsored by the Department for Work and Pensions (DWP), which has no role in promoting nuclear technology or responsibilities for facilities or activities. However, the Secretary of State for Trade and Industry is answerable to Parliament for civil nuclear safety in the UK. In this respect HSE can provide factual information to this Minister on matters of nuclear safety regulation, but this Minister is not responsible for HSE’s nuclear regulatory actions. HSE works closely with a number of other governmental authorities as it relates to nuclear installation activities. Memoranda of understanding have been established and the independent role and authorities of HSE are well established and understood.



The Nuclear Safety Directorate is one of six organizations that report to 1 of 2 Deputy Director General positions in HSE (please see Appendix VI). The HSE mission is “to protect people’s health and safety by ensuring that risks in the changing workplace are properly controlled.” The mission of NSD is “To secure effective control of health, safety and radioactive waste management at nuclear sites for the protection of the public and workers and to further public confidence in the nuclear regulatory system by being open about what we do.” Notwithstanding NSD’s independent role and responsibilities, NSD staff are occasionally requested to participate in reviews and assessments outside of the NSD mission. While this practice has several benefits to the government as a whole, HSE and NSD, it places an unplanned resource demand on an already stressed resource situation.

NSD is funded through HSE which in turn receives its funding from Parliament. Although the majority of NSD costs are recovered from the operators through the imposition of fees, the NSD funding authorization is established and fixed by HSE as part of its annual budget process. Throughout the review, the IAEA experts obtained information indicating that NSD currently has fewer resources than required to complete all of its assigned work. This situation has required frequent adjustments in staff work assignments in order to make progress on the highest priority work. As discussed in section 3 of this report, this situation is due to a combination of current staffing levels being below the authorized limits and the potential that the authorized staffing levels may not be sufficient to complete all assigned work.

1.2.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 2.2 (4) states: *“The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.”*

see section 3

1.3 OTHER REQUIREMENTS FOR GOVERNMENTAL RESPONSIBILITIES

A recent infrastructural arrangement for providing closure and decommissioning of nuclear facilities, site rehabilitation, and the safe management of spent fuel and radioactive waste is the establishment of the Nuclear Decommissioning Authority (NDA). This organization is given the ownership of several nuclear sites with a wide variety of nuclear facilities. These facilities are still operated by previous licence holders under a contract from the NDA. The responsibility for safety is thus with the licence holders and the provisions of licence conditions are in force.

The role and safety responsibility of the NDA is not well defined in the current circumstances. While the NDA is authorized to make decisions on the use of its property and on the financing of the work done by its contractors, arrangements do not exist that are normally specified through the site licence conditions and would permit comprehensive regulatory oversight of the NDA. The situation would become even more complicated if there would be a proposal to change contractors who are currently operating at the sites for the NDA.

It is not clear whether the NDA should be considered as an operator and how the NSD should regulate its activities.

1.3.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 2.3 of GS-R-1 states: *“The prime responsibility for the safety shall be assigned to the operator”.*

S3) **Suggestion:** *NSD should take an initiative to clarify*

- *What is the NDA’s responsibility for safety in view of its authority to decide on activities and their financing at the nuclear sites; and*
- *Whether the NSD should, regulate the NDA activities and what means it would have available for such regulation.*

2. AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

2.1 GENERAL SITUATION

The NSD is a long-established and well-regarded nuclear regulatory agency which is respected internationally for its leadership role in ensuring nuclear safety. The statutory authorities under which it operates are the Health and Safety at Work Act and the Nuclear Installations Act, which give the NII, as an agency of the HSE, clear and strong authority to achieve its purpose. The Health and Safety at Work Act is ‘enabling legislation’ which permits the HSE to make regulations. The Nuclear Installations Act gives the NSD the authority to issue licences, which may contain any conditions it considers necessary in the interest of safety and with which the licensees must comply.

The licences which the NSD issues under authority of the Nuclear Installations Act are for sites where prescribed activities are undertaken, these being nuclear power plants, nuclear fuel enrichment, fabrication and reprocessing plants, radioactive waste management facilities, research reactors, radioisotope production facilities, Atomic Weapons Establishments and naval dockyards.

In order to discharge its responsibilities, the NSD sets national regulatory standards, assesses safety cases and submissions, inspects sites and enforces compliance with the law and licence conditions. It also sets operational policy and strategy for the regulation of nuclear sites, gives guidance and administers nuclear safety research.

The practice in the UK is for each licensee to develop its own health and safety standards and criteria. The NII assesses the licensees’ safety submissions against its Safety Assessment Principles, which are backed-up by internal Technical Assessment Guides. The Safety Assessment Principles are currently undergoing public consultation.

Although current licensees are familiar with the manner in which applications or safety submissions are reviewed by NSD staff, this may not be the case for an applicant for new build. A revised draft document “The Regulations of Nuclear Installations in the U.K., including note for Licence Applicants” was issued in November 2005 to give stakeholders an insight into the nuclear regulator regime and the process involved in licensing – and delicensing – nuclear sites in the U.K.

Further to this document, internal processes are being developed for eventual inclusion in the Quality Management System. The scope of these should include roles and responsibilities and they should be subject to consultation. No process currently exists to describe how a technical decision of NSD staff may be appealed other than reviewing the process which had been followed.

The UK has historically been very active internationally, which has benefited the nuclear safety regime in many countries.

The legal authority of the NSD is very strong. Of particular note is the ability of the Chief Inspector to amend a licence at short notice in order to ensure safety, should a particular situation so require.

2.1.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 3.3 (1) of IAEA GS-R-1 states: *“the regulatory body: shall establish a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption, or for removal from regulatory control”*
- (2) **BASIS:** Section 3.3 (2) of IAEA GS-R-1 states: *“the regulatory body shall establish a process for changing conditions of authorization”*.
- R2) **Recommendation:** *processes should be developed and documented that describe the steps to be followed for the issuance or amendment of a licence, including the activities, responsibilities, inputs and outputs.*
- S4) **Suggestion:** *NSD should review, document and publicize its internal practices and procedures for the appeal of technical decisions.*
- (3) **BASIS:** Section 2.6 (14) of IAEA GS-R-1 states: *“The regulatory body shall have the authority: liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information.”*
- (4) **BASIS:** Section 3.3 (6) of IAEA GS-R-1 states: *“In order to discharge its main responsibilities, as outlined in para. 3.2, “the regulatory body: shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public.”*
- G1) **Good Practice:** *The NSD has long been very active internationally, has promoted the implementation of good regulatory practices in many countries and has openly shared its knowledge and expertise.*
- (5) **BASIS:** Section 2.6 (5) of IAEA GS-R-1 states: *The regulatory body shall have the authority: to issue, amend, suspend or revoke authorization and to set conditions.*
- (6) **BASIS:** Section 3.2 (3) of IAEA GS-R-1 states: *“In fulfilling its statutory obligations, the regulatory body shall provide for issuing, amending, suspending or revoking authorization, subject to any necessary conditions...”*
- G2) **Good Practice:** *The ability of the Chief Inspector to amend a Site Licence to revise a licence condition or add a new one, following consultations with the Environmental Regulators, allows the regulator to respond swiftly when circumstances require,*

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

The Health and Safety Commission (HSC) is responsible to “make arrangements to secure the health, safety and welfare of persons at work, and the public, in the way undertakings are conducted.” The HSC reports to the Secretary of State for Work and Pensions, but also provides advice to other Secretaries of State including the Secretary of State for Trade and Industry. The Health and Safety Executive (HSE) reports to the HSC on matters of industrial safety. HSE develops health and safety policy, performs inspection and enforcement activities, and conducts investigations. The Nuclear Safety Directorate (NSD) is a free standing directorate within HSE.

NSD is headed by HM Chief Inspector Nuclear Installations & Director Nuclear Safety Directorate. The NSD organization consists of 4 Divisions:

Division 1, Nuclear Power Stations Regulation

Division 2, Nuclear Fuel Cycle & Decommissioning Regulation

Division 3, Defence Facility Regulation

Division 4, Nuclear Safety Research & Strategy

The NSD resource allocation is provided by HSE based upon prior year budgets and a general consideration of projected staffing and resource needs. The NSD management team actively manages implementation of the budget during the year by reallocating resources within NSD to the highest priority work as needed to accommodate emerging work. However, NSD has not defined what work activities constitute the minimum needed to fulfill its basic responsibilities and therefore is not able to define what constitutes adequate resources to accomplish new work assignments and still accomplish its core mission.

Throughout this mission, each of the review team experts gained an appreciation for the challenge NSD managers face on a daily basis of assuring that available resources are being spent on the highest priority work activities. This is not an uncommon challenge in many organizations since there is frequently more work to be done than available resources can accomplish. However, because NSD has not routinely defined and documented a budget beginning with “must be completed” work resources and then adding various levels of lower priority work to the budget it is not really possible to know what the “appropriate” level of resources are. Conversely, when emergent work is identified there is no established method of identifying which work will be cancelled or deferred. The recommendation in this section is based upon the findings and issues discussed throughout this report.

3.1.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 4.1 of IAEA GS-R-1 states: *“The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model. The regulatory body’s reporting line in the governmental infrastructure shall ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or activities.”*
- R3) **Recommendation:** *It is recommended that NSD clearly define and document the minimum elements of its annual responsibilities (in relation to its strategic goals and key business activities (KBA)) and estimate the resources required to accomplish those elements. Future budget requests would then be based on these minimum resource needs plus an allocation for additional work as appropriate.*
- S5) **Suggestion:** *NSD resources necessary to accomplish new build activities need to be established and included into budget planning.*

3.2. STAFFING AND TRAINING

The authorized staffing level of NSD is 179 inspectors and 76 support staff, although current staffing is approximately 10% below the authorized level despite several staff staying beyond their retirement eligibility date. NSD has had some difficulty hiring sufficient staff to reach the authorized staffing level. A review of current staff age demographics indicates that a significant number of staff will retire over the next few years which will add to the hiring challenge. In addition, any work associated with new build activities will create the need for additional staff above current allocations. A recent analysis conducted by NSD of staffing needs based upon current work load concluded that 192 inspectors were needed without any allocation for new build activities.

Recent recruitment and hiring efforts have not kept pace with attrition. Although studies and evaluations are underway, there does not appear to be a defined plan on how NSD will address future staffing needs. The ability to hire staff will become even more challenging if new build activities were to escalate due to competition from industry. Current NSD hiring practices search for candidates that have a technical degree, a minimum 5 to 7 years of applicable industry experience, are members of recognized professional institutions and have both the theoretical understanding and practical hands-on experience necessary for the NSD position. It is not clear that NSD will be able to meet future staffing requirements without revising the current hiring practices and developing a new approach. Other nuclear regulatory bodies have implemented programmes that include hiring individuals with appropriate technical degrees, but limited or no industry experience. There are resource implications related to the training and indoctrination of the new and inexperienced hires, and these must be taken into account in the overall resourcing. These programmes are an important and successful part of a long term human capital strategy.

Retention and hiring are both important aspects of ensuring that the regulator has adequate levels of staffing. Physical work conditions, adequate salaries, and meaningful work each contribute to an organization's ability to hire and retain appropriate staff. HSE's review and implementation of personnel practices, including its review of the Nuclear Inspectorate remuneration and reward package will significantly impact NSD staffing in the future.

NSD has established a detailed and thorough training programme for the indoctrination of new employees as well as the continuous professional development of existing staff. Necessary competencies are identified for each job category and existing staff skills are compared to these requirements. This allows a gap analysis to be performed and the development of a prioritized training programme for the organization and each individual.

NSD relies heavily on experienced staff to perform its review and assessment functions. In numerous areas there is only a single individual who has the necessary competencies to adequately complete activities in a specific technical area. This situation creates severe resource constraints and productivity challenges when the specific individual is assigned to other work. In addition, it would take several months to replace an expert if that expert were to retire or leave NSD. During that vacancy period it is unclear how NSD would meet its responsibilities. The operators have been impacted by NSD's limited resources also. NSD has been unable to meet numerous timeliness requests for regulatory approval which then delayed licensee activities.

3.2.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 4.6 of IAEA GS-R-1 states: *"The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions."*
- R4) **Recommendation:** *It is recommended that NSD consider developing and implementing an integrated recruitment, retention and training programme that hires staff, with appropriate technical qualifications into all levels of an appropriately sized organization.*
- R5) **Recommendation:** *NSD should review current and anticipated expert staffing needs for all relevant safety assessment positions. This review should consider which areas of expertise require a staffing defense-in-depth approach by having more than a single expert in the organization.*
- (2) **BASIS:** section 4.7 of IAEA GS-R-1 states: *"In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts."*
- G3) **Good Practices:** *The skill assessment and staff individual training programmes are thorough and well managed.*

3.3. INTERNATIONAL CO-OPERATION

NSD has an active international cooperation programme through numerous bilateral arrangements with regulatory bodies of other countries. In addition NSD participates in a wide range of activities at the International Atomic Energy Agency, the Organization for Economic Co-operation and Development's Nuclear Energy Agency, the Western European Nuclear Regulators Association, and the International Nuclear Regulatory Association. Due to resource constraints, NSD is making adjustments to its level of support to some international activities.

3.4 RELATIONS BETWEEN THE REGULATORY BODY AND THE OPERATOR

NSD has a long and well established history of open and frank interactions with the nuclear facility operators. The regulatory process requires that frequent and timely discussions take place to enable adequate reviews of the safety cases as well as timely authorizations to allow operational activities to take place.

3.4.1. *Recommendations, Suggestions and Good Practices*

- (1) **BASIS:** Section 4.10 states *“Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered.”*
- G4) **Good Practices:** *The formal designation of 4 specific levels of NSD-Operator meetings sets clear expectations to all parties as to purpose and expected participation.*

4. AUTHORISATION PROCESS

4.1 AUTHORISATION FOR NUCLEAR FACILITIES

There is a long tradition on authorizing nuclear facilities in the UK. The existing authorization and regulatory process was developed in circumstances where the Government had direct control of the nuclear industry, and strong domestic organizations were supplying equipment and services to the licensees. There was close interaction between the regulators and the industry during the preliminary design and pre-licensing stage of the current fleet of Magnox and AGR stations. The regulatory concerns related to design of those facilities could be resolved in conditions where all parties had adequate financing from the Government, and thus there was no need to take into account the question on financing regulatory work in the pre-licensing stage.

Compared with the other countries, the UK system has two unique features:

- authorization is based only on one licence called Site Licence; this is granted for an indefinite term and covers all stages of the facility life; under this licence the NSD has an authority to decide on hold points for licensed activities as it finds appropriate;
- authorization is not based on evidence on meeting prescriptive regulations, instead the authorization is managed through licence conditions, which require the licensee to suggest the design requirements and other arrangements needed for ensuring safety.

Licence conditions are identical for all facilities, and they form a strong tool that permits the NSD to keep the entire authorization process firmly under its control. In addition, they provide a comprehensive framework for the entire regulatory process and necessary authorities for the oversight of the facility throughout its lifetime. Consistent regulatory review as part of the authorization is supported by a set of detailed Safety Assessment Principles (SAP) that are intended to give guidance for the NII assessors. The SAPs are currently being revised by incorporating the lessons learned from their use since previous issue in 1992, and their scope is being extended to cover new areas such as leadership and management for safety, emergency preparedness, radioactive waste management, decommissioning, and contaminated land. There is also more accurate guidance than before on regulatory assessment of safety cases, radiation protection, fault analysis, and numerical targets and deterministic limits. Although the SAP's are written for the internal use by the NSD, they also provide useful guidance for the applicants on the expectations of the regulators. (See also Chapter 6).

An issue to be specifically noted is that the NSD has power to vary or revoke the licence conditions, or to attach further conditions to the licence.

The experience from the authorization process has shown that it functions well and provides sound basis for safe operation of the existing nuclear facilities. All authorization needs for those facilities could be handled also in the foreseeable future in a way that ensures due consideration of safety issues.

In its invitation of the IRRT mission, the UK Government asked the team to conduct a review of how HSE intends to go about the appraisal of reactor designs in advance of specific proposals for new build. This reflects a concern on whether the current approach would be successful also in the new situation where foreign owned licensees might be interested in nuclear power generation in the UK, and the potential suppliers of facilities are international companies. It has already been

experienced that the authorization of a foreign designed nuclear power plant in Sizewell B took a very long time and consumed a lot of resources of the society.

A general conclusion from the review is that the existing arrangements for the authorization can be used also to address the current challenges (privatised utilities, use of contractors, international nuclear industry), and they would provide the necessary mechanisms for ensuring safety of the new build plants. However, in order to achieve this there is an evident need to modify the front end of the authorization process and to give extensive guidance on this process to new vendors and licensees possibly entering to the UK nuclear markets. The NSD proposal on conducting a pre-licencing review before a site licence is applied for is most commendable. Pre-licensing discussions between the NSD and the future applicant before large investments are committed to a new project would reduce the regulatory uncertainties and make the subsequent licencing process more efficient. They would also facilitate timely development of changes in the plant safety features, if such changes would be required by the NSD.

4.1.1 Recommendations, Suggestions and Good Practices

(1) **BASIS:** IAEA GS-R-1 states the following:

- In section 5.3, *“Prior to granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures.”*
- In section 3.3 (3), *“The regulatory body shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information.”*
- In section 5.4, *“The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. ...For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages, each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stages.”*

R6) **Recommendation:** *Processes should be developed and documented for potential new build nuclear power plants that describe the steps to be followed by an applicant for the issuance of a site licence, including pre-licensing phase. Respectively, formal guidance should be developed on the content and format of required safety submissions, to improve efficiency and effectiveness of the entire licensing process (see also suggestion 1.1.1/S1 on financing the regulatory work in pre-licensing phase, and more detailed proposals given in separate Appendix for the authorization of potential new builds).*

G5) **Good Practice:** *The approach of asking the licence applicants to propose safety requirements for a new plant, and using the SAP's proven in the UK conditions to judge the acceptability of these requirements, provides both flexibility towards alternative technical solutions and a strong and transparent mechanism for maintaining the safety decisions firmly in the hands of the NSD. This approach gives a freedom to consider each design on its technical merits and to require additional safety features if found necessary with solid arguments from the UK point of view. It is thus ideally applicable for dealing with international nuclear industry.*

4.2 NUCLEAR FACILITY MODIFICATIONS

NSD has through the Site Licence, under licence condition 22, approved arrangements that obligate the licensees to classify the modifications planned on the existing facilities or processes according to their safety significance. Modifications in the highest category, safety class 1, shall not be commenced without the consent of the NSD. NSD review and agreement is not mandatory for safety classes 2, 3 and 4, although these can be called in for review and agreement.

Site inspectors are generally informed on modification plans, and similar information is also available through various channels to the NSD assessors. However, the NSD has not established a process that would ensure its due consideration of the safety classification correctness from risk point of view and a decision on modifications that require a regulatory review before implementation.

4.2.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 5.11 of IAEA GS-R-1 states: *“Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account”.*
- R7) **Recommendation:** *Enhance the process to ensure a more systematic NSD review of the safety classification of planned modifications, and a consideration of the need for NSD review.*

4.3 AUTHORISATION OF SELECTED LICENSEE PERSONNEL

Condition 12 of the Site Licence provides that only suitably qualified and experienced persons perform duties which may affect the safety of operations on the site and that only duly authorized persons are appointed to control and supervise operations which may affect plant safety. The same licence condition gives the NSD an opportunity to specify how it wants to approve the arrangements made to fulfil the requirement concerning qualified and duly authorized personnel.

The verification of staff qualifications and the provision of required authorizations are left to the licensee, and there is no direct involvement of the NSD in this process. Neither does the NSD oversee the licensee activities for fulfilling the licence condition 12.

4.3.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 3.3(12) of IAEA GS-R-1 states: *“the regulatory body shall confirm the competence of personnel responsible for the safe operation of the facility or activity”.*
- R8) **Recommendation:** *Consider developing an approach that includes appropriate levels of direct evidence on adequate qualification of licensee’s control room operators and other personnel in positions with direct influence on safety, and also ensures verification of consistent qualification requirements throughout the UK nuclear industry.*

5. REVIEW AND ASSESSMENT

5.1 ESTABLISHMENT AND USE OF REVIEW AND ASSESSMENT CRITERIA

Reviews and assessments are one of NSDs core business activities. Among other things NSD performs review and assessments for the consent after outages, for safety significant incidents and modifications, for organizational changes of the plant organisation and for Periodic Safety Reviews.

The Regulatory Body reviews the submitted documents based on SAPs and the corresponding TAGs. The SAPs provide the licensee with information on the regulatory expectations against which their submissions will be judged. The TAGs give additional information on the Regulatory Body's expectation on how a SAP should be fulfilled. The licensee should develop its own design safety guidelines to ensure it meets the SAPs. The licensee is expected to address in its report(s) the relevant SAPs and make judgements on its risk impact. In summary, the licensee has to demonstrate that all safety cases are kept up to date and any risk increase is acceptably low. The SAPs have been revised and have just been placed on the internet for consultation with the public. The intention is for the revised SAPs to be formally issued towards the end of 2006. The revised SAPs reflect the most recent IAEA Safety Standards and are considered to form a good basis for existing licensees, and potential new build applicants. (See also Chapter 6).

5.2 MANAGEMENT OF REVIEW AND ASSESSMENT

The review and assessment process is well established at NSD (AST/002). Each task is initiated by an Assessment Request Form (ARF) which includes the time allocation for each assessor to complete the work and an agreed completion date. For the different assessment tasks corresponding guidance are available. However, there is no formal audit of the review and assessment process to identify lessons learned.

NSD performs many different types of safety reviews. This includes the Periodic Safety Review which is mandatory every 10 years, and systematic safety reviews which give the basis for the start-up consent and mid-cycle safety reviews. On a quarterly basis each division of NSD performs a Regulatory Review Meeting (RRM) where the site-inspectors and the assessors report findings and issues arising from their assessment and inspection. The RRM reviews strategies and set priorities for the coming quarter. The newly introduced Integrated Intervention Strategy gives NSD a more proactive planning tool to review, assess and inspect facilities and activities under scrutiny.

NSD has begun to give more attention to the safety implication of the licensees human factor (HF) and organisational aspects, which are key elements to judge on the safety culture of a nuclear installation; however, NSD has not (yet) developed a process for recording and analysing these observation in a systematic and auditable way.

5.2.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 4.2 of IAEA GS-G-1.2 states: *“The regulatory body should have a system to audit, review and monitor all aspects of its review and assessment process so as to ensure that it is being carried out in a suitable and efficient manner and that any changes to the process necessitated by advances in knowledge or improvements in methods or for similar reasons are implemented.”*

- S6) **Suggestion:** *When a project is completed, a formal audit of the review and assessment process should be performed to identify lessons learned.*
- (2) **BASIS:** Section 3.46 of IAEA GS-G-1.2 states: *“The review and assessment by the regulatory body should cover all aspects of the operator’s managerial and organizational procedures and systems which have a bearing on nuclear safety”.*
- S7) **Suggestion:** *NSD should develop a process for recording and analyzing its observation of Human Factors and organizational aspects of the licensees activities in a systematic and auditable way.*
- (3) **BASIS:** Section 2.3 of IAEA GS-G-1.2 states:
The management of review and assessment should include responsibility for:
- (e) *Monitoring the progress of documents submitted by the operator and the progress of the review and assessment process against the tentative programme agreed by the operator and the regulatory body (if there is such a programme);*
 - (f) *Making the necessary arrangements whenever different parts of the regulatory body need to combine their expertise to make a decision in a timely manner;*
 - (g) *Making arrangements for co-ordination between review and assessment activities and inspection activities, as appropriate*
- (4) **BASIS:** Section 5.10 of IAEA GS-R-1 states:
The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny.
- G6) **Good Practice:** *The regulatory review meetings (RRM) which take place every three months and where the site-inspectors and the assessors report findings and issues of the plants and strategies are reviewed and priorities set for the coming quarter is a good practice.*
- G7) **Good Practice:** *The newly introduced Integrated Intervention Strategy, which gives NSD a more proactive planning tool to review, assess and inspect facilities and activities under scrutiny, is a good practice.*
- G8) **Good Practice:** *NSD performs a systematic and detailed review and assessment of work undertaken by the licensee during an outage. These reviews are all documented and the site-inspector produces a summary report including their own judgement regarding the readiness of the plant for start-up. Before the final consent for start-up is given, a start-up meeting takes place where all safety-relevant issues are discussed between the plant operator and the regulatory body. This review process is considered to be a good practice.*
- G9) **Good Practice:** *The mid-cycle review meeting held between the licensee and NSD covers a wide range of important issues such as significant plant modifications, the management of safety cases, licensing issues, operational experiences. This review process is considered to be a good practice.*

5.3. AREAS OF EXPERTISE AND TECHNICAL SUPPORT ORGANISATIONS

NSD depends heavily on experienced inspectors for the review and assessment tasks. In several specialist areas there is only one assessor with no redundancy. In some areas it was noted positions had been vacant for some time. This could result in NSD not having enough in-house expert knowledge to perform its oversight duties if staff were to resign or retire. (See also Chapter 3).

One approach to address this shortfall would be to use external consultants to carry out independent analyses and validation of codes. NSD is using HSL as one of its consultants. However it is important to identify those areas where technical support may be needed and where the expertise is available, e.g. thermal hydraulics, to enable NSD to make sound technical decisions and recommendations in a timely way.

5.3.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 4.3 of IAEA GS-R-1 states: *“If regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibility for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultant”*.
- R9) **Recommendation:** *NSD should identify expertise and technical support available inside UK or abroad to support it in its review and assessment work. This should include the possibilities to perform independent analysis and validation of codes in areas such as PSA, Thermal Hydraulics, Severe Accident Analyses. Appropriate arrangements should be made to assure that for all safety relevant topics high qualified expertise can be identified by NSD.*

5.4 REVIEW AND ASSESSMENT OF OPERATIONAL EXPERIENCE FEEDBACK

A systematic evaluation of operating experience (OE) by the operator and the regulator is essential for continued safe operation of nuclear power plants. In addition to overseeing the operator’s programmes, the regulator has the broader responsibility for monitoring industry-wide trends, both nationally and internationally. To meet these responsibilities, the regulatory body must have its own operating experience programme.

The IAEA Safety Guide on “A System for the Feedback of Experience from Events in Nuclear Installations,” provides a good rationale for the importance of a vigorous OE programme to promote nuclear safety:

- to identify and quantify events and conditions that are precursors to more serious events;
- to identify the root causes of these events and suggest corrective actions;
- to discover emerging trends or patterns of potential safety significance;
- to assess the seriousness of the events and conditions by analyzing what could have happened;
- to assess the generic applicability of events; and
- to recommend steps to prevent the recurrence of similar events.

The regulator's operating experience programme should be guided by a detailed procedure and it should include all of the elements such as collection, screening, analysis, corrective actions, tracking and follow-up.

NSD do not have such a programme and no clear process in place to decide which events should be assessed. In addition the dissemination of the information on events to NSD staff is not clearly defined.

NSD should also assure that the operational experiences are shared between the operators inside UK and abroad. In addition NSD should assure that the licensees make use of the world wide operating experiences, e.g. that the WANO, INPO and AIRS information are systematically analysed.

5.4.1. Recommendations, Suggestions and Good Practices

(1) **BASIS:** Section 3.3(7) of IAEA GS-R-1 states: *"In order to discharge its main responsibility, the regulatory body shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated"*.

R10) **Recommendation:** *NSD should review its processes and resources to ensure that assessment of events from UK plants as well as from foreign plants is carried out. A formal process for reviewing events should put in place to ensure that lessons learned are available in due time.*

R11) **Recommendation:** *NII should further develop a means by which it can ensure that the operators share operating experience among themselves, analyse the international operating experiences and take appropriate corrective action.*

5.5. PERFORMANCE OF MAJOR REVIEW AND ASSESSMENT TASKS

NSD concentrates mostly of the review of the submitted reports, on inspections at the plant site and on discussion with the licensee and its experts to determine the adequacy of the licensee's safety submission. Only very few inspections and audits are performed at vendors and manufacturer sites, even for important safety components, e.g. the new vessel head for Sizewell B. The increasing pace of change in industry and its globalization do have an impact on the quality of plant and equipment. It is therefore important that the regulatory body convinces itself on the quality of the product.

As mentioned under 5.2 NSD does have processes in place to assess major review and assessment tasks. NSD documents its review and assessment work in reports. The reports contain the basis for any decision which has been made. However, NSD does not annex the basis of its decision to the formal letter on its decision to the licensee. By the Freedom of Information Act the licensee have the right to receive this information. Therefore it would be reasonable to send the basis of the NSD decision to the licensee.

5.5.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 2.33 of IAEA GS-G-1.2 states: “...As review and assessment progress, it may be necessary for the regulatory body, with the knowledge of the operator, to have direct contact with a contractor”.
- S8) **Suggestion:** NSD should carry out audits and inspections themselves or/and through a contractor on the QA process of manufacturer and vendors on important safety components (e.g. the fabrication of a new vessel head).
- (2) **BASIS:** Section 4.10 of IAEA GS-R-1 states: “Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship shall be fostered.”
- Section 5.10 of IAEA GS-G-1.4 states: “However, the licence should contain information, such as:
- Fulfilment of requirements. The licence should include a summary statement that all legal and technical requirements in respect of safety have been fulfilled and that the proposed activities can be carried out without undue radiological risk to workers, the public or the environment.”
- S9) **Suggestion:** When NSD issue a formal regulatory decision the basis of its decision should be sent to the licensee.
- (3) **BASIS:** Section 5.5 of IAEA GS-R-1 states; “The regulatory body shall formally record the basis for decisions”.
- G10) **Good practice:** The documentation providing the basis for decision making in project assessment report is a good practice.

5.6. USE OF PROBABILISTIC SAFETY ASSESSMENT

HSE philosophy is based on the Tolerability of Risk (ToR). Therefore it is logical, that NSD uses risk insight as part of its decision making process. To be sure that the PSA insights used for the decision are sound, it is important that the PSA model used for the analysis reflects the actual state of the plant, is complete and has been reviewed by the regulator.

As mentioned already under 5.2, NSD depends heavily on experienced inspectors for the review and assessment tasks. This is especially also true for the PSA area, where little redundancy is available inside NSD (see also Chapter 3).

5.6.1. Recommendations, Suggestions and Good Practices

(1) **BASIS:** Section 3.60 of IAEA GS-G-1.2 states: “The regulatory body should review and assess the PSA in order to gain confidence that it has been carried out according to an acceptable standard so that the results can be used as input to the regulatory decision making process. ... In the review and assessment, it should be considered: whether the data used in estimating frequencies and probabilities are sufficiently well founded; whether the treatment of supporting systems, dependent failures and human intervention is appropriate; whether the bounding of PIEs into groups for analysis, if used, is sound; whether the identification of failure scenarios is comprehensive; and whether the analyses of the facility’s response and consequences are acceptable”.

S10) **Suggestion:** NSD should review the completeness of the PSA model of each plant to ensure it reflects the actual state of the modeled plant. This should be carried out periodically to assure that the insights gained from the analyses are sound and robust.

(2) **BASIS:** Section 3.61 of IAEA GS-G-1.2 states: “The insights gained from PSA should be considered together with those from other analyses in making a decision on the acceptability of the safety of a facility. An important aspect of PSA is that, apart from giving an estimate of risks, it also provides information on whether the design is balanced, on the interaction between design features of the facility, and on where there are weaknesses. These additional aspects should be given due consideration by a regulatory body reviewing a PSA”.

G11) **Good practice:** The use of risk insights from PSA for regulatory decision making in NSD is a good practices.

6. DEVELOPMENT OF REGULATIONS AND GUIDES

6.1. PROCESS FOR DEVELOPMENT OF REGULATIONS AND GUIDES

The HSE has issued a number of regulations under authority of section 15 of the Health and Safety at Work Act which are relevant to the mandate of NSD. Among these are ‘Public Information for Radiation Emergencies Regulations 1992’, ‘Management of Health and Safety at Work Regulations 1999’, ‘Ionising Radiation Regulations 1999’, Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999’ and ‘Radiation (Emergency Preparedness and Public Information) Regulations 2001’. The 1994 Nuclear Review had considered the need to issue new legislation but HSC had concluded that there was no need.

The NSD has also issued a number of high-level guides, such as ‘Management of Health and Safety at Nuclear Installations’, ‘Nuclear Site Licences – Notes for Applicants’ and ‘Safety Assessment Principles’. In addition, a large number of internal guidance documents (Technical Inspection Guides and Technical Assessment Guides) have been developed to assist staff in performing inspections and assessments. These are available on the HSE website.

The NSD had considered issuing the SAPs as formal guidance to licensees but concluded that they should continue to be internal, since no Regulations exist for them to explain. They continue to serve the purpose of prompting assessors as to the sort of questions to ask when reviewing submissions. As such, they indicate to licensees or applicants the kind of information to submit but they stop short of being formal guidance.

6.1.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** sections and 3.2 (1) of IAEA GS-R-1 states: *In fulfilling its statutory obligations, “the regulatory body: shall establish, promote or adopt regulations and guides upon which its regulatory actions are based”*
- (2) **BASIS:** sections and 5.27 of IAEA GS-R-1 states: *Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.*
- (3) **BASIS:** sections and 2.22 of IAEA GS-G-1.4 states: *“The regulatory body may facilitate its task if, instead of attempting to issue many detailed regulations, it establishes some of the provisions in the form of guides to advise the operators of ways of meeting more general regulatory requirements. Since guides are advisory, they allow the operator more flexibility in applying new technologies and developing new procedures which, in some cases, may enhance safety. They also allow the regulatory body to promote learning by modifying its guides to include innovative good practices and to revoke impractical or unnecessary features.”*

S11) **Suggestion:** *That the NII issue by formal means the various internal guides that indicate ways of meeting general regulatory requirements, such as the current 36 licence conditions.*

- G12) **Good Practice:** *A comprehensive set of internal guidance documents exist to describe many elements of how the regulatory body functions.*
- G13) **Good Practice:** *The document “Safety Assessment Principles for Nuclear Facilities” (first issued 1979, revised 1992 further draft issued for public consultation April 2006) is a comprehensive description of the principles that are the foundation of nuclear safety and offers guidance as to how they may be achieved.*

7. THE REVIEW OF THE MANAGEMENT SYSTEM

The NSD Business Management System (BMS), which is described in the Business Management Manual (BMM) works downwards from the Vision and Mission of the organization, which are themselves set within the Vision and Mission of the HSE. The BMS/BMM describe the way in which the organization is led and managed, by describing the values, principles, policies, practices, roles and responsibilities which guide management behaviour in delivering the Vision and Mission. The BMM also describes how the BMS itself is managed. Since the BMS is a work-in-progress, the review against GS-R-3 has been at a high-level only.

The BMS as it currently stands has provided a framework onto which can be applied the procedures and practices that describe the manner in which NSD currently operates. This is a necessary step in the development of any management system manual for an operating organization. As the BMS is developed further however, the organization should take the opportunity to consider the manner in which it should be operating in order to achieve its goals, as described in the Strategic Plan 2004-2010, effectively and efficiently. This will likely lead to identifying the need to revise some existing procedures and practices or develop new ones.

A number of processes and procedures that are common across HSE, such as those for inspection, investigation or enforcement, are referred to in the BMM. Other processes which are unique to NSD, in key business areas such as permissioning or compliance, remain to be developed. For example, the process by which the BMM itself is maintained up-to-date is one that has not yet been developed.

7.1.1. Recommendations, Suggestions and Good Practices

- (1) **BASIS:** Section 2.1 of IAEA GS-R-3 states: *“a management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement”*. The main aim of the management system shall be to achieve and enhance safety by:
- *Bringing together in a coherent manner all the requirements for managing the organization;*
 - *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied.*

R12) **Recommendation:** *the development of the BMS be continued in order that the BMM can contain the policies, processes and procedures necessary to describe the functioning of the organization. As an initial step, the BMM should be made consistent with Annex 4 of the Strategic Plan 2004-2010, or contain the information directly.*

- (2) **BASIS:** Section 2.8 of IAEA GS-R-3 states: *The documentation of the management system shall include the following:*
- *The policy statements of the organization;*
 - *A description of the management system;*
 - *A description of the structure of the organization;*
 - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;*
- A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.*

See also section 5.1, 5.2 and 5.3.

- S12) **Suggestion:** *The Business Management Manual should include all the processes that describe how work is to be prepared, reviewed, carried out, recorded, assessed and improved.*
- (3) **BASIS:** Section 3.12 of IAEA GS-R-3 states: “Senior management in the organization shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved”.
- (4) **BASIS:** Section 3.13 of IAEA GS-R-3 states: *An individual reporting directly to senior management shall have specific responsibility and authority for:*
Coordinating the development and implementation of the management system, and for its assessment and continual improvement;
Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;
Resolving any potential conflicts between requirements and within the processes of the management system.
- R13) **Recommendation:** *A senior manager should be given responsibility for the management system. The person responsible for developing the management system should report directly to the senior manager.*
- (5) **BASIS:** Section 2.9 of IAEA GS-R-3 states: “The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be legible, readily identifiable and available at the point of use.”

Section 6.9 of IAEA GS-R-3 states: “Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.”
- S13) **Suggestion:** *A process should be developed to describe the means by which the Business Management Manual is maintained up-to-date. This for example may permit immediate updating for minor alternations to the document, whereas changes to the BMS itself would be identified on some regular basis and approval given by the Management Board before the Manual is revised.*
- (6) **BASIS:** Section 6.4 of IAEA GS-R-3 states: “An organizational unit shall be established with the responsibility for conducting independent assessments. This unit shall have sufficient authority to discharge its responsibilities.”
- S14) **Suggestion:** *A process for conducting independent assessments (audits) should be developed and a means by which they be performed proposed. This could require the establishment of an internal unit or use of external resources.*

APPENDIX I EXPERTS OPINION ON NEW BUILD

This appendix provides our experts opinion for consideration by NSD in the planning and execution of new build activities in addition to those findings documented in the main report. The following proposals were derived from the IRRS team members' opinions and recent experiences, but not from IAEA requirements. This input is provided in response to the UK's request (see introduction). The IRRS follow-up mission will not evaluate NSD's response to these proposals unless requested by the UK government.

Proposal 1: *The Government authorities who have a decision making role in new plant licensing should establish a contact forum with the aim of producing a joint plan for an integrated licensing process. The objective should be to separate the political decision making process from the technical review to be conducted later by the NSD. The integrated process should provide a logical order of decisions needed from different authorities and it should ensure the consistency of all regulatory requirements. The joint plan should incorporate the public inquiry under the Electricity Act 1989, and seek for an early decision on how and when the inquiry will be implemented. The public inquiry should be held as early as possible, in order to permit public input at the stage where all safety concerns can be adequately addressed and taken into account in the NSD review process. A preferred time might be soon after the NSD decision has been achieved on the design safety requirements, and after the site relevant design conditions have been specified by the competent authorities.*

Proposal 2: *The NSD should develop a process for stepwise licensing of new NPP projects that may be proposed by power generation companies including pre-licensing steps. The process could start as soon as a company has expressed its intention to apply for a new NPP site licence and has committed to cover the costs of the related regulatory work in the pre-licensing stage. NSD should inform the potential applicants on:*

- *the integrated licensing process that takes into account all legislation relevant for issuing a site licence*
- *the contents and expected schedule for safety submittals to the NSD and their review, both during the pre-licensing stage and after issuing the site licence*
- *the holdpoints and the related NSD decisions during the entire process*

Proposal 3: *The stepwise approach for combined assessment of new NPP design, site, and licensee organization should include at least the following steps:*

- *as first step in the pre-licensing stage, an early NSD review and approval of the proposed design safety requirements for the plant in question*
- *as second step in the pre-licensing stage, review of the key features of the new design, as needed to identify safety issues (potential "show-stoppers") that would require modifications, further development, or additional analysis to achieve a regulatory approval of the design*
- *in parallel with the above design review, assessment of the site-specific aspects of the prospective sites and the organization of the licence applicant, as needed to identify the issues that need to be adequately addressed to achieve regulatory approval of the site and organization*

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- *in site licensing stage, review and assessment of the safety relevant design features that would be costly to modify after construction start; the review should cover also deterministic and probabilistic safety analysis as needed to verify the design safety*
- *in parallel with the above design review, assessment of the technical strength and management structure of the licence applicant;*

after construction start, review and assessment of the detailed design of systems, structures, and components.

Proposal 4: *NSD may want to seek co-operation with regulatory bodies that have reviewed and possibly licensed the NPP designs proposed to be built in the UK. However, it should be kept in mind that an in-depth review by the NSD's own staff is necessary for gaining the thorough knowledge, which is needed for regulation of the plant during its operating stage. Foreign regulatory advice could make the licensing process more efficient and effective by providing direct information on*

- *technical issues discussed at length elsewhere and the respective technical judgment of the resolution adopted;*
- *independent analytical work done by the foreign regulators or their consultants to resolve complicated technical issues;*
- *experiments used to support the approval of specific technical solutions or to qualify the analytical models used for licensing assessment;*
- *information on audits conducted by a foreign regulator to verify adequate third party qualification of vital safety systems and equipment (e.g., environmental testing of equipment, qualification of digital I&C software and hardware);*
- *information on observations made during audits to the vendor, to the equipment manufacturers, and to other contractors;*
- *quality problems encountered during manufacturing and construction.*

APPENDIX II – LIST OF PARTICIPANTS

COMPOSITION OF THE IAEA REVIEW TEAM

IAEA EXTERNAL EXPERTS:

1. R. W. BORCHARDT	US Nuclear Regulatory Commission (USNRC)	RWB1@nrc.gov
2. Jukka LAAKSONEN	Radiation and Nuclear Safety Authority (STUK)	Jukka.Laaksonen@stuk.fi
3. Kuniyisa SODA	Nuclear Safety Commission (NSC)	Kuniyisa.Soda@cao.go.jp
4. Ulrich SCHMOCKER	Swiss Federal Nuclear Safety Inspectorate (HSK)	Ulrich@Schmocker@hsk.ch
5. Philip WEBSTER	Canadian Nuclear Safety Commission (CNSC)	Websterp@cnscccsn.gc.ca

IAEA STAFF MEMBER:

1. Gustavo CARUSO	Division of Nuclear Installation Safety	G.Caruso@iaea.org
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OFFICIAL HSE/NSD LIAISON OFFICER:

HSE/NSD – HEALTH AND SAFETY EXECUTIVE / NUCLEAR SAFETY DIRECTORATE

1. Peter ADDISON	Health and Safety Executive HSE HM Principal Inspector Nuclear Installations Inspectorate	Peter.Addison@hse.gsi.gov.uk
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APPENDIX III – MISSION PROGRAMME

Sunday, 26 March 2006		
19:00 – 21:00	Opening Team Meeting at Hotel -IAEA – Mr. Taniguchi -IAEA – Mr. Caruso -Self Introduction of Experts -Briefing by the Team Leader	
Monday, 27 March 2006		
09:45- 09:45 – 11:00	Entrance Meeting at HSE Headquarters Welcome and Introduction Opening remarks IRRS remarks IAEA experts introduction General Briefing of IRRT Team	Ms. M. Burns Mr. T. Taniguchi Mr. G. Caruso
11:00 – 11:15	Coffee break	
11:15 – 11:30	Working and domestic arrangements	Mr. P. Addison
11:30 – 13:00	Presentations – Plenary A & B C Management Systems	Mr. M. Weightman Mr. L. Creswell Mr. R. Gray
13:00 – 14:00	Lunch	
14:00 – 16:00	Presentations – Plenary D E Sizewell B G UK IRRT Self Assessment Closing remarks	Mr. A. Hall Mr. A. Hall Mr. B. Ascroft-Hutton Mr. A. Hall Mr. D. Lacey Mr. G. Caruso
16:00 – 16:45	Identify Emerging Issues Planning for Interviews	
Tuesday, 28 March 2006		
09:30 – 13:00	Interviews as agreed with Counterparts Subject Areas A, B, D + UK IRRT Self Assessment	
13:00 – 14:00	Lunch	
14:00 – 15:30	Interviews as agreed with Counterparts Subject Areas C and E	
15:45 – 17:30	Team Coordination Meeting	
Wednesday, 29 March 2006		
09:30 – 11:00	Interviews as agreed with Counterparts Subject Area C, E and Sizewell B	
11:00 – 13:00	Interviews as agreed with Counterparts Subject Areas C, X, E and Sizewell B	
13:00 – 14:00	Lunch	
14:00 – 15:30	Interviews as agreed with Counterparts Subject Areas C, X, D, E, and New Build	
15:45 – 17:30	Team Coordination Meeting	

Thursday, 30 March 2006		
09:30 – 11:00	Interviews as agreed with Counterparts Subject Area G, C (UK Self Assessment)	
11:00 –13:00	Interviews as agreed with Counterparts Subject Areas D/E (UK Self Assessment)	
13:00 – 14:00	Lunch	
14:00 – 15:30	Draft findings	
15:45 – 17:30	Team Coordination Meeting: Reach Consensus on findings	
Friday, 31 March 2006		
09:30 – 11:00	IRRS Team preliminary discussions with Counterparts for clarification	
11:00 –13:00	Issue draft report for Counterparts to review (by Monday)	
13:00 – 14:00	Lunch	
14:00 – 15:30	IRRS Team drafting technical notes and team agree all issues	
15:45 – 17:30	Team Coordination Meeting	
Saturday, 1 April 2006:		
09:00	Departure Hotel	
11:30	Arrival Wylfa	
11:30 – 14:30	Introductory talk Site VIP visitor tour Lunch Questions / answer session	
14:30	Departure Wylfa	
17:00	Arrival Hotel	
Sunday, 2 April 2006		
	Team Coordination Meeting IRRS Team drafting technical notes and team agree all issues Final comments from HSE	
Monday, 3 April 2006:		
11:15 – 13:00	Exit Meeting General Technical aspects Reviewers comments in each topic Closing Remarks	Mr. G. Caruso IRRS Team Mr. K. E. Brockman
13:00 – 14:00	Lunch	
14:00 – 14:30	Interview with Mr. K. E. Brockman – HSE internal house magazine	
14:30	Departure to Sellafield	
Tuesday, 4 April 2006:		
08:30	Departure Hotel	
09:00	Arrival Sellafield	
09:00-12:00	Introductory talk Site VIP visitor tour – THORP only Lunch Question / answer session	
12:00	Departure Sellafield	

APPENDIX IV MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Lead Counterparts	NII Team	Support Staff
A	Legislative and governmental responsibilities	<ul style="list-style-type: none"> • Mr. R. Borchardt • Mr. P. Webster 	<ul style="list-style-type: none"> • Mr. L. Creswell 	<ul style="list-style-type: none"> • Mr. F. Boydon • Mr. J. Teasdale • Mr. P. Addison 	<ul style="list-style-type: none"> • Mr. M. Robbins
B	Authority, responsibilities and functions of the regulatory body	<ul style="list-style-type: none"> • Mr. P. Webster • Mr. R. Borchardt 	<ul style="list-style-type: none"> • Mr. L. Creswell 	<ul style="list-style-type: none"> • Mr. F. Boydon • Mr. J. Teasdale • Mr. P. Addison 	<ul style="list-style-type: none"> • Mr. M. Robbins
C	Organization of the regulatory body	<ul style="list-style-type: none"> • Mr. K. Soda • Mr. R. Borchardt 	<ul style="list-style-type: none"> • Mr. L. Creswell 	<ul style="list-style-type: none"> • Mr. C. Patchett • Mr. D. Watson • Mr. R. Gray • Mr. A. French • Mr. N. Byrom • Mr. D. Porter • Mr. S. Gibson • Mr. D. Lacey 	<ul style="list-style-type: none"> • Mr. A. Williams • Mr. A. Roberts • Mr. I. Britten
D	Authorization process	<ul style="list-style-type: none"> • Mr. J. Laaksonen • Mr. U. Schmocker 	<ul style="list-style-type: none"> • Mr. A. Hall 	<ul style="list-style-type: none"> • Mr. C. Patchett • Mr. B. Ascroft-Hutton • Mr. B. Slominski • Mr. D. Watson • Mr. D. Lacey 	<ul style="list-style-type: none"> • Mr. A. Williams • Mr. A. Roberts • Mr. I. Britten
E	Review and assessment	<ul style="list-style-type: none"> • Mr. U. Schmocker • Mr. J. Laaksonen 	<ul style="list-style-type: none"> • Mr. A. Hall 	<ul style="list-style-type: none"> • Mr. B. Jennings • Mr. Len. Bruce • Mr. P. Harrop • Mr. B. Ascroft-Hutton • Mr. M. Bassett • Mr. R. Nevell • Mr. D. Lacey • Mr. D. Watson 	<ul style="list-style-type: none"> • Ms. A. Gomez

Item	Subject Area	IRRS Experts	Lead Counterparts	NII Team	Support Staff
G	Development of regulations and guides	<ul style="list-style-type: none"> • Mr. P. Webster • Mr. K. Soda 	<ul style="list-style-type: none"> • Mr. A. Hall 	<ul style="list-style-type: none"> • Mr. D. Watson • Mr. M. Bassett • Mr. B. Jennings • Mr. R. Nevell 	
X	The Review of the Management System	<ul style="list-style-type: none"> • Mr. P. Webster • Mr. R. Borchardt 	<ul style="list-style-type: none"> • Mr. R. Gray 	<ul style="list-style-type: none"> • Mr. N. Byrom • Mr. D. Porter • Mr. S. Gibson 	<ul style="list-style-type: none"> • Mr. A. French

APPENDIX V RECOMMENDATIONS/SUGGESTIONS FROM THE IRRS MISSION

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
A	Legislative and governmental responsibilities	S1	<i>HSE should make arrangements to charge fees for pre-licence application work.</i>
		R1	<i>HSE should review and document the legislative authority that allows the appeal and review of technical basis for regulatory decisions in addition to the procedural review that is currently allowed, and take appropriate actions. (S1 of section 2.1.1. addresses the NSD internal practices and procedures related to this recommendation.)</i>
		S2	<i>HSE should initiate actions to establish and document the role of the public in the regulatory process.</i>
		S3	<i>NSD should take an initiative to clarify</i> <ul style="list-style-type: none"> ▪ <i>What is the NDA's responsibility for safety in view of its authority to decide on activities and their financing at the nuclear sites; and</i> ▪ <i>Whether the NSD should, regulate the NDA activities and what means it would have available for such regulation.</i>
B	Authority, responsibilities and functions of the regulatory body	R2	<i>processes should be developed and documented that describe the steps to be followed for the issuance or amendment of a licence, including the activities, responsibilities, inputs and outputs.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		S4	<i>NSD should review, document and publicize its internal practices and procedures for the appeal of technical decisions.</i>
		G1	<i>The NSD has long been very active internationally, has promoted the implementation of good regulatory practices in many countries and has openly shared its knowledge and expertise.</i>
		G2	<i>The ability of the Chief Inspector to amend a Site Licence to revise a licence condition or add a new one, following consultations with the Environmental Regulators, allows the regulator to respond swiftly when circumstances require,</i>
C	Organization of the Regulatory Body	R3	<i>It is recommended that NSD clearly define and document the minimum elements of its annual responsibilities (in relation to its strategic goals and key business activities (KBA)) and estimate the resources required to accomplish those elements. Future budget requests would then be based on these minimum resource needs plus an allocation for additional work as appropriate.</i>
		S5	<i>NSD resources necessary to accomplish new build activities need to be established and included into budget planning.</i>
		R4	<i>It is recommended that NSD consider developing and implementing an integrated recruitment, retention and training programme that hires staff, with appropriate technical qualifications into all levels of an appropriately sized organization.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		R5	<i>NSD should review current and anticipated expert staffing needs for all relevant safety assessment positions. This review should consider which areas of expertise require a staffing defense-in-depth approach by having more than a single expert in the organization.</i>
		G3	<i>The skill assessment and staff individual training programmes are thorough and well managed.</i>
		G4	<i>The formal designation of 4 specific levels of NSD-Operator meetings sets clear expectations to all parties as to purpose and expected participation.</i>
D	Authorization process	R6	<i>Processes should be developed and documented for potential new build nuclear power plants that describe the steps to be followed by an applicant for the issuance of a site licence, including pre-licensing phase. Respectively, formal guidance should be developed on the content and format of required safety submissions, to improve efficiency and effectiveness of the entire licensing process (see also suggestion 1.1.1/S1 on financing the regulatory work in pre-licensing phase, and more detailed proposals given in separate Appendix for the authorization of potential new builds).</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		G5	<i>The approach of asking the licence applicants to propose safety requirements for a new plant, and using the SAP's proven in the UK conditions to judge the acceptability of these requirements, provides both flexibility towards alternative technical solutions and a strong and transparent mechanism for maintaining the safety decisions firmly in the hands of the NSD. This approach gives a freedom to consider each design on its technical merits and to require additional safety features if found necessary with solid arguments from the UK point of view. It is thus ideally applicable for dealing with international nuclear industry.</i>
		R7	<i>Enhance the process to ensure a more systematic NSD review of the safety classification of planned modifications, and a consideration of the need for NSD review.</i>
		R8	<i>Consider developing an approach that includes appropriate levels of direct evidence on adequate qualification of licensee's control room operators and other personnel in positions with direct influence on safety, and also ensures verification of consistent qualification requirements throughout the UK nuclear industry.</i>
E	Review and assessment	S6	<i>When a project is completed, a formal audit of the review and assessment process should be performed to identify lessons learned.</i>
		S7	<i>NSD should develop a process for recording and analyzing its observation of Human Factors and organizational aspects of the licensees activities in a systematic and auditable way.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		G6	<i>The regulatory review meetings (RRM) which take place every three months and where the site-inspectors and the assessors report findings and issues of the plants and strategies are reviewed and priorities set for the coming quarter is a good practice.</i>
		G7	<i>The newly introduced Integrated Intervention Strategy, which gives NSD a more proactive planning tool to review, assess and inspect facilities and activities under scrutiny, is a good practice.</i>
		G8	<i>NSD performs a systematic and detailed review and assessment of work undertaken by the licensee during an outage. These reviews are all documented and the site-inspector produces a summary report including their own judgement regarding the readiness of the plant for start-up. Before the final consent for start-up is given, a start-up meeting takes place where all safety-relevant issues are discussed between the plant operator and the regulatory body. This review process is considered to be a good practice.</i>
		G9	<i>The mid-cycle review meeting held between the licensee and NSD covers a wide range of important issues such as significant plant modifications, the management of safety cases, licensing issues, operational experiences. This review process is considered to be a good practice.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		R9	<i>NSD should identify expertise and technical support available inside UK or abroad to support it in its review and assessment work. This should include the possibilities to perform independent analysis and validation of codes in areas such as PSA, Thermal Hydraulics, Severe Accident Analyses. Appropriate arrangements should be made to assure that for all safety relevant topics high qualified expertise can be identified by NSD.</i>
		R10	<i>NSD should review its processes and resources to ensure that assessment of events from UK plants as well as from foreign plants is carried out. A formal process for reviewing events should put in place to ensure that lessons learned are available in due time.</i>
		R11	<i>NII should further develop a means by which it can ensure that the operators share operating experience among themselves, analyse the international operating experiences and take appropriate corrective action.</i>
		S8	<i>NSD should carry out audits and inspections themselves or/and through a contractor on the QA process of manufacturer and vendors on important safety components (e.g. the fabrication of a new vessel head).</i>
		S9	<i>When NSD issue a formal regulatory decision the basis of its decision should be sent to the licensee.</i>
		G10	<i>The documentation providing the basis for decision making in project assessment report is a good practice.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		S10	<i>NSD should review the completeness of the PSA model of each plant to ensure it reflects the actual state of the modeled plant. This should be carried out periodically to assure that the insights gained from the analyses are sound and robust.</i>
		G11	<i>The use of risk insights from PSA for regulatory decision making in NSD is a good practices.</i>
G	Development of regulations and guides	S11	<i>That the NII issue by formal means the various internal guides that indicate ways of meeting general regulatory requirements, such as the current 36 licence conditions.</i>
		G12	<i>A comprehensive set of internal guidance documents exist to describe many elements of how the regulatory body functions.</i>
		G13	<i>The document “Safety Assessment Principles for Nuclear Facilities” (first issued 1979, revised 1992 further draft issued for public consultation April 2006) is a comprehensive description of the principles that are the foundation of nuclear safety and offers guidance as to how they may be achieved.</i>
X	The Review of the Management System	R12	<i>the development of the BMS be continued in order that the BMM can contain the policies, processes and procedures necessary to describe the functioning of the organization. As an initial step, the BMM should be made consistent with Annex 4 of the Strategic Plan 2004-2010, or contain the information directly.</i>
		S12	<i>The Business Management Manual should include all the processes that describe how work is to be prepared, reviewed, carried out, recorded, assessed and improved.</i>

	Areas	IAEA Comment No <i>R: Recommendations, S: Suggestions, G: Good practices</i>	Recommendations, Suggestions or Good Practices
		R13	<i>A senior manager should be given responsibility for the management system. The person responsible for developing the management system should report directly to the senior manager.</i>
		S13	<i>A process should be developed to describe the means by which the Business Management Manual is maintained up-to-date. This for example may permit immediate updating for minor alternations to the document, whereas changes to the BMS itself would be identified on some regular basis and approval given by the Management Board before the Manual is revised.</i>
		S14	<i>A process for conducting independent assessments (audits) should be developed and a means by which they be performed proposed. This could require the establishment of an internal unit or use of external resources.</i>

APPENDIX VI A - REFERENCE MATERIAL PROVIDED BY HSE

- [1] *UK National Report on compliance with obligations of the international convention of NS*
- [2] *UK 3rd National Report on compliance with the convention on NS obligations*
- [3] *Convention on Nuclear Safety – Questions Posted to UK in 2005*
- [4] *Nuclear Safety Directorate Plan of Work for the year/2006 (and Functional Directorate Operating Plan 2005-2008)*
- [5] *Health and Safety Executive, Nuclear Safety Directorate - Strategic Plan 2004-2010*
- [6] *HM Nuclear Installations Inspectorate - Safety Assessment Principles for Nuclear Plants*
- [7] *The Proposed Architecture for NII's revised Safety Assessment Principles for Nuclear Safety and Radioactive Waste Management - SAPS discussion document*
- [8] *Nuclear Safety Directorate - Business Management Manual*
- [9] *Health and Safety at Work etc Act 1974*
- [10] *Nuclear Installations Act 1965*
- [11] *Management of Health and Safety at Work Regulations - 1999*
- [12] *Nuclear Site Licence 2/1/04 – Schedule 2*

APPENDIX VI B - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1] *No. **GS-R-1** Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
- [2] *No. **GS-R-3** – The Management System for Facilities and Activities*
- [3] *No. **GS-G-1.1** – Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- [4] *No. **GS-G-1.2** – Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [5] *No. **GS-G-1.4** – Documentation for Use in Regulatory Nuclear Facility*

APPENDIX VII NSD ORGANIZATIONAL CHART

