

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

GERMANY

Bonn and Stuttgart, Germany

8 to 18 September 2008

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation; and (e) the International Physical Protection Advisory Service (IPPAS) that is conducted to review the effectiveness of State systems of physical protection and to provide advice and assistance to strengthen and enhance these systems.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste, transport safety and nuclear security, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety of radioactive sources, the safe management of radioactive waste, the safe transport of radioactive material and nuclear security. The IRRS is carried out by comparisons against IAEA regulatory safety standards and against international legal instruments and IAEA guidance on nuclear security with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management

systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and nuclear security. The aim is to make the IAEA services 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 the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than 85 Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

The first IRRS missions were held in Romania and the United Kingdom in 2006. The first full scope mission was held in November 2006 in France. In March 2007, the French Nuclear Safety Authority (ASN) organized an international workshop in Paris, France, to disseminate the lessons learned from the first full scope IRRS mission, to share experiences from the 2006 missions and to provide information to Member States interested in availing of this service. The workshop, which was attended by more than 100 participants representing 35 countries, emphasized the importance of IRRS missions as a key tool in enhancing the effectiveness of a

regulatory body and noted that such IRRS missions have begun a positive process for nuclear and radiation safety throughout the world.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and security guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety and security 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 global levels of safety.

REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) REPORT TO

THE GOVERNMENT OF GERMANY

Bonn and Stuttgart, Germany

8 to 18 September 2008





REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF GERMANY

Bonn and Stuttgart, Germany

Mission date: 8 to 18 September 2008

Regulatory body: BMU and UM BW

Location: BMU, Headquarters Bonn and UM BW, Headquarters Stuttgart, Germany

Regulated facilities and practices: Nuclear power plants

Organized by: International Atomic Energy Agency (IAEA)

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FOREWORD

by Mohamed ElBaradei Director General

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS."

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: "The Agency's safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators."

"A reduced scope IRRS was conducted for the United Kingdom Nuclear Installations inspectorate in March of this year. A full scope service will be conducted in France in November. The Agency has also received requests for IRRS missions from Australia, Canada, and Spain, and other Member States have expressed interest in having such missions in the near future. I would request all countries to take advantage of this service. I remain convinced that transparency and introspection are essential ingredients of an effective nuclear safety culture."

Statement To the Sixty-Second Regular Session of the United Nations General Assembly

by IAEA Director General Dr. Mohamed ElBaradei

29 October 2007

As the nuclear industry becomes increasingly international, IAEA Safety Standards are used as a reference point by an ever greater number of countries, and serve as a benchmark for IAEA safety review services. Last year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS), which combined previous services ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. IRRS missions have been conducted in France, Australia and Japan over the past year. This is contributing towards a more active exchange of knowledge among senior regulators, and promoting harmonized nuclear regulatory approaches worldwide. With its modular approach, the IRRS is contributing towards a more active exchange of knowledge among senior regulators and harmonized regulatory approaches worldwide.

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EXECUTIVE SUMMARY

Context

Nuclear safety is not just about applying technical or engineering standards. It is also crucially dependent on the people and organizations that control the technology, both in the operating organizations and regulatory bodies. Thus it is also based on the attitudes and motivations of people. It requires all those involved to have a challenging and questioning attitude, a never ending quest for improvement, and a passion for nuclear safety as the prime goal. This is especially true for those who lead organizations impinging on nuclear safety if excellence in both nuclear safety and operation is to be achieved.

In this context, it is noteworthy that that two recent IAEA OSART missions¹ reported very favourably on the standards of safety and operational excellence at nuclear power plants in Germany. Reviewers from the IRRS team, who visited the Neckarwestheim nuclear power plant to witness regulatory inspectors' work, were similarly impressed. This reflects well on both the German nuclear regulatory system, particularly the work of the direct regulatory body – Ministry of the Environment of Baden- Württemberg (UM BW) – and the commitment, investment and leadership and management of the operating organization.

This report, in particular its recommendations and suggestions, should be seen in this context. And, in inviting the IAEA to conduct such a mission, the German government has expressed its commitment to the basic principle for excellence in nuclear safety – a quest for continuous improvement.

Background

At the request of the Government of the Federal Republic of Germany, an international team of experts in nuclear safety visited the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit BMU) and the Ministry of the Environment of Baden-Württemberg (Umweltministerium Baden-Württemberg UM BW) from September 8th to 18th, 2008. The purpose of the visit was to conduct an Integrated Regulatory Review Service (IRRS) mission in Germany. The IRRS Review Team consisted of 12 external senior regulatory experts from 11 Member States, two staff members from the IAEA and an IAEA administrative assistant.

The purpose of the IRRS mission, which was limited to the regulation of operating nuclear power plants, was to review the German regulatory framework, functions and activities; to assess the effectiveness of the application of the regulatory framework, functions and activities; and to exchange information and experiences in the areas covered by the IRRS. IAEA safety standards served as the basis for the IRRS review.

The federal structure of the German state is founded on a division of authorities between the Federation ('Bund') and 16 federal states ('Länder'). Two German regulatory bodies participated in the mission: BMU at the federal level and UM BW at the state level (Baden-Württemberg). BMU and the nuclear regulatory bodies in each state, form the system of authorities designated by the

 $^1\,$ IAEA document NSNI/OSART/07/142, "REPORT OF THE OPERATIONAL SAFETY REVIEW TEAM (OSART) MISSION TO THE NECKARWESTHEIM NUCLEAR POWER PLANT, GERMANY (8 to 24 October 2007)"

government as having legal and competent authority in matters pertaining to nuclear safety and radiation protection in Germany. Together the federal regulatory body and the state regulatory body form the regulatory body as defined in the IAEA Safety Standards. UM BW is one of the five Länder in Germany that currently have operating nuclear power plants; representatives of the regulatory bodies in the other four Länder that have operating nuclear power plants did not participate in the mission.

IRRS Methodology

The IRRS mission addressed both regulatory technical and policy issues. The relevant regulatory areas discussed included: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities and functions of the regulatory body, including the authorization process, review and assessment, inspection and enforcement and the development of regulations and guides; and the management system. The policy issues that were discussed included: human resources and knowledge management; use of insights from operating experience feedback in the regulatory process; enhancing regulatory effectiveness and competence; ageing management for nuclear power plants; management of safety; maximizing nuclear safety through co-operation, mutual understanding and respect; and communicating with stakeholders, particularly the public.

The mission included a series of interviews and discussions with key personnel at BMU and UM BW, observation of an inspection by the regulator at Neckarwestheim 1 Nuclear Power Plant (GKN1), and discussions with the operator of GKN1, and senior management of EnKK, the operating company. The IRRS Review Team also had discussions with representatives of other organizations, including the Federal Office for Radiation Protection (BfS), the Reactor Safety Commission (RSK), BMU's technical support organization Gesellschaft für Anlagen- und Reaktorsicherheit (GRS), the Nuclear Safety Standards Commission (KTA), the relevant technical support organizations in Baden-Württemberg (TÜV SÜD and KeTAG), and the International Commission on Nuclear Technology (ILK). Senior members of the IRRS Review Team also met with the responsible ministers of both BMU and UM BW to discuss regulatory matters of mutual importance.

Results

BMU and UM BW supplied substantial documentation and the results of a detailed self-assessment, including an evaluation of the strengths of BMU and UM BW and proposed actions for further improvement of the regulatory effectiveness of both BMU and UM BW. The IRRS Review Team was impressed by the extensive preparation, expertise and dedication of the staff at BMU and UM BW. Throughout the review, the administrative and logistical support was outstanding. In addition, the Team was extended full cooperation in technical regulatory and policy discussions with management and staff of both BMU and UM BW.

The IRRS Review Team identified several good practices in both BMU and UM BW that should be promoted at an international level to improve nuclear safety worldwide. In addition, in the spirit of continuous improvement, the Team made a number of recommendations and suggestions to improve the German nuclear regulatory practices. Many of the recommendations and suggestions relate to areas in which BMU and UM BW previously identified opportunities to improve and have initiated programme changes.

Particular strengths of BMU and UM BW associated with their policies, the application of the regulatory framework and their regulatory activities identified by the IRRS team included:

- The strong joint commitment of the senior regulators and the staff of both BMU and UM BW to improving nuclear safety;
- Committed and dedicated technical staff in BMU and UM BW supported by experienced and competent technical support organizations;
- The commitment to learning and self improvement in both BMU and UM BW;
- The effectiveness of UM BW's activities in enhancing the safety of operating nuclear power plants;
- The approach to systematic assessment and oversight of organizational and human factors (the 'KOMFORT' system);
- The comprehensive and systematic process for developing technical safety standards for reactors.

The report includes recommendations and suggestions where improvements are either necessary or desirable to further enhance the legal and governmental infrastructure for nuclear power regulation in Germany. Consideration of the following issues identified by the IRRS Review Team may significantly enhance the overall performance of the regulatory system. There is a need for:

- Greater shared understanding of the respective roles and responsibilities of the various authorities (within the Bund and Länder) that constitute or support the German nuclear regulatory system;
- Improvement in cooperation and continued investment in developing mutual trust between BMU and UM BW to enhance public confidence;
- A comprehensive strategic plan for internal and external activities of the regulatory bodies, including staffing;
- An ordinance to provide the legal basis for the fundamental safety objectives and basic requirements for nuclear power plants;
- Limiting the vulnerability of the resourcing of BMU and UM BW to public sector financial control and pay policies in a changing market;
- An integrated management system at both federal and state levels;
- Increased transparency, openness and communication among stakeholders within and outside the state regulatory body.

The IRRS Review Team findings are summarized in Appendix V. There was a strong consensus among the IRRS Review Team that insights were gained from this mission that have contributed to the regulatory experience and safety perspective of each member of the Team. It is expected that the results of the IRRS mission will also contribute to the continued improvement of the safety regulation of nuclear power in Germany. In addition, it is also the IRRS Review Team's hope that the knowledge and experience gained from the mission will be shared among BMU and UM BW staff, as well as the regulatory bodies other Länder regulating nuclear power in Germany.

The review team noted that the regulatory bodies of other Länder that did not take part in the mission missed the opportunity to inform the world of their good practices (letting others learn

from them) and, to the extent necessary, learn from international experience. However, with the aim of continuous improvement in nuclear safety regulation, the IRRS Review Team hopes that they will take advantage of such opportunities in the future by, for example, undertaking self-assessments against IAEA safety standards.

I. INTRODUCTION

In March 2005, at the request of the Government of the Federal Republic of Germany, an international team of 12 IAEA external experts in nuclear safety, two staff members from the IAEA and an IAEA administrative assistant visited the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and the Ministry of the Environment of Baden-Württemberg (UM BW) from 8th September 2008 until 18th September to conduct an Integrated Regulatory Review Service (IRRS) mission limited to the scope of the regulation of nuclear power.

During April 2006 and March 2007 the IAEA provided IRRS information meetings in order to discuss the IRRS service, its purpose and the needs in order to prepare it. In November 2007 and May 2008, two preparatory missions were conducted at BMU headquarters, Bonn and UM BW, Stuttgart to discuss specific aspects of the German regulation, objective, purpose, details and resources of the review as well as its scope in connection with all aspects of the work of BMU and UM BW.

Based on the federal structure of the German state, on which the division of authorities between the federation (Bund) and 16 federal states (Länder) is founded, the two regulatory bodies participating for Germany in the mission are: BMU at the federal level and UM BW at the state level. Baden-Württemberg is one of five federal states utilizing nuclear power. The federal regulatory body together with all states regulatory bodies are the system of authorities designated by the government as having legal and competent authority in matters pertaining to nuclear safety and radiation protection in Germany (called the 'regulatory body' in the IAEA Safety Standards). Note that the mission was conducted without the participation of remaining four state regulatory bodies.

The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides and the management system. In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear safety. Regulatory technical and policy issues were identified by BMU and UM BW as a result of their self-assessment and considering insights resulting from the conclusions of the review meetings of the Convention on Nuclear Safety, international conferences and forums and previous IAEA safety review services.

Before the mission, BMU and UM BW made available a collection of advance reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IAEA questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the advance reference material, interviews with BMU and UM BW staff, other involved organizations and direct observation of their working practices during inspections carried out by UM BW.

IRRS activities took place mainly at the BMU headquarters, Bonn and UM BW headquarters, Stuttgart. The mission included a series of interviews and discussions with key personnel at BMU and UM BW, the regulatory inspectors at Neckarwestheim 1 Nuclear Power Plant (GKN 1) to witness a regulatory inspection first hand and to discuss nuclear safety regulation with operational

staff. Other organizations such as the Federal Office for Radiation Protection (BfS), the Reactor Safety Commission (RSK), the technical support organization Gesellschaft für Anlagen- und Reaktorsicherheit (GRS), the Nuclear Safety Standards Commission (KTA), the competent Technical Inspection Agency (TÜV), and the International Commission on Nuclear Technology (ILK) were involved. The mission also included discussions of regulatory aspects with the relevant ministers at both federal level (BMU) and state level (UM BW).

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct a full scope IRRS mission to review the German governmental and regulatory infrastructure for nuclear safety of nuclear power plants and the effectiveness of the German Regulatory Body and to exchange information and experience among BMU, UM BW and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among senior regulators.

The key objectives of this mission were to enhance nuclear and radiation safety and nuclear security by:

- ✓ Providing Germany (BMU, UM BW and governmental authorities) with a review of their regulatory technical and policy issues relating to nuclear safety of nuclear power plants;
- ✓ Providing Germany (BMU, UM BW and governmental authorities) with an objective evaluation of their nuclear safety regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States:
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff (BMU, UM BW and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Germany (BMU, UM BW and governmental authorities) with recommendations and suggestions for further improvement;
- ✓ Providing other Member States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- ✓ Providing BMU and UM BW through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards;
- ✓ Providing BMU and UM BW with a confidential review of Germany's national nuclear security regime and the evaluation of BMU and UM BW regulatory activities against international instruments.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work was carried out by organizing information and preparatory meetings. The first IRRS information meeting was conducted in April 2006 in Munich to present the concept, purpose and objectives of IRRS and to explore the different options to organize the IRRS mission in Germany. The second information meeting was conducted in March 2007, to clarify details for preparation and to discuss federal states involvement and to describe the procedures under which the mission could be conducted.

The meetings were attended by Mr. Mike Weightman Chief Inspector of the UK Regulatory Body, Health and Safety Executive, Nuclear Safety Directorate, (HSE/NSD) appointed as IRRS team leader; Mr. Peter Addison, Principal Inspector, International Coordination Officer from the same organization (assisting the team leader); Mr. Gustavo Caruso Section Head, Regulatory Activities Section/IAEA (IRRS Team coordinator), and Mr. John Wheatley, NSRW/IAEA.

The preparatory meetings took place in November 2007 in Bonn considering specific aspects of BMU and May 2008 in Stuttgart considering specific aspects of UM BW. The preparatory missions were focused on:

- Discussing and confirming the subject areas to be reviewed and the material that the regulatory body needs to provide;
- Discussing Germany's self-assessment and new technical and policy issues to be reviewed during the main mission
- Providing all applicable IRRS questionnaires and explaining the importance of the regulatory preparation for the self-assessment to be made by the BMU and UM BW prior to the conduct of the IRRS mission;
- Informing BMU and UM BW how the IRRS review process works,
- Explaining the roles and responsibilities of the IRRS team members and the way they should interact with the regulatory body, other organizations and facility representatives;
- Explaining the role of the liaison officer and the counterparts before and during the review;
- Agreeing an outline schedule for the mission and agree to logistical aspects; and
- Explaining IAEA policies, e.g. funding, contact with the mass media.

The IAEA staff had extensive discussions with the senior management of BMU and UM BW represented by Mr. Wolfgang Renneberg - DG RS, Mr. Dieter Majer - Head RS I BMU (IRRS Liaison Officer), Mr. Oskar Grözinger -Head Division 3 UM BW, Mr. Ulf Winter - Head Section 32 UM BW, Mr. Wolfgang Scheitler - Head Section 33 UM BW, Mr. Lothar Hahn (also Deputy Chairman of RSK) Director of GRS, Mr. Jurgen Ortwein - Technical Officer UM BW (IRRS Liaison Officer), and supporting representatives from the Bundesministerium fur Strahlenschutz (BfS) and Gesellschaft fur Anlagen und Reaktorsicherheit (GRS), Mr. H. Klonk and Mr. E. Kersting.

As a result of these discussions, the scope of the mission was confirmed to cover all activities of BMU and UM BW concerning the regulation of nuclear power plants. The main organizational and logistical issues related to the conduct of the mission were also discussed. In addition, it was agreed that the following documentation would be provided by the beginning of July 2008 in order to be discussed in a pre-mission: self-assessment (completed questionnaires; detailed analysis and draft action plan); national reports of Nuclear Safety Convention; relevant legislation and regulations; BMU and UM BW organization charts; Management System documentation describing relevant policy and procedures for BMU and UM BW; GRS reports; Supplement to the Information Notices; training of regulatory staff; main findings of NPP in BW; Baden-Württemberg - ILK Report on the Assessment of Nuclear Oversight Activities; and the existing regulatory strategy (present and future).

During the preparatory phase, a number of documents of the advance reference material (ARM) that had been received from BMU and UM BW were distributed to the experts. These documents underwent a preliminary systematic review based on the IRRS modules and using the appropriate review criteria (IAEA safety standards). A list of the main documents provided by BMU and UM BW as part of the ARM are included in Appendix VI and VII. The most relevant IAEA safety standards used as review criteria were GS-R-1, "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety;" GS-R-3, "The Management System for Facilities and Activities;" GS-G-1.1, "Organization and Staffing of the Regulatory Body for Nuclear Facilities;" GS-G-1.2, "Review and Assessment of Nuclear Facilities by the Regulatory Body;" GS-G-1.3, "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body;" and GS-G-1.4, "Documentation for Use in Regulating Nuclear Facilities."

The preparatory mission consisted of a review of all eight IRRS modules identified in the mission's scope, with the objectives of:

- Identifying main issues to be focused on during the main mission;
- Clarifying the answers provided to the IRRS questionnaires
- Identifying additional information and material to be prepared for the main mission.
- Discussing the team composition (senior regulators from Member States and observers to be involved in the review in accordance with the scope) as well as logistics including meeting and work spaces, counterpart identification, lodging and transportation to accommodate site visits and observations.

In accordance with the discussions with BMU and UM BW, and taking into account the scope as indicated above, it was agreed that the IAEA review team would comprise 12 external experts from 11 Member States (see Appendix I). The working areas and the BMU and UM BW counterparts were distributed according to Appendix IV.

During the preparatory period all documents of the advance reference material (ARM) were sent to the IAEA and distributed to the experts. A significant amount of work was carried out by the reviewers and by the IAEA staff before the main review in order to prepare initial impressions about the ARM, to review the answers to the questionnaire sent by BMU and UM BW, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

C) REFERENCE FOR THE REVIEW

The main reference documents provided by BMU and UM BW for the review mission are listed in Appendix VI and VII. The most relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VIII.

D) CONDUCT OF THE REVIEW

An initial team meeting was conducted on 7th September 2008 at the BMU Headquarters by the IRRS Team Leader and the IRRS Team Coordinator discuss the specifics of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and evaluation among all reviewers. Opening remarks were also provided by the Liaison Officers from BMU and UM BW at the initial team meeting in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 8th September 2008, with the participation of BMU and UM BW senior management. Opening remarks were made by Mr. Wolfgang Renneberg - DG RS and by Mr. Oskar Grözinger -Head Division 3 UM BW. During this meeting, Mr. Dieter Majer - Head RS I BMU (IRRS Liaison Officer), Mr. Ulf Winter - Head Section 32 UM BW, Mr. Wolfgang Scheitler - Head Section 33 UM BW, Mr. Lothar Hahn (also Deputy Chairman of RSK) Director of GRS, Mr. Alfred Seibold - Managing Director TÜV Süd, Mr. Henning Rösel - Vice President BfS, Mr. Jurgen Ortwein – Technical Officer UM BW (IRRS Liaison Officer), section heads of BMU and UM BW and professional belonging to regulatory bodies attended the discussions.

During the mission, a systematic review was conducted for all the review areas with the objective of providing BMU and UM BW with recommendations and suggestions as well as the identification of good practices. The review was conducted through meetings, interviews and discussions as stated in the previous sections, visits to relevant organizations, assessment of the ARM, and direct observations regarding the national practices and activities.

The team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Wednesday, 17th September 2008, with representatives from BMU and UM BW. The meeting was attended by Mr. Wolfgang Renneberg - DG RS and by Mr. Oskar Grözinger -Head Division 3 UM BW, as well as department heads, division heads, section heads, technical staff and support staff.

The opening remarks of the exit meeting were presented by Mr. Rennenberg and Mr. Grözinger. The results of the IRRS mission were presented by Mr. Victor McCree, Deputy Team Leader. Closing remarks were made by Mr. Philippe Jamet, Director of the Division of Nuclear Installation Safety with IAEA.

The draft technical notes of the IRRS mission were handed over to BMU and UM BW at the end of the exit meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. GENERAL

The Federal Republic of Germany comprises 16 federal states (Länder), in five of which there are a total of 17 operating nuclear power plants distributed over 12 sites. Germany's Regulatory Body is structured to reflect this national federal system with a federal component provided by the Directorate-General RS - Safety of Nuclear Installations, Radiological Protection and the Fuel Cycle (DG-RS) within the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), and five Länder government authorities. The IRRS mission was supported by the Division for Nuclear Supervision and Environmental Radioactivity (Division 3) within the Ministry of Environment, Baden-Württemberg (UM BW) which provided an example of the Länder component of the Regulatory Body. The Land of Baden-Württemberg has 4 operating nuclear power plants on 2 sites.

The lack of participation of the other Länder means that this Module of the report cannot comment on the legal and governmental infrastructure in those areas.

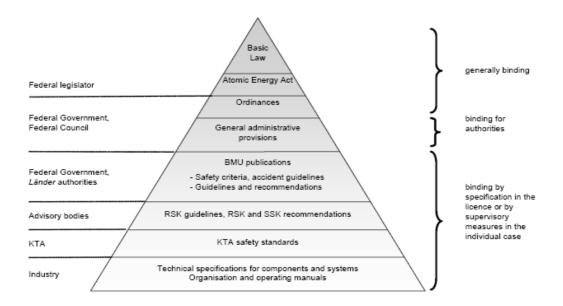
Legislative and statutory framework

The German constitution (or 'basic law') states that Germany is a federal republic. German federalism can be described as a national state comprising 16 parts where the individual parts themselves exhibit many criteria of states. The 16 Länder in Germany are characterized by individual:

- constitutions,
- elections,
- parliaments,
- governments, and
- competences from the federal constitution.

For historical reasons, the federal system in Germany is a complex system of power division in two directions. The classical division of powers among the legislature, the executive and the judiciary, the so called horizontal division of power, is complemented by a vertical division of power between the federation (Bund) and the federal states (Länder). The German constitution identifies which legislative and which executive powers the Bund and the Länder shall have. Generally speaking the Bund has the power of legislation, whereas the Länder have the power to execute the law (the power of administration).

However, there is a complex system of mutual checks and balances between Bund and Länder within which they have extensive experience of working together. A particular feature of German federalism is that the federal states participate directly in the legislative decisions of the federation. This is done through the federal council, or Bundesrat, which provides a "second chamber" consisting of Länder members which represents all 16 Länder at the federal level. Furthermore, ordinances and general administrative provisions need to be consented by both the Federal Government and the Bundesrat.



This diagram represents the hierarchy of the national legislation, rules and regulations in Germany, the authority or institution issuing them, and the extent to which they are binding on the authorities and the operators of nuclear installations.

The Constitution

The Constitution forms Germany's basic law, from which subsequent legislation is developed. Articles of the Constitution of special relevance to the IRRS mission are:

- Article 30, which requires that execution of the legislation shall be within the competence of the Länder, unless otherwise specified in the Constitution;
- Article 73, which states that making of legislation remains exclusively within the competence
 of the Bund in a number of areas, and specifically identifies that the Federation has the
 exclusive power to legislate the generation and use of nuclear energy for peaceful purposes,
 the construction and operation of facilities serving this purpose, the protection against hazards
 arising from a release of nuclear energy or ionizing radiation, and the disposal of radioactive
 materials;
- Article 83, which addresses Administrative competence, and requires that matters delegated to the Länder remain within their competence and, similarly, matters retained by the Bund remain within their competence;
- Article 85, which provides that:
 - (1) Where the Länder execute federal laws on federal commission, establishment of the authorities shall remain the concern of the Länder, except insofar as federal laws enacted with the consent of the Bundesrat otherwise provide. Local authorities and local authorities associations must not be assigned any duties responsibilities by federal law.
 - (2) The Federal Government, with the consent of the Bundesrat, may issue general administrative rules. It may provide for the uniform training of civil servants and other salaried public employees. The heads of intermediate authorities shall be appointed with its approval.

- (3) The Land authorities shall be subject to instructions from the competent highest federal authorities. Such instructions shall be addressed to the highest Land authorities unless the Federal Government considers the matter urgent. Implementation of the instructions shall be ensured by the highest Land authorities.
- (4) Federal oversight shall extend to the legality and appropriateness of execution. For this purpose the Federal Government may require the submission of reports and documents and send commissioners to all authorities.
- Article 87(c), which allows that acts of law passed on the basis of this provision may stipulate, with approval of the Bundesrat, that they be executed by the Länder on behalf of the Federation.

This means that in executing the Atomic Energy Act and its statutory ordinances, the Länder are subject to supervision by the Federation with regard to the legal compliance and appropriateness of their actions, and they are subject to directives issued by the Federation (in accordance with Article 85 of the Constitution). The licensing and supervisory authorities for nuclear facilities are the ministries of the Länder in which the facilities are located and the Federal regulatory body is BMU.

The Constitution was reviewed in 2006 and, whilst problems were noted with implementing Article 85, it was felt that there were sufficient advantages to retain it for the purposes of nuclear safety. A further review of the Constitution is ongoing but it is not anticipated that there will be any change to this situation.

Atomic Energy Act

The Act on the Peaceful Utilization of Atomic Energy and the Protection against its Hazards (Atomic Energy Act) was promulgated on 23 December 1959, and subsequently amended and promulgated a number of times, the last amendment being on 26 February 2008. The purpose of the Atomic Energy Act after the amendment of 2002 is to end the use of nuclear energy for the commercial production of electricity in a structured manner and to ensure on-going operation up until the date of discontinuation, as well as to protect life, health and property against the hazards of nuclear energy and the detrimental effects of ionizing radiation and, furthermore, to provide for the compensation for any damage and injuries incurred.

Article 7 of the Atomic Energy Act specifies that no further licences will be issued for the construction and operation of nuclear installations, however, it identifies that there is a continuing licensing activity for the modification of existing nuclear installations or their operation.

Article 17 of the Atomic Energy Act provides for the inclusion of restrictions and obligations in the nuclear site licences.

Article 19 of the Atomic Energy Act provides for legal oversight rights for the competent authorities.

Article 19a (1) of the Atomic Energy Act requires the operator of a nuclear installation to conduct a safety review of the installation and to submit the results thereof to the supervisory authority.

Article 24(1) of the Atomic Energy Act, specifies that all administrative functions under Chapter 2 of the Act (Supervision) and the statutory ordinances issued thereunder shall be discharged by the Länder on behalf of the Federation. It goes on to say that the supreme Länder authorities designated by the Länder Governments shall be responsible for the granting of licences, the withdrawal and revocation of such licences as well as the plan approval procedure, and the

cancellation of the plan approval notice. These authorities shall supervise the installations, and the use of nuclear fuel outside such installations. Also, in particular cases, they may delegate their functions to subordinate authorities.

Directives

As noted above, in accordance with the Constitution and the Atomic Energy Act, each Land is the authority responsible for the regulation and licensing of nuclear installations in their region. However, Article 85 of the Constitution allows for the Federal Government to exercise supervision of each Land's activities and if, in its judgement, action needs to be taken in respect of the Land's fulfilment of its responsibilities then a Directive or instruction can be issued to enforce a solution regarding lawfulness or appropriateness. Article 85(2) requires that general administrative rules (applicable to all Länder in all cases) need the consent of the Bundesrat. In accordance with Article 85(3), a Directive can be issued on 'specific' matters in regard of a single Land for a specific purpose, in which case no such consent is required. So far, decisions of the Federal Constitutional Court have not exactly defined the meaning of 'specific' in relation to the content of Directives.

Decisions of the Federal Constitutional Court have determined that, in the case of 'specific' Directives, the Land has no recourse except to implement the requirements of the Directive (unless the Land is unable to understand, and therefore implement, the requirements or it infringes higher law such as Human Rights). Where this Directive modifies the oversight of the plant by the Land or a particular nuclear site licence, the operator of the plant has normal recourse in law to challenge the Directive.

If an operator challenges any aspect of the oversight or site licence (whether or not this is the result of a Directive), then the challenge is against the Land which issues the licence. The Federal Government, by issuing the Directive, assumes responsibility and liability for its implementation and so is required to support, and if necessary reimburse, the Land in the event of such a challenge.

Ordinances

The Atomic Energy Act, in Articles 11 and 12, provides enabling provisions for issuing a number of ordinances which are listed. These ordinances require approval by the Bundesrat and thereafter become binding legislation once published in the Federal Law Gazette.

Revision of the ordinances is not carried out on a programmed basis, rather changes are driven by needs such a new developments, events, identified needs from operators or Länder, or if determined by BMU. Examples of these latter two reasons were identified by two of the revisions currently being developed by DG-RS.

General administrative provisions

Ordinances may include additional authorizations for issuing general administrative provisions. Such regulate the actions of the authorities, but they only have a direct binding effect for the administration. They have an indirect effect since they are considered in the administrative decisions. In the nuclear sector, there are general administrative provisions relevant to radiation protection and environmental issues only, there are none specific to nuclear safety.

BMU publications

These safety criteria, guidelines and recommendations are developed by BMU as the need is identified. The Länder have to be closely involved in this process as such publications have no

binding legal status unless specified by the Länder in either the nuclear plant licence or other supervisory measure.

Other publications

Advisory bodies, such as the Reactor Safety Commission (RSK), or the Nuclear Safety Standards Committee (KTA), or the industry itself, produce publications in the form of guidance, recommendations, standards or specifications. These documents, as for the BMU publications, have no binding legal status unless specified by the Länder in either the nuclear plant licence or other supervisory measure.

Regulatory body independence

BMU and UM BW are both headed by the Ministers of their respective Environment Ministries, neither of which have responsibilities for the promotion of nuclear energy. Both Ministers have other responsibilities in addition to nuclear safety, but these do not appear to conflict with their responsibilities for nuclear safety.

The Minister of BMU has direct involvement as head of the regulatory body and participates in the decision making process for politically sensitive decisions such as the issue of Directives. Day to day, technical responsibilities are delegated to the head of the Directorate-General RS - Safety of Nuclear Installations, Radiological Protection and the Fuel Cycle. The Minister of UM BW has a less direct involvement and the role of the head of the regulatory body in the Land of Baden-Württemberg is delegated to the head of the Division for Nuclear Supervision and Environmental Radioactivity.

Some issues relating to perceptions of effective regulatory independence are addressed further in Chapter 3.

Regulatory Body Responsibilities

The Regulatory Body in Germany fulfils the requirements of GS-R-1 regarding regulatory body responsibilities when viewed as a whole. The Federal arrangements provide for clear legal definition of the functions and responsibilities of BMU and the competent supreme Länder authorities. This regulatory body fulfils four basic functions:

- the development of safety procedures and regulations,
- licensing procedures,
- regulatory examination and assessment, and
- execution and inspection.

Further functions to be fulfilled by the regulatory body include:

- regulatory safety research,
- system for the application of operating experience,
- radiation protection,
- emergency preparedness and
- international co-operation.

In Germany, these functions are distributed among federal and Länder government authorities. Nuclear regulatory bodies exist in all of the Länder. The table below (extracted from Germany's

Report to the Convention on Nuclear Safety 2008) lists the licensing and supervisory authorities of those Länder in which nuclear installations are located.

In principle, federal as well as Länder government authorities are involved in all functions, albeit with different competences, responsibilities and duties to co-operate. This distribution is also shown in the table below.

However, the 'supervision' responsibilities of BMU DG-RS (as required under Article 85 of the Constitution) leads to the potential for an apparent duplication of effort. In order to clarify the respective roles of DG-RS and the Länder, and to enable BMU DG-RS to fulfil its responsibilities for federal harmonization, it could be appropriate for the Länder Committee for Nuclear Energy (LAA) (see Chapter 3) to develop an agreement in this respect that BMU and each Land could accept as mutually binding. A Recommendation addressing this issue is included in Section 3.

Assignment of the Regulatory Functions to the Nuclear Authorities of the Federal and Länder Governments (extracted from Germany's Report to the Convention on Nuclear Safety 2008)

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Grey Leading function, execution within area of competence
Light grey Function with separate competences but common objectives

White "Federalism function" federal supervision or participation (e.g. in the Länder Committee for Nuclear Energy (LAA), by provision of information)

^{*} This also means that the Federal Government may execute its power to decide the respective matter in hand itself and initiate on its own authority the corresponding detailed examinations.

DG-RS and UM BW identified a number of budgetary and staffing issues. These are addressed in greater detail in Chapter 3.

Emergency response

Detailed consideration of Emergency Arrangements was not a review topic for this IRRS mission, however, the self assessment carried out by the German Regulatory Body prior to the IRRS mission, as recorded in the Advance Reference Material (ARM), identified that the current emergency management system in Germany has potential inefficiencies due to the number of interfaces between the Federal and Land authorities. It also highlighted the consequent difficulties with coordination, information loss, and time delay.

The legislation in this area identifies the various responsibilities of the Federal and Land authorities. In order for this complex system to work efficiently there is a need for regular exercises to test the various interfaces. The staff resourcing issues at DG-RS lead to less exercises than they would wish to enable them to confirm that the process is efficient and, where appropriate, suitably harmonized across the Länder. This staff resource concern is addressed in more detail in Chapter 3.

As the Emergency Arrangements were not reviewed in detail, the issue could not be pursued further. However, it may be appropriate for BMU to ensure that, during any future IRRS mission, suitable international participants are invited in order to give more expert advice in this area.

Technological Infrastructure

The ARM identified that UM BW have sufficient technological infrastructure in order to fulfil their regulatory licensing and supervision function. Consideration of this issue is addressed further in Chapters 3 and 8.

The ARM also identified that BMU DG-RS has concerns that it has insufficient infrastructure in place to enable it to fulfil its Article 85 supervisory function. However, in our view the concern expressed by DG-RS relates to its ability to fulfil its supervisory obligation under national law. The responsibility for oversight of safety at the nuclear installations remains with UM BW.

Proposals by DG-RS to resolve its concerns in this area can be supported insofar as a common information system, allowing all parts of the regulatory body access to safety relevant information, is appropriate.

1.2. LEGISLATIVE

Legislative requirements

The legal system in Germany fulfils the requirements of GS-R-1. In particular, in addition to the legislation discussed above, there are a number of Ordinances in place to address issues of nuclear safety. These include Ordinances on Radiation Protection, Licensing Procedures, Nuclear Safety Officer and Reporting, Reliability Assessment, Financial Security, and Costs. However, as identified in Germany's report to the Convention on Nuclear Safety 2008, there are as yet no Ordinances, as provided for under the Atomic Energy Act, in a small number of areas including on the technical plant safety or safe operation, which are currently the subject of non-legally binding regulatory guidance instruments.

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Proposals by DG-RS to ensure that modern standard criteria for reviewing the installations are available, and that basic safety principles and requirements are laid down in an Ordinance, are supported.

Funding of the Regulatory Body

BMU is funded directly from the national budget, as negotiated by the Ministry with the Government. Historically there have been shortfalls in the budgetary provisions to DG-RS, in line with cutbacks in Government funding for all Ministries including BMU. This has resulted in the current staffing deficiencies which is discussed in more detail in Chapter 3.

In discussions with DG-RS staff, based on their own assessment of their function as part of the Regulatory Body, they consider that, due to financial and staffing constraints, they are under pressure regarding their ability to discharge their regulatory activities. This issue is also addressed further in Chapter 3.

In the context of the proposals in Chapter 3, regarding the need to evaluate the assignment of tasks at the federal level, to ensure that nuclear safety regulatory functions can be fulfilled in the future the budget should be maintained at a sufficient level to support the continuous improvement of nuclear safety in Germany.

UM BW receives its funding by direct charges made on the operator. These charges are established by the Atomic Energy Act and the associated Federal Ordinance on Cost. This provides that costs can be recovered for routine activities of the Land regulatory body, including inspections of modifications that are not subject to licensing; modifications subject to licensing; the remote monitoring system; and costs of the TSO and other expenses. To simplify the administration of recovery of these costs (which, by law, can be charged on an activity by activity basis), the UMBW has an agreement with the operators that a fixed charge shall be paid annually in advance of the work. This fixed charge is renegotiated every two or three years as required.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS**: GS-R-1 § 2.2. (4) states that 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.
- (2) **BASIS**: GS-R-1 § 2.4. (5) states that *legislation shall arrange for adequate funding of the regulatory body*.
- R1 <u>Recommendation</u>: The German Government should make arrangements to establish adequate resources at a federal level in the future to ensure that it can discharge its determined and agreed roles and responsibilities for nuclear safety, in addition to those assigned by law.

This Recommendation should be read in conjunction with recommendations and suggestions regarding the need to determine roles and responsibilities in Chapter 3.

Financial provision for radioactive waste management and decommissioning

The law in Germany (German Commercial Code) adequately fulfils the requirements of GS-R-1 regarding the financial provisions for nuclear safety. However, DG-RS expressed a concern regarding the incompleteness of current legislation regarding the funding risks for

decommissioning and radioactive waste management, due to the inherently long timescales associated with these tasks, if an operator is no longer in a position to contribute to the funds (e.g. goes into financial liquidation). DG-RS proposals to enhance the regulatory arrangements in this regard are supported.

2. AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

2.1. GENERAL

Regulatory body - fulfilling statutory obligations

Between 1998 and 2000 UM BW developed their oversight concept, which was last updated in 2007. The current document, "Concept for Regulatory Oversight", provides the basis of regulatory oversight, addressing tasks, standards, regulatory powers, methods, interventions and recovery of costs. This document clearly addresses the relevant IAEA standards. This document and its implementation by UM BW are addressed further in Chapters 3, 5 and 8.

The ARM identified that DG-RS does not have such a comprehensive set of definitions of its roles, responsibilities and functions. Proposals by DG-RS to develop a Federal Supervision Manual are supported.

Non legally binding interfaces

The Atomic Energy Act does not exclude other interfaces or arrangements, beyond those specified in the law, between Federal and Land authorities in the interests of maintaining and improving nuclear safety. An example was given of information being obtained by DG-RS from its international contacts, which it shares with the Länder for them to adopt and implement within their competence – without any legal obligation to do so.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS**: GS-R-1 § 3.1 states that in order to fulfil its statutory obligations, the regulatory body shall define policies, safety principles and associated criteria as a basis for its regulatory actions.
- R2 <u>Recommendation</u>: BMU DG-RS should develop its Federal Supervision Manual as it has proposed. The Supervision Manual should include arrangements for cooperation and interaction with the Länder in order to develop consensual processes (whether required by the law or voluntary) to continuously improve nuclear safety.

Review and assess submissions on safety from the operators

The arrangements for review and assessment by UM BW, the responsible regulatory body, are addressed in Chapter 5.

BMU DG-RS, with its responsibilities for 'supervision', informed us that, due to resource constraints, it is unable to carry out the necessary harmonization oversight in a systematic manner, to the depth necessary or provide suitable follow up. DG-RS regards this to be a concern insofar as, without direct access to plant safety data, it deems itself unable to form an opinion (and therefore reach assurance itself) at the national level, regarding nuclear plant safety in Germany. UM BW informed us that all of the necessary information is available at the Länder level. Recommendations on this issue are provided in Chapter 3.

Regulatory body – discharging its main responsibilities

BMU is responsible at federal level to provide information to Parliament, other government bodies and to international organizations. It has been recognized by both BMU DG-RS and UM BW that

the expertise at Länder level could be significantly enhanced by participation in international activities. This would benefit both Germany and the international community and is to be encouraged.

Proposals, as identified by both DG-RS and UM BW, to progress this issue, are supported.

Similarly, both DG-RS and UM BW recognize the benefits of enhancing their public information by expanding their websites. Again, these proposals are supported.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS**: GS-R-1 § 3.3. (6) states that the regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public
 - S1 <u>Suggestion</u>: DG-RS and UM BW should ensure that their commitments to develop and share participation in international activities are included in their respective organization management manuals.

3. ORGANIZATION OF THE REGULATORY BODY

- This Chapter includes policy discussions on Human Resources
- This Chapter includes policy discussions on Mutual Trust and Communications
- This Chapter includes policy discussions on Regulatory Effectiveness

3.1. GENERAL ORGANIZATION

In line with the federal structure the tasks and responsibilities of the German Regulatory Body are divided between the central level (Bund) and the federal states (Länder). The division of responsibilities can be deducted from the figure below.

checks and balances (regarding nuclear energy)	Legislature	Executive	Judiciary
Bund	Parliament "Bundestag" Enacting of the Atomic Energy Act with consent of the federal council "Bundesrat"	Government "Bundesregierung"	Federal Courts
Länder	Parliament "Landtag"	Government "Landesregierung" Execution of the Atomic Energy Act with federal supervision	Länder Courts

FIG. 1 Checks and Balances

In the German Federal Court of Auditors' report II 3 - 2006 - 1229 (II) (Potsdam, May 9, 2007) the roles and responsibilities of the Länder and the Federal Level are described as follows:

The Länder are responsible for nuclear energy supervision within the framework of the administration on behalf of the federal government. Depending on the assignment of the task, the licensing and supervision authorities for the operators of the nuclear energy plant are the senior authorities of the Länder (state ministries), which on their part mainly involve the technical monitoring associations (TUV) as experts within the framework of their nuclear energy supervision procedures. One of them is Baden Württemberg. In Baden Württemberg, the Ministry of Environment (UM BW) executes the task of Regulator for Nuclear Safety.

The federal government, represented by the Ministry of Environment, Nature Protection and Reactor safety (BMU), as the federal supervision authority, guarantees and is responsible for legally correct and purposeful enforcement of nuclear energy law with a view to nuclear safety, etc. The task of the Ministry is to monitor the licensing and supervision activities of the Länder and to guarantee standardized enforcement of the Atomic Energy Act. For coordination of a nationwide standardized procedure in the field of nuclear safety, etc., the

federal government and the Länder have created the Committee of the Länder for Nuclear Energy (LAA). More information about the LAA is provided in paragraph 3.4.1.

On the federal level BMU is aided by Federal Office for Radiation Protection (Bundesamt für Strahlenschutz- BfS), a subordinate body of BMU. BfS was established in 1989.

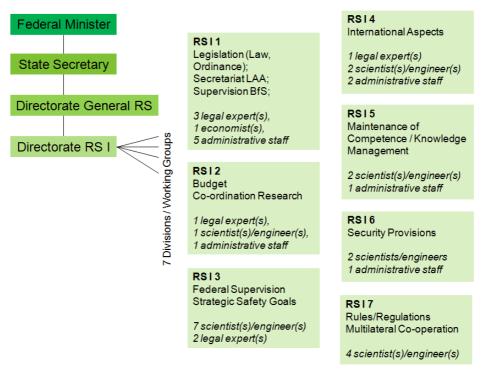
In the next paragraphs the organization of BMU/BfS and UM BW with respect to the regulation of nuclear safety is described.

3.1.1. BMU/BfS

The top-regulator for nuclear safety is the Minister. On behalf of the Minister the Director-General for Reactor Safety, Radiation Protection and Fuel Cycle is charged with the regulatory activities for reactor safety. The same organization BMU RS is dealing with governmental functions in the field of nuclear safety. Since 2001 the DG RS Global Objective I follows § 1 Atomic Energy Act, the termination/minimization of the risks associated with nuclear technology, in two ways:

- The risks from commercial operation of nuclear power stations and other nuclear installations and facilities have been eliminated for the long term and the risks from non-commercial installations have been minimized.
- It is assured that the necessary precautions required, in light of the state of the art in science and technology will be taken throughout the remaining operational periods.

It is the directorate RS 1 that deals with safety of nuclear reactors. It has 7 Divisions. In the picture below the organizational structure within BMU is given, including a global description of the tasks of the divisions.



The organizational entities RS I 1 through RS I 7 are called working groups or sections.

The responsibilities are:

RS I 1 (working group)

Legislation (Law and ordinance), Management of the activities of the LAA, Technical supervision of the BfS. Administrative management of GRS-contracts.

<u>RS I 2</u>: Fundamental Aspects of Nuclear Politics (not in scope of the IRRS mission), planning and execution of the budget of RS, Coordination.

<u>RS 1 3:</u> Federal Supervision of Nuclear Power Plants, Fundamental Aspects of Nuclear Safety.

<u>RS I 4:</u> International Aspects of Nuclear Safety, Radiological Protection and the Nuclear Fuel Cycle

<u>RS I 5</u>: Strategic Concepts and Maintenance of Competence

<u>RS I 6</u>: Security Provisions for Nuclear Installations (not in the scope of the IRRS-mission), Aspects of Technical Competence the personnel of Nuclear Installations, Supervisional or Support Organizations

<u>RS I 7</u>: Nuclear Rules and Regulations, Multilateral Regulatory Co-operation.

BfS was established by a Creation Act in 1989, last amended in 2000. According to the act it is responsible for:

- Attending to the administrative tasks of the Federal Government in the field of Nuclear Safety (paragraph 2, subsection 1, creation act)
- Support the Federal Ministry technically and scientifically, in particular in performance of the Federal Supervision, production of legal and administrative directives and in inter-state cooperation (paragraph 2, subsection 2, creation act)

For the fulfillment of its tasks, BfS undertakes scientific research (paragraph 2, subsection 3, of the Creation Act).

With the creation of BfS in 1989 the enforcement tasks of the federal government according to the Atomic Energy Act and Radiation Protection Precaution Act were to be consolidated and an institute for technical, scientific and administrative support (radiation protection, nuclear safety, disposal of waste) was to be created. As a result of the official and technical supervision, the prerequisites for an unambiguous comprehensible allocation of the political and technical responsibility were to be created (according to the document Reasoning for the Act on the creation of the BfS, 1989).

Within the BfS the responsibility for matters of nuclear safety are concentrated in the directorate SK (Fachbereich Sicherheit in der Kerntechnik). It contains 5 sections (Fachgebiete) and the group that handles the KTA system (KTA-GS). According to the current documentation, they have the following tasks:

- Management (2 technical/scientific staff members)
- SK1 International cooperation on nuclear safety (4 technical/ scientific staff members)
- SK2 Safety analysis and –criteria (6 staff members)
- SK3 Decommissioning (not in the scope of the IRRS-mission)

- SK4 Installation- and Licensing Status (5,5 technical/scientific staff members)
- SK5 Report centre for events (3,5 technical/scientific staff members)
- KTA-GS (5 technical/scientific staff members)

3.1.2. UM BW

In the federal state of Baden Württemberg the Minister of Environment is the top nuclear regulator. The regulatory functions for nuclear safety are delegated to the head of Division 3. The structure organigram is shown in Appendix X. The different colors explain the professional background of the employees. Division 3 is responsible for the regulation of nuclear safety and the environmental radioactivity.

Since the start of nuclear power in Baden-Württemberg the main organization principle is that the supervision of a power plant (site) is concentrated in sections and the employment of mainly technical staff with sufficient competence to judge. The latter means that to a great extent it is the responsibility of the individual supervisor to decide about the scope and depth of the independent (from the TSOs) evaluations and its documentation. In several important areas of work there is some safety related guidance (e.g. event evaluation, ageing management).

Since 1998 the organization has been evaluated a number of times:

- Self-assessment (1998)
- Evaluation of the relation with the TSO and effectiveness by the Accountancy Chamber of BW (2000/2001)
- Self-assessment in relation with organizational changes/evaluations in the Ministry of Environment of Lower-Saxony (2001)
- Several investigations in reaction to a major safety issue in KKP
 - o Investigation of the organization by Kienbaum Consultants (2002)
 - o Investigation by a committee of the BW Parliament (2002/2003)
 - o Task Force of the BW Government (2002/2003)
- Colloquium "Oversight of Nuclear Power and Radiation Protection in BW Yesterday, Today, Tomorrow" (2005)
- ILK-Review (2006)

The Kienbaum recommendations were to improve oversight activities in the areas of Man-Technology Organisation (MTO) and event analysis, to commission a second TSO and increase the capacity of UM BW. This was confirmed by the Parliament Committee. The Task Force confirmed the necessity to create a second TSO, but also recommended to increase the responsibility of the operator by reducing the "overregulation". The UM BW accepted these and created an extra section (the current 32) dealing with general affairs. This section created an MTO-group and the clearing centre for events. A second TSO was created that carries out dedicated jobs that no longer will be handled by TÜV ET. The budget is about 5% of the TÜV budget. The operator will get more responsibility in the area of

modifications and changes of documents. The IRRS team was informed that in relation to that the amount of controls by the $T\ddot{U}V$ will be reduced, based on the outcome of discussions that are still going on.

3.2. STAFFING AND TRAINING

3.2.1. BMU/BfS

The total number of staff in BMU dealing with safety of nuclear installations (RS I) is 35, including temporary jobs:

• Scientist/engineer: 15

• Legal expert: 7

• Economist: 1

• Administrative staff: 10

The BfS section SK has 33 staff members:

• Scientist/engineer: 26

• Administrative staff: 5

In the last 15 years the BMU and BfS have suffered from a general budget cut of 1.5% per year. This has prevented the structural recruitment of new personnel after the retirement of experienced people. This has been partly compensated by the use of temporary jobs (2-4 years), but due to the constraints mentioned the majority of those young people has left and now works in other organizations. Due to recent nationwide reductions in the starting salaries for young people in the government it is increasingly difficult for BMU to attract young experienced experts. For BMU the situation is worse because of a continuously high demand for dealing with political/safety questions by parliament, citizens etc. and public information affairs, assessments of applications by the operating organizations for the transfer of electricity. The top management of BMU RS estimates that this effort consumes 50% of the available capacity. They also characterize the personnel's work as multitasking in an extreme sense. Under these conditions it is extremely difficult to maintain the knowledge of experienced people within the organization. Furthermore, although it is the management's will to work in a structured way, the introduction of this structured approach has been tried several times. It turned out, however, that it is not possible under the current circumstances. It is doubtful that under these circumstances BMU RS is able to fulfill all its tasks. Also it is doubtful that corporate knowledge can be maintained in the future, if not already eroded.

Since 2005 there have been a number of separate investigations of the regulatory system in the area of staffing and training. The final outcome will be contained in a report by the Bundesrechnungshof which currently is in final draft.

In a report of March 2008, BMU included the development of a staffing plan for the years 2009 – 2011, which the Minister of BMU has endorsed. The idea is to strengthen BMU RS and BfS based on this staffing plan. The intention is to increase the staff at BMU RS I and at BfS. The staffing plan anticipates a number of employees that are going to retire in the near future.

The IRRS team was not presented with documented evidence of a strategic plan to define the functional needs for resourcing of BMU. On this basis the team was unable to form an 36

opinion regarding the necessary staffing within BMU. It is the responsibility of BMU and BfS to work out the strategic plan. However, the IRRS Team is of the opinion that BMU should carry out a comprehensive review of the tasks necessary on a federal level. Unnecessary duplication of the activities carried out by Länder should be avoided. Therefore the team is of the opinion that the outcome of the LAA discussion on an integrated, effective and efficient oversight process in Germany (see recommendation R7) is an important input for the strategic plan.

According to BMU there have been discussions through the years in order to make the regulatory body system in Germany more efficient and effective by structural modification. The possible solutions ranged from a complete integration of all functions into one body to variations of transfer of tasks and responsibilities within the federal level, including GRS. These proposals were never carried out for several different reasons. Notwithstanding this, according to the report (December 2006) from the working group on the modernization of BfS there was a statement that seemed to indicate that there are many possibilities to improve efficiency at the federal level:

"From the information gathering of the working group the problems in the relation between BMU, BfS and GRS [...] can be seen as particularly important. It seems that a number of tasks are worked on by two organizations, in particular BfS and GRS, in parallel.[....]. The actual redundancy is mainly the result of unclear distribution of tasks or uncoordinated execution of these tasks. With the current distribution of tasks the execution of the work is partly carried out threefold".

BMU – DG RS stated that comprehensive discussions to strengthen efficiency and effectiveness with regard to the distribution of tasks between BMU, BfS and GRS were performed in 2007 and 2008. BMU is going to adapt the distribution of tasks where appropriate. The tasks of BfS are laid down in the annual planning of the BfS which was approved by BMU in February 2008.

The tasks of GRS are identified in the yearly work program of the BMU (UFOPLAN, additional documents especially project data sheets).

The three year staffing plan submitted by BMU was only 50% agreed with for 2009. Future budget allocations for BMU are uncertain.

As mentioned above about 50% of the capacity of BMU DGRS is spent on matters like questions from parliament, public communications and energy transfer. Therefore the people that mainly should concentrate on nuclear safety matters are to a large extent distracted from that. This has potentially a high impact on the efficiency and effectiveness of DG RS. Although dealing with such issues is not abnormal for a regulator, to improve the efficient execution of its nuclear safety duties, BMU DG RS should consider identifying a clear separation within its organization between these activities and the work on nuclear safety.

In carrying out its governmental and nuclear safety functions, BMU is affected by conflicting governmental priorities, high workload and staffing constraints. The view of the IRRS mission is that the federal government should ensure that nuclear safety remains the highest priority.

As far as the efficiency and effectiveness of the organization is concerned the number of working groups and sections within BMU RS 1 (7) versus the number of staff (35) can be questioned. In the development of the future staffing plans this should be reconsidered.

Requirements for the staff positions and basic and refresher training are not formally documented. In the case where a replacement is necessary a profile is created for the recruitment process. BMU RS is of the opinion that the section heads of RS I 3 and RS I 7 must have a high scientific technical background and experience. On an annual basis the training activities of all staff members are proposed to the management team. These training activities are mainly carried out by GRS. In the action plan a training academy is mentioned. The idea is that before new personnel enter BMU they will be educated by the GRS training academy over a two year period. It is intended that the Länder also take part.

For the recruitment of new scientific/technical staff there are a number of impediments mentioned in the discussions with BMU:

- Salaries are too low compared to the industry with no possibility to add labor market salary supplements as in several other countries,
- The ministerial internal rules determine that the DG for personnel can override the DG RS I in the decision to attract staff, because the educational background would be too specific. That may prevent the future possibility to transfer this employee to other directorates within the ministry.

But it is up to the leadership to push this within the ministry for the benefit of nuclear safety.

The intended multistage increase of the BfS SK is in the following areas:

- Plant and licensing status
- Decommissioning
- Safety review of NPPs
- Digital safety instrumentation and control
- Source term identification
- Safety management
- External effects
- Human/technical organization
- Internal effects
- Materials issues
- Emergency procedures
- *International regulations)*
- Bilateral cooperation

3.2.1. UM BW

UM BW has about 43 staff members that have a background as technical scientist/engineer. Like BMU, UM BW has also suffered from the continuous reductions of staff due to general

budgetary decisions of the BW Government. The 2003 Kienbaum report led to an increase of 6 staff, in addition to 6 anticipating retirement. Recently the Minister UM BW decided to fix the maximum formation to 50 and exclude the UM BW regulator from further budget cuts in the future. Additionally an allowance was created for temporary increases with a maximum of 5 staff in order to recruit replacement experts well before the retirement.

UM BW also suffers from difficult market conditions in the recruitment of new staff. The nuclear and other industries pay much better. There are several examples where recruitment was not successful (MTO-expert, electrical engineers). Like in BMU, it is not allowed to implement a labor market salary supplement. Therefore more efforts should be put toward recruitment. The gap between the actual and allowed number of staff should be closed soon.

Requirements for the staff positions and the basics for initial and further training are documented. Individual initial training programmes are composed by the section heads and usually take two years. After that annual further training programmes are composed. An electronic database is available to evaluate the progress. All the tasks in the section have been assigned to individuals in that section. The principle is that one experienced person is the first person responsible, and is backed up by a second, less experienced person. Furthermore, there is an official list of competences that are needed in the whole organization. But like in BMU there is no overall competence matrix created where the necessary competences are combined with the available competences. Also, there is no mid-term and long-term staffing plan. The total training budget for 2007 was 37000 € in the division and 39000 € in the Ministry dedicated to the division. Because of several cost-efficient arrangements with different training institutions this amount appears to be sufficient.

3.3. ADVISORY BODIES/TSO'S

3.3.1. BMU

There are several advisory bodies and (technical) support organizations working for BMU.

The reactor safety commission (RSK) is an independent advisor consisting of 60 experts nominated by BMU and appointed by the Minister. BMU manages the RSK. The RSK has several subcommittees on different technical subjects, where BMU, UM BW, the TSOs and the industry discuss general safety issues or specific issues. BMU can ask RSK for advice and RSK can start a discussion on its own initiative. UM BW needs are also addressed sufficiently. The output of the RSK is statements (on a single issue) or recommendation (general issue). They are self-binding.

The main TSO for BMU is GRS. Every year there is a special budget allocated in the Government Budget for activities by GRS. The activities have to be contracted on a case by case basis. There is a framework contract based on an old agreement. GRS is also funded by the Ministry of Economy (mainly safety research). In 1976 GRS was founded by BMU, several federal states and TUV. GRS has approximately 100 experts related to the BMU supervision process on NPP. GRS also subcontracts work to several other organizations. The expenses are not reimbursed by the operators.

The BMU budget for research by GRS is 21 M€ per year. Of this 12M€ is use for the safety research in relation with the supervision of nuclear power plants. Other safety research is carried out by the ministry of economy (17M€). BMU RS staff is allowed access to meetings and results, but there is no direct influence on the programme. Through the so called bi-

annual meetings of the Knowledge Association for Nuclear Technology, where all nuclear research programmes are discussed, BMU RS I can indirectly influence the research by other organizations. BMU RS is of the opinion that they should be responsible for regulatory research on nuclear safety and assume the necessary budget. BMU indicated that it will use this budget for both its supervision tasks and the strategic safety research needs that will have to be determined in the framework of the LAA on a regular basis in the future.

3.3.2. UM BW

UM BW has two main TSOs: TUV SUD ET and KeTAG. TUV SUD has 200 people working in the nuclear area. Per year approximately 120 full time equivalents (FTEs) are used (annually about 30 M€). Compared to TUV the second TSO has a contract volume of about 5%. In addition, a similar level of effort is spent with other experts. All costs of the work of the TSOs are reimbursed to the regulator by the operator. TUV and KeTAG reports are evaluated by UM BW.

The UM BW also seeks support by the International Länder Committee (ILK). The team interviewed the ILK chairman. The ILK is an advisory body founded by three federal states (Baden Württemberg, Hessen and Bavaria). The committee currently has 9 members, of whom four are non-German. The ILK convenes three times a year. The organization is a platform for discussion of oversight, safety issues and incidents (German and foreign). It generates statements or guidance on oversight, waste management, energy policy and regulations. The work is contracted by the member states. The work is publicly available. Examples are:

• Oversight:

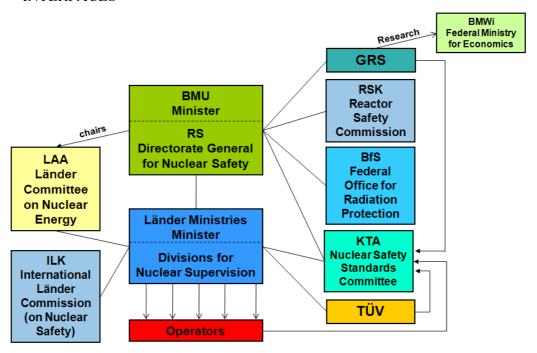
- o How to assess the self-assessment of the NPP on safety culture
- o Further development of PSR in Germany
- Use of PSA in licensing and supervision

• Regulation:

- o Fundamental safety requirements of nuclear power plants (to be finalized)
- Statement on BMU-project "update of nuclear regulatory guidelines

The IRRS Team was able to confirm that, within Baden-Wuertemberg, there is a clear understanding of the roles and responsibilities of the TSOs between all the involved parties within the Land. Additional discussion on the role of the TSOs is included in Chapters V and VI.

3.4. INTERFACES



This diagram shows the interactions between the various organizations, although these indicate the formal lines of communication. The TUV has contact with the operator and GRS also has contact with the operator and the federal states. BfS manages the KTA process.

3.4.1. BMU

The inter-relationships between BMU, the Länder and BfS are discussed in the following paragraphs.

A lack of mutual trust was observed in the relationship between BMU RS and UM BW. The IRRS team had no opportunity to review the relationship with the other Länder and therefore can make no comments on it. The state regulatory body considers itself an independent regulator with exclusive responsibilities. The constitution states that the UM BW is an execution body on behalf of BMU. BMU RS supervises that UM BW and the regulatory bodies of other states with NPPs execute the atomic law and the binding regulations in a harmonized way. Therefore they have expressed the need for an electronic database consisting of several types of documents. BMU stated that the information needed is not given. UM BW refers to the constitution, whereby information would be restricted to individual cases. Another concern by UM BW is that there would be a large workload to keep the database up to date. UM BW is concerned that BMU RS will re(do) their work in parallel (doubling), which would, according to UM BW, be against the constitution. According to the legal system BMU RS has the right to intervene in individual cases. UM BW is also concerned that the number of interferences and directives will increase and that these interventions are initiated at the same time that UM BW is just starting the assessment. UM BW is of the opinion that the state regulatory body should first act, together with the operating organization, and when the assessment by UM BW is complete the information including the statement of the TSO can be sent to BMU. BMU has produced a list of information they need, which will be discussed in the Länder Committee on Nuclear Safety (LAA). A letter containing this list has been withheld because of the fact that the issue is discussed during this mission.

In the case of BfS the IRRS Team found some evidence that there might be opportunities to improve the effectiveness of the relationship between BMU and BfS. This was illustrated in the report of the earlier mentioned independent working group on Modernization of BfS (December 2006).

Länder Committee on Nuclear Safety (LAA)

In 1982 in agreement between the federal government and federal states the LAA was founded. The Länder Committee for Nuclear Safety (LAA) is a permanent Federation-Länder Committee composed of representatives from the Länder nuclear licensing and supervisory authorities and the BMU. It serves for the preparatory co-ordination of Federal and Länder authorities in connection with the execution of the Atomic Energy Act as well as for the preparation of amendments and the further development of legal and administrative provisions, and also for non-legally binding guidance instruments.

In the interest of the progression of a uniform nuclear law throughout Germany, the competent nuclear licensing and supervisory authorities of the Länder and the BMU draft any regulations on the uniform handling of nuclear law in consensus. These regulations are then promulgated by the BMU. The BMU chairs the LAA and also manages its affairs. The Committee's decisions are usually by mutual consent and thereby self-binding.

The Technical Committees and the permanent Working Groups convene at least twice a year and more frequently if necessary. The General Committee convenes at least once a year.

The development of Ordinances requires the participation of the LAA's main committee.

In order to ease the exchange and maintenance of information, a web portal-based database has been created with access allowance for participants. BMU and UM BW both consider the LAA as the platform for an exchange of information and as a good organizational structure to promote harmonization. Since it has been almost impossible to create binding legal instruments in the last 10 years, the consensus/majority outcome of the LAA is one of the main promoters/contributors of nuclear safety improvements. One of the working groups deals with supervision practices. That would be the right platform to work out an agreement of the modalities of working together for the improvement of nuclear safety.

BMU's working relation with the LAA is addressed through a framework contract. In the framework contract all aspects are addressed.

In the case of a reportable incident the federal state sends the report in parallel to other states, BMU, GRS and BfS. BfS manages the reporting database. BfS conducts the initial assessment function and GRS will do a subsequent in-depth review and conclude by written documents with recommendations that BMU will then send to the federal states. During an emergency situation in Germany the federal states handle the incident with support of BfS, GRS and BMU.

3.4.2. UM BW

UM BW is the organization directly dealing with the operators. This consists of regular presence on site and discussions with the plant on several levels (see also Section 6). It takes part in the LAA and RSK and is advised by ILK. The TUV will carry out controls and

assessments. Like BMU with GRS, the UM BW has a framework contract with the TSOs where all modalities are addressed.

3.5 RELATIONS BETWEEN THE REGULATORY BODY AND THE OPERATOR

Based on the visits to the operator of the power plants (EnKK) and other discussions throughout the mission, the impression of the IRRS team is that the relationship between the operator and the UM BW can be characterized by openness, mutual understanding and respect. For additional details regarding the team's visit to the EnKK plant see chapter 6.

However, the relationship between the operator and the federal regulator appears to be the opposite, with a high level of mistrust and a perception that the federal regulator is politically driven. This perception is no doubt influenced by the organizational arrangements for the federal regulator, its global objective, and divergent views on what constitutes an adequate level of safety required to support safe operation of existing nuclear power plants.

The relationship between the various regulatory bodies within the overall regulatory framework has been addressed in paragraph 3.4.1.

3.6. INTERNATIONAL COOPERATION

3.6.1. BMU

With the support of GRS and BfS, BMU RS cooperates with other countries in many forums: EU HLG, WENRA, IAEA, OECD/NEA. With neighbouring countries there are memoranda of understanding for cooperation in nuclear safety and emergency preparedness, and participation in support programmes for the new EU members in Eastern Europe. Because of the staffing problems in BMU and BfS, GRS increasingly supports or even represents the federal government. With the 2009-2011 staffing plan, the aim is to return to the intended situation where BMU, supported by BfS, takes care of international relations.

3.6.2. UM BW

UM BW has an international presence in several areas, for instance the OECD/NEA Working Group on inspection practices. It will also take part in the OECD/NEA Working Group on Human and Organization Factors. UM BW also takes part in the bilateral committees with Germany and France on the subjects of emergency preparedness, nuclear safety and radiation protection. Furthermore, it has appointed an individual in the organization to track the IRRS mission results in other countries and to take part in a future mission.

MODULE III: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES UM BW

- (1) **BASIS**: GS-R-1 § 4.6 states that "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.
 - S2 <u>Suggestion</u>: UM BW division 3 should introduce a near-term recruitment and staffing plan, as well as a long-term succession planning strategy. UM BW should develop a competence matrix to support the plan and strategy. These plans and strategies should be periodically reviewed and used to develop the training program. The process should be incorporated in the management system.
- G1 <u>Good Practice</u>: UM BW allows its regulatory body a 10% increase of staff in order to recruit new technical people in anticipation of retirement.
- (1) **BASIS:** GS-G-1.3 § 3.18 states that "It is neither necessary nor practicable for the regulatory body to be entirely self-sufficient in all technical areas relating to inspection. It may therefore be necessary for it to use consultants in specialized areas. It may occasionally be necessary owing to a heavy short term workload to augment the regulatory body's inspection staff with consultants having as much knowledge and experience as the regulatory body's inspection staff. Such consultants may be any of the following:
 - —Experts provided by other governmental bodies, technical societies or research institutes:
 - —Consultants or members of advisory committees with recognized skills and experience, provided that they are effectively independent of the operator and its contractors;
 - —Experts provided by or under the auspices of international organizations. When consultants are engaged, arrangements should be made for them to have access to the facility and to any information necessary to perform their tasks. "The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated." (Ref. [1], para. 4.4.)
- (2) **BASIS:** GS-R-1 § 4.6 states that "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."
- S3 <u>Suggestion</u>: BMU and UM BW should execute their plans to acquire additional staff to supplement the current staff, thereby enabling management's flexibility to support advanced training, develop regulatory infrastructure, and benchmark best

practices of other regulatory bodies.

- S4 <u>Suggestion</u>: BMU and UM BW should consider introducing means to adapt to market conditions to ensure that the required level of staffing is achieved and secured for the future.
- (1) **BASIS**: GS-R-1 § 4.6 states that "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.
- R3 <u>Recommendation</u>: BMU should introduce a near-term recruitment and staffing plan, as well as a long-term succession planning strategy. Both the plan and strategy should include a competence matrix based on the agreed roles and responsibilities. (as referenced in this and other chapters). These plans and strategies should be periodically reviewed, used to develop the training programme, and the process should be incorporated in the management system.
- (1) **BASIS**: GS-R-1 § 4.2 states that "If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated."
- S5 <u>Suggestion</u>: BMU should evaluate the assignments of tasks of the regulatory body at the federal level to further improve effectiveness and efficiency, and avoid unnecessary duplication.
- (1) BASIS: GS-R-1 § 4.2 states that "If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated.

- (2) **BASIS**: GS-R-1 § 2.2 (3) states that responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides."
- (3) **BASIS**: GS-R-1 § 3.2. (2) states that the regulatory body shall review and assess submissions on safety from the operators both prior to authorization and periodically during operation as required."
- (4) **BASIS**: GS-R-1 § 3.2. (5) states that the regulatory body shall ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected.
- (5) **BASIS:** GS-R-1, § 4.10 states that "Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered."
- R4 **Recommendation**: In the interest of nuclear safety BMU DG RS and UM BW should cooperate in order to improve mutual trust by the development of an agreement at the LAA (possibly aided or led by a facilitator) to address all relevant topics, including:
 - clarification and understanding of the respective roles and responsibility of the BMU DG RS and the Länder, and the execution of these roles and responsibilities;
 - identification of the means of communication between BMU DG RS and the Länder;
 - identification of the rules of the exchange of information regarding the supervision of nuclear safety. These rules should take regard of needs, in such a way that BMU DG RS has confidence in the data content and accuracy and it is able to:
 - o use the data without the need for further technical analysis; and
 - o assure itself that each Land is carrying out its regulatory responsibilities appropriately.
 - Secondment of staff between BMU DG RS and the Länder to improve mutual understanding and experience.
 - The establishment of a strategic nuclear safety research plan for the existing NPPs

4. AUTHORIZATION

According to the IAEA Safety Glossary, authorization is the granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification or registration. The term authorization is also sometimes used to describe the document granting such permission. Authorization is normally a more formal process than approval. Approval is the granting of consent by a regulatory body. The term is typically used to represent any form of consent from the regulatory body that does not meet the definition of authorization.

4.1. BMU

Because the Länder regulators are responsible for the licensing process and also the authorization of modifications that are non-essential, and thus need no license, the BMU is not directly involved in the authorization process, apart from rare cases when the BMU issued directives to Länder regulators. According to §85 of the Constitution (Basic Law), the subject of federal oversight is the legality and appropriateness of execution of federal laws by the Länder. Therefore, there are no observations on how the BMU directly grants authorizations.

There are, however, observations below on how the BMU oversees the authorization process of the UM BW and some observations concerning the lack of guidance on authorizations. The latter are treated in 4.3 since they apply both to the BMU and the UM BW.

Supervision of Licensing

Section 4.2.1 of the BMU Quality Management Handbook: Process Description for "Federal Supervision – Licensing Procedures," describes the criteria and process under which the BMU may, or shall, conduct further review of licensing activity. Discussions with both the BMU and the UM BW staff indicated that the conditions that mandate review by the BMU were well understood (specified in letters with requests by the BMU, not directives). The criteria that allow the BMU to conduct additional review are listed in its Quality Management Handbook. Whether a specific licensing issue is selected for review appears to be subjective and up to the discretion of the BMU. The Quality Management Handbook states the following main criteria for deciding whether review by federal supervisory authorities is required:

- There are grounds to suppose that a relevant procedure contains legal errors;
- the pertinent risks have increased;
- pertinent risk reduction does not conform to the latest scientific and technological findings;
- the Federal Government and a Land disagree on the question of what procedure is most suitable, or different Länder disagree on the question of what procedure is most suitable (need to ensure a consistent approach nationwide);
- departures from the subordinate regulations and resolutions agreed on in pertinent committees have occurred;
- the case is of fundamental technical / specialized importance;

- high subsequent costs for the federal budget are to be expected for example, in connection with remediation of mining damage;
- the remediation entails special technical difficulties;
- the matter is of special political importance;
- federal supervisory authorities always carry out review in cases involving:
 - Initial partial licences;
 - increases in thermal output, or significant increases in material throughput;
 - initial authorizations for decommissioning.

Formal intervention by the BMU prior to the issuance of authorization approvals are communicated to the UM BW in the form of a directive according to §85(3) of the Constitution. A directive issued by the BMU to the UMBW has been determined to transfer full responsibility for the specific licensing or regulatory decision addressed in the directive to the BMU according to Court decisions based on §85 of the Constitution.

If a decision has already been taken by the Land, and the BMU would want to intervene to verify the "lawfulness" and/or "appropriateness" of the decision, according to §85(4) of the Constitution, the Federal Government may require the submission of reports and documents and send commissioners to all authorities. If the BMU determined that the lawfulness or appropriateness of the original decision by the UM BW was incorrect, it should issue a directive to take action according to §85(3) of the Constitution.

In practice, there is an informal communication process by which the transfer of licensing-related information between the BMU and the UMBW appears to function reasonably well. If informal requests for information by the BMU are not fulfilled, the formal directive process is an option, although this need is very seldom experienced.

According to the view of the UM BW, the BMU should issue general guidance instead of issuing case by case directives in order to assure the legality and appropriateness of the Länder decisions.

The practical involvement of the BMU in the licensing process is as follows: The BMU is informed about an application for a nuclear licence. In certain cases, the BMU will desire to examine the project in more detail. There are no general criteria to review the plausibility of the decisions made by the Länder authorities. Examples include the implementation of digital instrumentation, a capacity increase associated with an NPP or decommissioning of an NPP. The UM BW sends the draft of the licence together with the supporting technical assessment and evaluation to the BMU. The BMU will consult its own experts (RSK/SSK, GRS, etc.) as necessary. Any subsequent comments or concerns regarding the license project are sent to the UM BW and discussed as necessary. The UM BW will issue the license when all issues are adequately resolved. In the rare event that the BMU and the UM BW fail to reach agreement, the BMU has the option to overrule the UM BW by directive as described above.

4.2. UM BW

According to §7(1) of the Atomic Energy Act, "No further licences will be issued for the construction and operation of installations for the fission of nuclear fuel for the commercial generation of electricity or of facilities for the reprocessing of irradiated nuclear fuel." On the

other hand, the Atomic Energy Act states that "essential modifications" of a nuclear installation need licensing (§7(1) of the Atomic Energy Act). The supreme Länder authorities designated by the Länder Governments are responsible for authorizing essential modifications and for supervising the installations. This supervision also covers modifications that are not regarded as essential according to the Atomic Energy Act und therefore do not need authorization.

The procedure for essential modifications is defined in the "Ordinance on the Procedure for Licensing of Installations under § 7 of the Atomic Energy Act (Nuclear Licensing Ordinance)". In specified cases, an Environmental Impact Assessment or an Involvement of the Public is necessary. For certain licenses, a draft license is checked by the BMU before the UM BW issues it.

For the supervision of non-essential modifications, in its Land-wide Standard Modification Procedure the UM BW has defined categories to determine by which procedure these modifications have to be authorized:

Category	Type of authorization of the modification	Conducting body (for Baden-Württemberg)
A	licensing according to §7(1)	UM BW (based upon review and
		assessment by the TSO
В	confirmation that no licensing	UM BW (based upon review and
	according to §7(1) is necessary	assessment by the TSO)
	(implies consenting to the	
	modification)	
	setting conditions for the	
	modification if necessary	
С	examination report on the	TSO (UM BW gets copies of the licensee's
	fulfilment of the conditions of the	proposal and the TSO's reply and
	specification (implies consenting to	intervenes if necessary)
	the modification if nothing else is	
	stated)	
D	no authorization	licensee

The criteria to assign a planned modification to one of the categories in the table above are defined in the "Land-wide standardized modification procedure". The main criteria can be summarized in a table in Appendix III.

The criterion for a category B modification "modifications concerning the function or design features of installations or measures which are important in terms of nuclear safety or security" is not sufficiently specified. Therefore, the UM BW has been working on a revision of this criterion. In the present draft it is intended to refer to the criteria of structural integrity (K1 to K5) that were used in the licensing documents of the KONVOI plants. However, as is stated in 4.3, these criteria are not part of the regulation.

The Land-wide standardized modification procedure also specifies which safety considerations are necessary for each category of modification and have to be documented. The areas covered are extensive, however probabilistic analyses are not mentioned. Thus the

regulatory decision making on authorizations lacks probabilistic considerations. The decisions are almost exclusively based upon deterministic criteria.

When having to authorize modifications of categories A and most cases of category B of the Land-wide standardized modification procedure, the persons in charge do not base their review and assessment only upon the documents received by the operator, but they usually inspect the pre-modification state on site. This practice is regarded as a good observation. It is based on the principle that the same persons are involved in review, assessment and inspection of the plants.

Unless the UM BW rejects a modification application, or approves it only on a specific condition, the regulatory reasoning is not documented for modifications of category B. The technical arguments are only visible in the documents of the TSO that are attached to the letter of the regulator.

The UM BW has tools for systematically tracking the fulfilment of its conditions and requests to the operators. There is a unified procedure for tracking the higher level issues with a centralized IT tool (e.g. conditions to the approval of a modification), but the way the lower level issues are being tracked is in the individual responsibility of each person in charge (e.g. the delivery of documents about the completion of a modification). The legal requirements how the paper documents have to be logged are fulfilled also for lower level issues. But to get an overall view of all open requests, in the case of the lower level issues, one has to check the paper documents that are distributed in a number of offices as long as they are in progress.

- (1) **BASIS:** NS-G-1.2 § 2.7 states that "Regarding safety analysis, para. 5.69 in Ref. [1] states that "A safety analysis of the plant design shall be conducted in which methods of both deterministic and probabilistic analysis shall be applied."
- S6 <u>Suggestion</u>: The UM BW should take into account probabilistic insights where appropriate, in addition to existing deterministic criteria, in decision-making on authorizations.
- (1) **BASIS**: GS-R-1 § 5.5 states that "The regulatory body shall formally record the basis for these decisions."
- (2) **BASIS:** GS-R-1 § 5.8 states that "In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based."
- S7 <u>Suggestion</u>: For all categories of non-essential modifications, the UM BW should also include the bases and the rationale for the regulatory decisions in the documentation that is referenced in the authorization.
- (1) **BASIS:** GS-R-1 § 4.5 states that "The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."

S8 <u>Suggestion</u>: The UM BW should track all issues that require regulatory body action related to authorizations by using its instruments systematically. Also, for the lower level issues the use of an appropriate tracking tool should be mandatory and not be up to individual persons.

Withdrawal of Licenses

§17 of the Atomic Energy Act specifies the conditions under which revocation or withdrawal of a license would be conducted. This portion of the act has not been utilized to this point. As a result of never having needed to implement this provision of the Act, no internal process or procedure has been developed by UM BW.

4.3. ISSUES APPLICABLE TO THE BMU AND THE UM BW

The Land-wide standardized modification procedure that defines how the operators have to categorize modifications and how they have to apply for the authorization of modifications is not available in a regulation or guide. Most of the requirements are documented in the management system of the UM BW and have been voluntarily implemented by each NPP operator into its operation handbook and thus become binding, which is not a suitable method for issuing regulatory guidance. However, general guidance can only be issued with the consensus of the federal state and the Länder.

The documents that define how the operators have to categorize modifications do not specify all the criteria, e.g. the relation to the structural integrity categories K1, K2 and K3 and the underlying definitions, as was already stated at 4.2. The definitions are to be found in licensing documents of the KONVOI plant line and are thus neither part of the regulation, nor of the documentation of non-KONVOI plants.

- (1) **BASIS:** GS-R-1 §5.4 states that "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. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested....."
- (2) **BASIS:** GS-R-1 §5.27 states that "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."
- R5 **Recommendation:** The BMU should initiate the development, in collaboration with the Länder regulators, of formal guidance to define how the operators categorize modifications and apply for the authorization of modifications. This should include all the criteria and definitions that are necessary.

4.4. ADDITIONAL GOVERNMENTAL ACTIVITIES RELATED TO LICENSING

In Baden-Württemberg the Ministry of Economics (WM) and the Ministry of Interior (IM) have competences of their own in nuclear licensing. The WM is responsible for reviewing the draft of the license in the areas concerning energy policy and structural engineering (e.g. erection of buildings). The IM is responsible for reviewing the draft of the license in areas concerning physical protection and emergency management. The two ministries review the draft license, and then make recommendations for conditions to the license in their respective fields. They then sign the draft of the licence in order to document that their issues have been implemented into the draft correctly. However, responsibility for the licence stays with the UM BW alone.

Additionally, if there are issues related to radiation protection issues, the State Agency for the Environment, Measuring and Nature conservation – the BW (LUBW) reviews the draft license and provides input to the UM BW. If there are issues related to materials, the Materials Testing Institute (MPA) may review the draft license and provide comments. For issues related to health, safety and emission control, the affected Regierungspräsidium and lower administration authorities will review the draft and provide comments for consideration as license conditions.

Additional Licensing Requirements

Article 15 of the Ordinance on the Protection against Damage and Injuries Caused by Ionizing Radiation (StrlSchV, Radiation Protection Ordinance, or RPO) requires that anyone who employs persons under his supervision or performs tasks himself at external facilities or installations, such as NPPs, and wherever this may lead to an effective dose of more than 1 mSv per calendar year absorbed by these persons or by himself, requires a license. These licenses are issued by the respective Landratsamt.

Article 4 of the Atomic Energy Act states that the carriage of nuclear fuel outside an enclosed site where nuclear fuel is kept in Government custody or where practices licensed pursuant to §§ 6, 7 and 9 hereof are pursued, shall require a licence." The general provisions that must be met prior to issuance of the license are listed in the Act. Permission to move nuclear fuel is granted by the Federal Office for Radiation Protection (BfS) according to §23(1)3 of the Atomic Energy Act, and in accordance with Articles 16 and 17 of the Radiation Protection Ordinance (RPO) by the Regierungspräsidium (Regional Administrative Authority) in Baden-Württemberg (Verordnung des Umweltministeriums und des Sozialministeriums über Zuständigkeiten nach § 19 des Atomgesetzes und nach der Strahlenschutzverordnung (Strahlenschutz-Zuständigkeitsverordnung – StrlSchZuVO)).

Approvals are also required for clearance of previously radioactive or contaminated material from an NPP. The provisions that must be met prior to authorizing a release from control are stated in Article 29 of the Radiation Protection Ordinance. The way in which the Article is implemented is at the discretion of the competent authority. Until now, the BMU has not implemented codes of practices for the release process. In Baden-Württemberg release-notifications are conducted in accordance with the guidance in "Leitfaden zur Freigabe nach § 29 StrlSchV" (guiding material updated and published by the Ministry of Environment). The 2007 Annual Report related to Article 29 activity was reviewed by the team members.

Authorizations and Regulatory Approvals Related to Individuals

Each nuclear power plant is required to prepare an organization chart and submit it to the competent licensing and supervisory authority, in this case UM BW. This chart must show the assignment of major tasks and responsibilities to the nuclear power plant personnel and in particular the classification of each member of the personnel in one of the following categories to which this guideline applies. The Guideline Relating to the Proof of the Technical Qualification of Nuclear Power Plant Personnel (Richtlinie für den Fachkundenachweis von Kernkraftwerkspersonal) provides information related to the positions requiring verification. These positions include Plant Manager, Head of Department or Section, responsible shift personnel (shift supervisor, deputy shift supervisor, shift operating engineer, reactor operators), Radiation Protection Officer, Training Manager, Head of Quality Assurance, Nuclear Safety Officer, and Physical Protection Officer. Also listed are the documents and specific requirements associated with each position that must be provided to the competent authority. Additionally, specific training, experience and examination requirements are specified for certain positions, including the subjects to be covered. Examination requirements are specified including a written and oral examination, with the required oral board members specified as well. For each responsible person addressed in the Guideline, the licensee or applicant requests approval for a particular individual to fill that position. UM BW reviews the provided documentation associated with the individual and either grants or rejects approval for that particular individual. The licensee/applicant is notified of the decision in writing.

5. REVIEW AND ASSESSMENT

- This Chapter includes policy discussions on Operational Experience Feedback
- This Chapter includes policy discussions on Ageing Management
- This Chapter includes policy discussions on Management of Safety

Review and assessment of German plants is done at two levels, federal level and Länder level. Länder authorities are responsible for review and assessment specific to the plants in the respective Land, while BMU is responsible for review and assessment regarding important single cases as well as generic safety issues. It is allowed, although rarely used, for BMU to review and assess in single cases when it is found to be appropriate in order to provide directives from BMU to the Länder.

Review and assessment of safety is performed at UM BW in Stuttgart, in the Division 3 of Nuclear Supervision, Environmental Radioactivity for submissions from Baden-Württemberg's NPPs. The division consults external experts in accordance with § 20 of the Atomic Energy Act for the assessment of specific technical aspects. The general requirements for such expert assessments are specified in a special regulatory guideline. The authorized experts (mainly TÜV Süd Energietechnik) carry out a detailed review and assessment of the documents submitted by the applicant. They perform independent analyses and calculations, preferably with analytical methods and computer codes different from those used by the applicant. The results are evaluated in the expert assessment, which also gives the criteria used in the assessment. The persons participating in the expert assessment are reported by name to the licensing authority.

TÜV Süd ET has 190 technical staff dedicated for nuclear safety. There is a framework agreement between UM BW and TÜV Süd ET in force which covers activities related to design, construction, and operation of a vitrification plant, operation of 4 NPPs and decommissioning of one NPP (Obrigheim). TÜV is totally independent from the licensee.

When safety related issues, including lessons learned from operational experiences, are applicable to German plants BMU will review and analyze those issues and disseminate the results to relevant organizations including Länder authorities. BMU is strongly supported by GRS, BfS and, in some cases, by RSK.

5.1. PERIODIC SAFETY REVIEW

5.1.1. BMU

Since the early 1990s when RSK recommended the execution of a periodic safety review (PSR) every 10 years, PSRs have been carried out according to standardized national criteria (criteria established as a common consensus of RSK, BMU, state ministries for the environment and TSOs).

The Guides for Periodic Safety Reviews for Nuclear Power Plants were issued in 1997. The PSA part of the guides was updated most recently in 2005, and revisions of the Basics for PSRs and Safety Status Analysis (SSA) part of the guides are in progress. The description of the safety status of a plant in the course of a PSR shall comprise the results of a deterministic safety status analysis, a probabilistic safety analysis (PSA) and a description of the plant's physical protection concept. At the end of the 1980s, the operators of the German nuclear

power plants had voluntarily committed themselves to perform PSRs at 10 year intervals. For seven nuclear power plants, such a PSR was already a mandatory requirement that had been specified in the corresponding licensing decisions. The amended version of the Atomic Energy Act of April 2002 stipulates the performance of safety reviews (SRs) every ten years. Due to the limitations imposed on the operating lives of the nuclear power plants, the safety reviews are no longer referred to as "periodic". The dates for submission of the next SRs were included in the Atomic Energy Act (App. 4). The obligation to present the SR results is avoided if the licensee declarers to the regulatory body (UM) that it is definitively going to terminate power operation at the plant no later than three years after the final date for submission of the SR mentioned in the Atomic Energy Act.

5.1.2. UM BW

SR reports are submitted to the Länder regulatory (UM BW) by the operator. According to the PSR Guideline, the PSR reports include plant description, safety analysis results, PSA and security matters. Since operations management and the evaluation of operational experiences at that plant are also important, staff expertise and operations organization, inservice inspections, maintenance, feedback of experiences, radiation protection, emergency planning, ageing management, etc., are also covered in the reports.

However, it does not mean that all the review and analyses are carried out in the process of the SR. Whenever modifications are proposed by the operator, UM BW and TUV examine their impacts on safety of the plant and, when needed, carry out safety analyses. Whenever new requirements or guidelines are issued by BMU, UM BW and TÜV examine whether all the plants in the land satisfy them or, even in a case they do not completely fulfil the new requirements or guidelines, UM BW examine whether deviations could be accepted. The review and analysis in the SR are a double check process for examining the adequacy of the review and analyses in the past 10 years.

The in-depth evaluation of the SR report is usually done by TSO organizations (for UM BW mainly TÜV). After this review, the UM BW assesses all results of the SR and the results of TSOs evaluation and composes a final report. SR, TSOs' evaluation and the final report of UM is then sent to BMU.

5.2. PROBABILISTIC SAFETY ASSESSMENT (PSA)

5.2.1. General

The results of PSA are widely believed to give safety relevant insights which are different from those by conventional safety analysis and to be useful to support the regulatory safety assessment and decision-making process. Under this belief, PSA is required as a part of PSR in Germany, although there are no requirements for PSA in the Atomic Energy Act.

The regulatory framework in Germany is deterministic in essence and probabilistic proceedings are only addressed in the Guidelines for PSR. In BMU new draft regulations, there is only very limited reference to probabilistic methods to be applied.

5.2.2. PSA Manual

As for the PSA methods, the PSA manual is already provided with the consensus of PSA experts in Germany under the BMU PSA Guideline. The manual is very comprehensive and includes methods for:

- level 1 PSA for internal and external initiators (e.g. internal fire, aircraft crash, gas explosion, flooding, seismic motion) in power operation state,
- level 1 PSA for low power and shutdown (LPS) state,
- level 2 PSA for power operation state,
- treatment of uncertainties and
- assessment of results.

5.2.3. Methods and scope of PSAs by operator

According to the PSR Guideline, UM BW requests operators to carry out PSA and to submit the results to UM BW as a part of the PSR report. PSAs are conducted using plant specific reliability data as much as possible. When plant specific data are not available, generic data can be used after examining their applicability to the plant. Plant specific data are provided by the operator based on the operational experiences at the plant, while generic data are provided by GRS based on national and international operational experiences as well as data from VGB (http://www.vgb.org/). The PSA methods utilized by operators appear to reflect state-of-the-art knowledge.

The scope of PSA has been expanded, according to the maturity of the methods. The current scope required by the PSR Guideline is very wide, corresponding to those in the PSA Manual.

5.2.4. Submission and review of PSA results

When a PSA is submitted by the operator, UM BW requests TUV SUD ET to examine whether it was adequately conducted according to the PSA manual. During the IRRS mission, it was confirmed that the expert's review is being done with a high degree of competence. It was also found that TUV and UM BW well understand where and how large uncertainties exist in PSAs and hence know what can be said and what cannot be said based on the PSA results.

As a recent topic in BW Land, PSA for KKP 1 was submitted to UM BW in June 2006, as a part of PSR. Although the deadline of the PSR was 31 August, 2005, the PSA was submitted later since it was added to the PSR in a later stage. The TUV SUD report, which was expected to be completed within two years, is somewhat delayed but is expected to be submitted to UM BW very soon. However, BMU and GRS have not been informed about the results of the PSA, which was conducted more than two years ago, since the PSR report is not sent to BMU before the completion of expert or UM BW review.

5.2.5. Use of PSA results by operator

PSA results have already been utilized by the operator to improve the safety of its plants. For example, symptom-oriented procedures were developed for shutdown phases.

According to the "Concept of Regulatory Oversight of NPP in BW", UM BW is expecting the operator to develop, and make more extensive use of, PSA. PSA should be continued as

living PSA, and the results could then be used in, e.g. optimizing back fitting measures, maintenance activities and in-service inspection, etc.

5.2.6 Use of PSA results by UM BW

Länder authorities, including UM BW, are required to reflect the insights from PSA results in their supervision procedures, due to international developments and national recommendations by external reviewers. UM BW believes that PSA is of special importance in its oversight process, as it is the only method permitting the quantification of safety gains resulting from modifications and the balanced nature of a plant's safety status.

In the current state, however, the use of PSA is limited and mostly used for understanding the overall safety picture of the plant. There are no specific objectives to utilize the results in regulation. UM BW is now seeking to use PSA results more widely in its regulation. For example, planning of inspection programme is one of the candidate usages of PSA.

Although UM BW well understands the usefulness of PSA, it also believes that the following topics have to be addressed and clarified prior to development of a new framework to utilize PSA results (Action Plan UM BW [Item 13 and 14]: Expanded use of probabilistic methods to support a risk-informed decision-making process):

- ① the relation between deterministic and probabilistic approach,
- 2 the objective of probabilistic analyses,
- ③ PSA requirements,
- 4 the performance of analyses,
- (5) the application areas, and
- (6) the assessment standards.

UM BW believes that the interface and mutual influence between deterministic and probabilistic proceedings need to be clarified and defined to ensure the performance of consistent regulatory procedures and that the specific standards to assess the PSA insights and results are to be developed and decided upon, which represents an inevitable prerequisite for an integrated risk-informed decision-making process.

5.2.7. Use of PSA results by BMU

BMU is expected to provide guidelines on how to utilize PSA results in regulation in Germany. In addition, PSA results may be referred when BMU revises its regulatory guidelines to achieve more effective and efficient regulation.

However, BMU and GRS are not informed about the PSA results in a timely manner. PSR results have not been submitted to BMU (and hence GRS) under the PSR Guideline up to now. BMU and GRS may receive PSA results even though it is not a requirement of the PSR Guideline, but detail may not be sent to BMU and GRS.

GRS, which had a leading role in developing PSA methods and carrying out the first PSA in Germany, still has an important role in the PSA area. However, it may be helpful if GRS receives minor event data to develop generic reliability data.

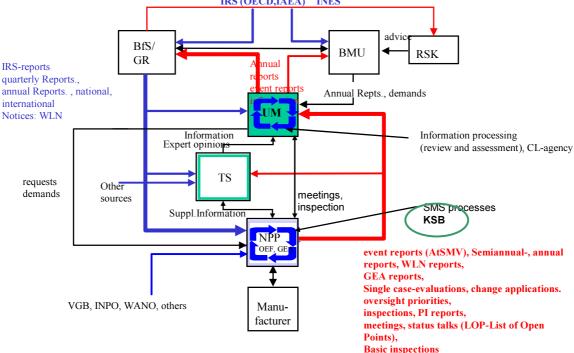
5.3. OPERATIONAL EXPERIENCE FEEDBACK

5.3.1. OEF System

The screening of events of German or foreign plants lies at the BMU and its TSO the GRS. Information about events and lessons learned from events are distributed by BMU to Länder UM, their TSOs, licensees and other competent organizations through GRS quarterly and annual reports in the case of events on foreign plants and by BfS quarterly reports in the case of German plants. GRS also prepares information notices (WLN) on behalf of BMU regarding events which could have potential significance and applicability to the safety of German plants.

IRS (OECD,IAEA) INES

Information and Communication of Event Evaluation and Follow-up



5.3.2. BMU

According to formal requirements of Ordinance on the Nuclear Safety Officer and Reporting of Accidents and other Events (AtSMV, from 1992) the licensees are required to report events based on the categories provided in the Ordinance. There are four categories of events. Category S events must be reported immediately after detection by telephone and in written form. Category E events must be reported by telephone and in written form not later than 24 hours after the event happens. Category N events must be reported with five days after the event date, and Category V events must be reported within 10 workdays. The events are reported to UM BW.

The central collection and documentation of event information on all reportable events is done by the BfS on behalf of the BMU.

International Nuclear Event Scale (INES) and Incident Reporting System (IRS) officers are staff members of GRS. They are performing their activities by order of the BMU.

5.3.3. UM BW

The operator in BW is under obligation to submit regular reports on the state of the plant and on operating events. Daily reports are submitted under the Integrated Safety Information System (ISIS). In addition, UM BW receives monthly reports containing operating data and all the information necessary for assessing plant safety. One copy of the monthly reports is sent to TUV SUD ET and also to BMU.

Further reports, e.g. about aspects of operation, safety, environmental exposure and environmental monitoring and fate of radioactive materials, are submitted at specified intervals. Some of these reports are intended to inform not only UM BW, but also other institutes, e.g. BMU or RSK.

If a reportable event happens in a NPP in BW or if there is an event of which the licensee is not definitively sure to be reportable, the licensee informs the authority by phone. When initial evaluation of the circumstances of category E and S events is done, the UM BW immediately informs BMU. Category N event evaluations are sent in proper time. At the same time BfS and GRS are informed by UM BW.

In order to assess the safety-related relevance of reportable events as soon and as comprehensively as possible and to perform independent assessment of events, a clearing agency was established in the Division 3 of UM BW in 2002. Following the procedure in the oversight manual, the information about the event first goes to the section of UM BW directly involved. The section itself normally informs the leader of the clearing agency and it establishes the time for discussion of the event. If it deals with a potential reportable event, the directly involved section decides whether there is a need for discussions in the clearing agency. There is also a target agreement of the division to discuss the event within three days after the authority gets the information of the event.

Reportable events are also important knowledge sources for the staff of the regulatory body. That is the reason why the UM BW clearing agency is composed of members from different sections and different qualifications and experiences. In order to increase the knowledge of the staff in the division, there is a periodic change in the clearing agency membership.

The clearing agency has conducted 270 meetings since its establishment in 2002 and 20 mandays have been spent annually for its activity. This practice is regarded as good observation.

TSO (KeTAG) has also established a clearing agency by order of the authority.

In BW, the operator is also under obligation to report twice a year on the possible consequences of events in other nuclear facilities and describe the necessary measures to be taken in its own plant. After having analysed the report and comments submitted, UM BW decides whether additional inspections are necessary and whether the corrective measures suggested, and already taken, at the various plants are adequate.

Germany is a participating Member State of the INES system and the Incident Reporting System (IRS) of IAEA. In the event of an incident occurring, the information and associated data are provided to DG-RS from the relevant Land to enable input to these systems. GRS, on behalf of DG-RS, checks the information received to confirm the INES rating has been correctly identified; analyzes and evaluates the data to share information on

the event within Germany (to Länder) and internationally (IRS); and passes the report data to BfS.

Since 2004, BMU indicated that Germany has provided all inputs to IRS in compliance with the minimum agreed requirements. Other States provide additional data on events below the obligatory reporting criteria. In view of this, DG-RS has formed the opinion that it would wish Germany to also provide this enhanced level of input internationally. In the action plan proposals, as identified in the ARM, DG-RS proposes to revise the criteria for reporting events with the aim to increase their number and to share learning more widely with international organizations. This proposal is supported.

The ARM identified that BMU considers that its need to strengthen its operating experience feedback arrangements e.g. increased input to IRS system, is constrained by the data currently received from Länder not all being suitably formatted or of sufficient quality for analysis by GRS. The data required is available to the Länder, in their role as the authority responsible for review and assessment of on-site events. As one of BMU DG-RS's roles is to provide an overview of events across Germany it would be appropriate for arrangements to be put in place to enable communication between GRS and the Länder (and/or their technical advisors on a specific issue) to clarify the details of events as necessary.

5.4. AGEING MANAGEMENT

5.4.1. BMU

RSK issued document "Management of Ageing Processes at Nuclear Power Plants "in 2004. The BMU sent a letter to Länder authorities to ask operators to implement the RSK document. Requirements on implementation of ageing management programs into NPPs operation will be included in the Safety Requirements for Nuclear Power Plants, the preparation of which is in progress. The LAA will discuss the status of implementation of management programs in the German plants operation in November 2008.

5.4.2. UM BW

Ageing management of NPPs means ensuring the availability of required safety functions throughout the plant service time, with account taken of changes which occur with time and service. The licensees have implemented ageing management programs at the end of the 1990s based on operational and maintenance data which have been recorded and collected since the very beginning of operation of NPPs. UM BW initiated an expert group (regulator, TSOs and operator) to prepare a draft of an ageing management guideline in 2005 based on its own initiative under the situation where there is no federal guideline. Preparation of the guide is still in progress. There are annual meetings on ageing effects (e.g. for mechanical, structural, I&C parts) between regulator, TSOs and licensees; and the licensees submit to the regulator annual reports on ageing management program results.

5.5. SAFETY MANAGEMENT SYSTEM (SMS)

UM BW is quite positive in adopting new concepts or technologies to assure a high level of safety of the plants in BW Land, although some of them are still at a preliminary stage.

The Guideline for Safety Management was published by BMU in 2004. The operators in Germany assured that SMS was fully implemented and reported it to BMU (August 2008). UM BW, in accordance with BMU, recommended the operator to adopt Safety Management System (SMS) for overall safety management and Ageing Management (AM) for examining 60

that all safety functions are maintained throughout plant lifetimes. UM BW also requests operators to carry out PSAs, whose results are utilized not only by the operators but also by UM BW. In addition, operators and UM BW developed their respective Safety Performance Indicators (SPIs). They are to be utilized to better understand the whole safety pictures of the plants.

required operators to apply SMS in the day-to-day operation and to improve it continuously. ims of the SMS are high safety culture, foresighted planning, acting in the interest of safety, and fortification of the licensee's initiative for continuous improvement. Annual discussions are held to assess the effectiveness of the SMS, to check if the processes of the SMS are implemented, and to identify different fields of supervision and oversight activities (controls on the plant, documents, reportable events etc.) that may be consolidated to provide an overall assessment ontents of the review include a summarized assessment of the management, assessment of the safety aims, coverage and evaluation of the performance indicators, results from audits and reviews, focal point of the oversight process, safety aims for the following year, and any additional safety measures the operator deems necessary.

5.6. SAFETY PERFORMANCE INDICATORS (SPIS)

The operators in Baden-Württemberg are utilizing their own SPIs, while UM BW independently developed its own SPIs. The UM BW's 72 SPIs are in 12 category groups. They are used for obtaining an independent picture of the NPP's safety performance, quick access to the collection of indicators, and for gaining experience in their interpretation. UM BW does not intend to utilize these indicators for ranking the plants. Most of the indicators are common to the indicators used by the operators. The data are collected by the authorities, KeTAG and the operator. Some are used for regulatory purposes and UM BW is evaluating them based on information submitted by the operator. Collection of SPIs was initiated in September 2004, after nearly two years of discussion between UM BW and the operator. At this moment, there are no significant trends identified by SPIs. How to utilize SPIs in regulation (e.g. aiming at more effective and efficient inspection) is still in a preliminary stage. The results of the analysis are an inherent part of the annual report and will be discussed in the annual meeting to assess the SMS.

5.7. ASSESSMENT OF ORGANIZATIONAL CHANGES

For the safe operation of the NPPs a licensee must have personnel in sufficient number and qualification. The ability of personnel in every single department or unit must be appropriate to cope with safe operation of the NPP. The professional competences must be identified such that, especially in the field of "basic competences," external personnel or commissions given to external companies can be correctly evaluated and overseen. Therefore oversight over the number of personnel and personnel development is also part of the basic oversight function provided by the UM. The UM BW has implemented the control of operator staff development plans to be able to react on personnel cuts to expense to nuclear safety on time. In 1998, the UM BW learned of the intent of one NPP to reduce the number of their staff by 40 percent. The change in organization provided amongst other things for the merging of the divisions mechanical engineering, electrical engineering and central services to one department called system techniques. Personnel from the department of operations (personnel from the operating shifts) were to boost the department's maintenance and system

techniques staffing. Moreover it was planned to integrate central services like quality control into the headquarters of the company outside the NPP.

The opinion of the oversight authority (UM) was that these changes were not conclusively safety oriented.

The UM found it was not principally possible that an organization changed in this way might work more efficiently and that a "slimmer organization" may guarantee safe operation. However, such a change in organizational structure was seen as a substantial change of plant operation and was thus liable to licensing according to the Atomic Energy Act. The licensee was told that it had to apply for such a change and was liable for implementing it only after appropriate examination and licensing.

In 1998-1999, the number of technical personnel was planned to be reduced on the basis of early retirement settlements. This kind of personnel reduction was prohibited prior to licensing of the organizational change.

The standards of the German nuclear set of rules are termed relatively general concerning staffing numbers and general personnel qualifications. Standards concerning the number of personnel only apply to the shift personnel on the control stand. Thus it was the authority's task to clarify with the licensee which documents had to be included in the license application and what the rules for regulatory assessment were. The essential document for in-depth evaluation and assessment was the operator's personnel organization specification, part of the operation manual, in which the structure of the organization and the competences of the individual departments and units is described.

To support the assessment of the authorities a TSO with specific qualification on organizational efficiency and organization was called in.

The license was granted in 1999. In addition to the new organizational structure, the minimum allowed number of personnel for the individual departments and units was established. The allowed number of plant technical personnel was about 20% below the unit's previous normal number of staff.

By license conditions the licensee was obliged to regularly report about staffing levels and personnel development.

Subsequent to this license the other licensees in the Land had similar conditions imposed. These supplementary conditions were made compulsory to the licensee according to § 7, sub. (2) of the Atomic Energy Act.

Relating to maintaining competence and personnel planning the supplementary license conditions read as follows:

- The personnel capacities and the necessary competences must be adjusted to changes in the plant. This is ascertained by annual personnel development planning.
- The annually updated personnel development planning is to be submitted to the authorities.

In the area of staffing levels and organizational changes was decreed:

• Of changes in the operators personnel organization as well as any planned reduction of personnel the authorities must be notified in time before implementation.

• The authorities must be notified semi-annually about the up-to-date exact headcount for department and unit respectively.

The oversight activities for review and assessment of license requirement fulfilment are fixed in the oversight manual.

The dominant job is the evaluation of the licensees' reports. Evaluation is conducted concerning the following subjects:

- Check if contents and amount are according to the conditions.
- Target-performance comparison with the license terms
- On-schedule submission

In addition to the report evaluation, an annual meeting with the operator is held if necessary. At this meeting the general strategy for maintaining competence and personnel acquisition may be discussed. When suspicions or negative trends were identified during the year, it is necessary to detect together with the licensee the means to counteract. If the licensee doesn't cooperate, corrective oversight measures may be necessary. The results of the meetings are documented in the original document as well as in the AGAVE data base.

The UM BW approach to assessment of organizational changes was recognized as a good practice by other Länder regulators and BMU. The general acceptance of this approach by all German regulators is in progress.

- (1) **BASIS:** GS-G-1 § 2.3 (j) states that "The management of review and assessment (by the regulatory body) should include responsibility for collecting and disseminating the overall findings of the regulatory body following the completion of the review and assessment process"
 - (2) **BASIS:** GS-G-1.4 § 3.16 states that "A regulatory system should include both types of regulations, striking an appropriate balance between performance based and prescriptive regulations (or guides) to match the anticipated workload and the skills of the regulatory body's staff."
 - S9 <u>Suggestion</u>: BMU and UM BW should agree on the information to be shared before UM BW's formal examination of a PSR report is completed. The PSR, including PSA, should be shared more timely to all the relevant organizations so that they will have a common view on the "current" state of safety of the plants.
 - (1) **BASIS**: GS-R-1 § 3.3. (7) states that "the regulatory body shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated."

- Suggestion: BMU DG-RS and UM BW should cooperate in progressing an agreement by the LAA of a process to ensure that the information required by BMU to fulfil its function regarding OEF, such as IRS and WL (Information Notice), is provided in a suitable format and content by each Land. The objective of this agreement should be to give DG-RS confidence in the data accuracy and to enable it to contribute more input and strengthen the OEF process within Germany. The agreement should include a mechanism to enable communications between DG-RS and each Land (including their respective advisory bodies) to clarify the details of the events.
 - (1) **BASIS:** GS-R-1 § 5.11. states that "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."
- G2 <u>Good Practice:</u> The UM BW has implemented regulatory control of NPPs' human resources to ensure adequate staffing for safety at all times.
- (1) **BASIS**: NS-G-2.10 §4.23 states that "4.23. Managing the ageing of SSCs important to safety requires the age related degradation of the SSCs to be controlled within defined limits.. Effective control of ageing degradation is achieved by means of a systematic ageing management process consisting of the following ageing management tasks, based on the understanding of ageing of SSCs"
- S11 <u>Suggestion</u>: BMU should complete its action plan to develop the guide for ageing management.
- (1) **BASIS:** GS-R-1 § 5.13 states that "- The main purposes of regulatory inspection and enforcement are to ensure that...(6) the operator is managing safety in a proper manner.
- (2) **BASIS:** GS-G-1.3 § 4.1 states that "To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Appropriate information and guidance should be provided to the inspectors and each inspector should be given adequate training in following this guidance. Consideration should be given to the extent to which this guidance should be made available to the operator or to the public. Appropriate subjects for guidance and instructions for inspectors could include:
 - (a) how to develop an inspection programme;
 - (b) the legal basis for regulatory inspection and the scope of the inspector's authority:
 - (c) the use of regulatory requirements, regulations and guides and industrial standards;
 - (d) implementation of the inspection programme, including:
 - —areas to be subject to inspection,

- —method of inspection to be used,
- —methods for selection of inspection samples,
- —relevant technical information and questionnaires;
- (e) reporting requirements and practices for inspectors;
- (f) policies of the regulatory body as they may affect inspection;
- (g) standards of conduct of inspectors;
- (h) enforcement policy, procedures and practices.
- Suggestion: UM BW should develop an approach to the inspection and assessment process that facilitates a more systematic and consistent method to assess operator performance. In considering such an approach, due regard should be given to the benefits of using state of the art evaluative tools, including probabilistic safety assessment (PSA), to plan inspections, determine the safety significance of inspection findings, assess the significance of operational events and plant conditions.

6. INSPECTION AND ENFORCEMENT

6.1. UM BW INSPECTION PROGRAMME

The inspections of nuclear facilities are carried out by Länder authorities which, in the case of the Land of Baden-Württemberg, is the Ministry of the Environment Baden-Württemberg (UM BW). Two groups of technical staff within UMBW, each led by a Section Supervisor, are assigned to oversee the safety performance of the two nuclear stations, GKN and KKP. Staff in each Section inspect operations at their assigned facility, although in some cases staff carry out inspections at the other Section's assigned facility in order to harmonize practices and promote objectivity.

If findings are identified during an inspection, UM BW inspectors are expected to communicate the findings to the operator at the completion of the inspection. The inspector also discusses the basis of the inspection findings with the Section Supervisor and consults on the safety significance. Depending on the safety significance of the finding, this discussion may occur while the inspector is onsite. A deterministic approach is used to discern the safety significance of the finding. The inspector records the results of significant findings in a report and the report is stored in UM BW's AGAVE database. If the finding also represents a deviation, violation of requirements, or non-conformance with an order, UM BW may send an administrative letter to the operator. The IRRS Team noted that UM BW lacks clear detailed guidance for inspectors regarding the classification of inspection results.

The inspections of the regulatory body are supplemented by technical advice from authorized experts. The authorized experts for UM BW consist of the Technical Support Organizations (TSOs), TUV SUD Energietechnik Baden-Württemberg GmbH (TUV) and Kerntechnik Gutachter-Arbeitsgemeinschaft Baden-Württemberg (KeTAG). The TUV provides technical expertise in specifically assigned areas on the basis of an annual schedule agreed upon by the regulatory body and TUV. TUV's authorized experts are not considered inspectors, nor are they empowered to make regulatory decisions. Their primary function is to perform technical checks on behalf of the regulator that enable UM BW to confirm that the plant is operated according to the rules and the conditions of the license. If any deviation is observed, the authorized expert must inform UM BW who will judge and carry out the appropriate regulatory action. During 2007, the authorized experts devoted an average of 2,600 days per unit to onsite technical review activities. In addition, UM BW employs experts from KeTAG to accompany inspectors from the authority during some inspections and when responding to reportable events.

During inspections, UM BW inspectors make observations and form impressions regarding the operator's safety culture to complement their inspection. Organizational and personnel aspects of operator performance are recorded, documented and analyzed through use of the recently developed KOMFORT oversight tool (Catalogue for recording organizational and human factors during on-site inspections). To assess whether operators effectively identify, evaluate, and correct deficiencies, UM BW also includes in its inspection program a review of integrated event analysis (GEA), which is a strategy used by operators to identify the root causes of plant problems. This inspection includes an assessment of the adequate application of the Safety through Organizational Learning (SOL) methodology, a causal evaluation tool

used by operators to determine the technical, as well as organizational and/or learning issues that may have contributed to a deficiency.

Additionally, UM BW uses an online remote system to monitor nuclear reactors that provides information for online monitoring, environmental surveillance and emergency response. The system includes several reactor system operational parameters (e.g., pressure, temperature, levels, and power) as well as an indicator of actuation of the reactor protective system. In addition, inputs to this mainly environmental and radiological assessment system include real time data on NPP gaseous and effluent radioactive release rates, meteorological data, as well as radiation monitoring data from fixed wireless dose rate monitors, mobile monitoring sources (during an actual event or emergency exercise), and external radiation monitoring networks.

Currently, UM BW allocates 18 staff for direct observation of plant operations. This staffing level, while sufficient to implement UM BW's annual inspection program, provides little margin for regulatory staff to respond to a higher than normal number of plant events and/or degraded performance of plant operators. As a result, UM BW has initiated actions to hire 9 additional staff.

The regulatory framework for inspection is defined in the Atomic Energy Act (Atomgesetz – AtG) that stipulates, among other things, the supervision by the government (§ 19 AtG). The performance of supervision (i.e. inspection and oversight) is the responsibility of the competent nuclear regulatory body (in this case, UM BW).

The objective of UM BW's inspections is to verify that the condition of structures, systems and components (SSCs) important to safety and the operation of the plant comply with the license. The on-site inspections are part of UM BW's oversight concept and include three essential functions:

- *Presence*: regular contact with plant and personnel, perception of plant changes, insight into the operational processes.
- *Communication*: contact for operator, receipt of information, talks with the shift supervisor on the current condition of the plant.
- *Control*: walkdowns/inspections in specific parts of the plant, control of the shift log, verification of fulfilment of requirements of the license.

The type, methods and scope of inspections are stipulated in the Concept for Regulatory Oversight of Nuclear Power Plants in Baden-Württemberg (Oversight Concept - OC), October 2007, and differ according to plant state (e.g. operation, revision and decommissioning). Within the framework of the oversight of operations, UM BW defines and performs an annual inspection program at each nuclear power plant. In addition, oversight priorities are established annually to perform an in-depth review of relevant topics. In case of major events, an event-induced oversight program is undertaken.

To ensure that UM BW's inspection findings are fed back into the regulatory process, regulatory staff participate in a number of technical committees and working groups. These groups include the Nuclear Safety Standards Commission (KTA) and working groups of the *Länder* Committee for Nuclear Energy (LAA) (e.g., Reactor Safety Subcommittee, Working Group on Oversight of Reactor Operations, Working Group on Physical Protection,

Technical competence, etc.). Findings and results from these meetings contribute to the experience exchange between the *Länder* and BMU officials.

In addition to insights from onsite inspections, UM BW has used a set of 72 performance indicators as part of its evaluation of the safety performance capability at its plants. The 72 performance indicators were created using data collected by UM BW, the KeTAG and the operators. UM BW analyzes and evaluates the data statistically, and includes the results in its annual assessment.

The staff within UM BW who are assigned the responsibility for reactor safety inspection and oversight meet annually to review the resources expended for inspections, evaluate the results of oversight activities using deterministic insights, and assess the safety status of the inspected areas. Based on this discussion, an inspection program for UM BW's operating reactors is defined for the upcoming year.

Basic, Event-Induced, and Priority Inspection Program of Nuclear Power Plants

The Basic inspection program of UM BW consists of onsite inspections at each nuclear facility. In addition, event-induced inspections resulting from reported plant events may be conducted. There are 276 Basic inspections of the four operating nuclear power plant units planned for the year 2008. In 2008, UM BW planned to conduct one Priority team inspection at both of its sites (GKN and KKP). This six-person team inspection will focus on the design, maintenance, and operational activities at each site that prevent and detect leakage from the reactor containment building.

The Basic inspections comprise 16 different inspection areas, which are conducted by 18 staff from UM BW. Some Basic inspections include support by 3 KeTAG consultant experts. In addition, UM BW's regulatory decision-making is supported by technical advice from up to 190 TUV technical experts. The UM BW inspection program includes the following areas:

- 1. Modification Procedure
- 2. Operating Management
- 3. Maintenance
- 4. In-Service Inspections
- 5. Quality Assurance
- 6. Technical Qualification
- 7. Radiation Protection
- 8. Chemistry

- 9. Integrated Event Analysis
- 10. Ageing Management
- 11. Accident Management
- 12. Physical Protection
- 13. Handling Of Fuel Elements
- 14. Fire Protection System Design
- 15. Documentation
- 16. Civil Engineering

In most cases, UM BW informs the plant operator in advance of the schedule for these inspections so that necessary preparatory arrangements can be made. While conducting the inspections, UM BW inspectors have the authority to inspect areas outside of that which has been announced. In addition, each year UM BW conducts 3 to 4 unannounced inspections at each plant. Some of the unannounced inspections may be performed outside the normal working hours (i.e., nights and weekends); however, UM BW does not explicitly plan or schedule such inspections to assure the adequacy of operator performance during these periods.

The periodicity of the UM BW inspections is such that inspectors from the regulatory body are onsite 48 to 50 days per year to conduct Basic inspections, with the goal of being onsite about 1 day per work week. However, during 2007, inspectors averaged 71 days onsite per unit conducting Basic, Event-induced and Priority inspections. Typically, at least one TUV technical expert is onsite each work day, and a KeTAG inspector accompanies an authority inspector about 12 days per year, per site.

Inspection at the Neckarwestheim (GKN) Nuclear Power Plant

The IRRS team observed an inspection at the Neckarwestheim NPP. The inspection was carried out by one inspector of the UM BW and covered the areas of Operations Management and Radiation Protection. The inspection areas were communicated to the operator in advance of the inspection. The Inspection Manual provides general language about the inspection scope and the required verifications, however, detailed inspection procedures are not available for the inspectors. The Operations Management procedure is performed quarterly and the Radiation Procedure is performed bimonthly at GKN. The inspection included a tour of the control room and in several rooms inside the radiological controlled area (RCA). The IRRS team observed the inspector's entrance and exit meetings, as well as the field inspections in the control room and in the RCA.

At the entrance meeting with the plant manager, the inspector received an overview of the status of the facility, detailed information on the malfunctions that occurred during the last week, the program of work carried out during the previous week, and the plan for the next week. The inspector discussed his inspection plan with the plant manager.

The inspector's control room visit included a briefing by the shift supervisor on the status of the unit, the planned work, an overview of the condition of safety equipment, including unavailable components. The shift supervisor also discussed ongoing tests with the inspector, and provided an overview of shift logs, Operation Manual revisions, and several other operational documents available in the control room. The RCA tour included the reactor building, the spent fuel pool area, component cooling water system spaces, as well as the residual heat removal system area.

The inspector was accompanied during the inspection by the plant manager. The total time devoted to the inspection was approximately 4 hours. At the exit meeting the inspector informed the plant manager of deficiencies that he identified during the inspection, which included only minor findings. In addition, the inspector identified and shared with the plant manager several observations regarding the organizational and personnel performance, including house keeping and qualification of personnel. In both cases, the operator's performance was characterized in an appropriate manner. These insights were input into the KOMFORT system. The operator acknowledged the findings and agreed to implement corrective actions.

In addition to the inspection, the IRRS team members had the opportunity to observe a turnover of responsibility by the control room shift, and meet with the plant manager and other operator representatives to discuss several subjects. Among the topics discussed was the relationship between the operator and UM BW, and the role of independent experts. The operator indicated a clear understanding of the difference between the role of the regulator and the independent experts.

In summary, the inspection was carried out in a professional and competent manner, and the operator was similarly responsive and professional. Based on the interactions between the inspector and the licensee's staff, the communications between the UM BW and the operators appeared to be open, frank, and safety-focused.

6.2 UM BW ENFORCEMENT PROGRAMME

The enforcement of applicable regulations in the nuclear field is supported by certain measures contained in the Criminal Code, in the Atomic Energy Act and the nuclear regulatory ordinances in case of any violations. Some violations can constitute punishable offences and the regulatory body can pass on its findings to other agencies, as e.g. the prosecuting authorities, which in turn have intervention powers of their own vis-à-vis the operators. When this is not the case, other enforcement tools are available:

- Orders can be issued by the regulatory body to enforce safe and lawful conditions. According to § 19 AtG, the authority may direct that unlawful or dangerous states be discontinued and, in particular, whether and which protective action must be taken; it may direct that radioactive materials be stored or kept in custody at a place it designates and that the construction and operation of nuclear power plants be suspended or, if a requisite licence is not granted or is definitely revoked, be discontinued. Interventions are administrative acts which are enforced under the Land Administrative Enforcement Act;
- Administrative fine: In addition to the possibilities of compulsory enforcement of administrative acts, the regulatory body can, under certain conditions regulated in the Atomic Energy Act, impose an administrative fine, especially when the operator contravenes an enforceable requirement under the Atomic Energy Act.

Even though the above tools are available to enforce operator action, their use has been limited as evidenced by UM BW's assignment of only one fine to an operator during the last ten years. Instead, UM BW makes routine use of informal oral communications with operators to prompt compliance with regulatory requirements. In addition to oral communications, the regulator uses an informal letter (redress letter), a non-administrative action used to identify deviations, violations or other performance matters and request remedial actions within a specified timeframe, if appropriate. In the past eight years, UM BW has sent 115 administrative (redress) letters to its nuclear operators.

- (1) **BASIS:** GS-R-1 § 5.13 states that "The main purposes of regulatory inspection and enforcement are to ensure that...(6) the operator is managing safety in a proper manner."
 - G3 <u>Good Practice:</u> The approach for the systematic assessment and oversight of organizational and human factors (KOMFORT system) represents an innovative, structured and useful means of incorporating safety culture insights into the regulator's annual assessment process.
 - (1) **BASIS:** GS-R-1 § 5.19 states that "Deviations from, or violations of, requirements, or unsatisfactory situations which have minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances,

- the regulatory body shall issue a written warning or directive to the operator which shall identify the nature and regulatory basis of each violation and the period of time permitted for taking remedial action"
- (2) **BASIS:** GS-R-1 § 5.22 states that "All enforcement decisions shall be confirmed to the operator in writing"
- R6 <u>Recommendation</u>: UM BW should review and enhance the enforcement system to ensure that deviations from, or violations of, requirements are documented in writing to the operator.
- (1) **BASIS:** GS-R-1 § 5.12 states that "Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations."
- S13 <u>Suggestion</u>: UM BW should review and expand the scope of the inspection programme, as appropriate, to assure that all areas of regulatory responsibility are covered.
- (1) **BASIS:** GS-G-1.3 § 4.1 states that "To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise.
- S14 <u>Suggestion</u>: UM BW should develop more detailed procedures for inspection activities to enhance the consistency of inspections. Such detailed procedures would be particularly helpful in the context of a future work force that includes staff with less experience than the current staff.
- (1) **BASIS:** GS-G-1.3 § 4.32 states that "Inspection reports should typically contain: —identification of the facility inspected, the purpose and date of the inspection and the inspectors' names; ...
 - —a record of any deficiency or violation found in regulatory inspections, including a record of which requirements or regulations have been contravened;
 - S15 <u>Suggestion</u>: UM BW should enhance the content of inspection reports to include reference to the applicable regulatory requirements associated with inspection findings.

- (1) **BASIS:** GS-R-1 § 5.13 states that "The main purposes of regulatory inspection and enforcement are to ensure that:
 - (1) facilities, equipment and work performance meet all necessary requirements;
 - (2) relevant documents and instructions are valid and are being complied with;
 - (3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
 - (4) deficiencies and deviations are identified and are corrected or justified without undue delay;
 - (5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and
 - (6) the operator is managing safety in a proper manner."
- (2) **BASIS:** GS-G-1.3 § 4.5 states that "Different methods may be used in establishing or modifying an inspection programme, with associated priorities, to achieve the objectives of regulatory inspections. The regulatory body should consider the following:
 - —the results of previous inspections;
 - —the safety analysis performed by the operator and the results of regulatory review and assessment;
 - —performance indicator programmes or any other systematic method for the assessment of the operator's performance;
 - —operational experience and lessons learned from operating the facility and other similar facilities as well as results of research and development;
- Suggestion: UM BW should enhance the annual assessment process used to evaluate plant performance and define the inspection program for the upcoming year, such that it more clearly and systematically incorporates relevant performance information available to the regulator (e.g., the annual operator reports on the Safety Management System Performance, the KOMFORT system data, the results of inspections and enforcement, as well as performance indicators). Particular attention should be given to the schedule and activities for obtaining all relevant information to enable an integrated assessment.
- (1) **BASIS:** GS-R-1 § 5.13 states that "The main purposes of regulatory inspection and enforcement are to ensure that:
 - (1) facilities, equipment and work performance meet all necessary requirements;
 - (2) relevant documents and instructions are valid and are being complied with;
 - (3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
 - (4) deficiencies and deviations are identified and are corrected or justified without undue delay;
 - (5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and
 - (6) the operator is managing safety in a proper manner."

- Suggestion: UM BW should review its performance indicators to confirm that the (72) safety indicators and the (8) safety culture indicators provide relevant and meaningful insights. The regulator should inspect the inputs used for the operators' performance indicators to verify their accuracy. The merits of a more frequent (e.g., quarterly) review and trending of the safety performance indicators should be considered to enable a more timely response to a declining trend in operator performance. In addition, UM BW should consider the merits of bench-marking the use of safety culture attributes of other regulatory bodies to optimize its approach to assessing safety culture.
- (1) **BASIS:** GS-R-1 § 5.12 states that "Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or noncompliance with, conditions and requirements.
- (2) BASIS: GS-G-1.3 § 3.10 states that "Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser events occurring at the particular facility under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another plant or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and consultants accordingly. For example, in implementing the inspection programme, the regulatory body should establish a graded approach in responding to unforeseen circumstances. All available resources may be needed in responding to a serious event, whereas in the simplest of cases only one inspector may be needed. This pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections."
- S18 <u>Suggestion</u>: UM BW should develop a procedure, that include criteria, for reactive inspections
- (1) **BASIS:** GS-R-1 § 5.13 states that "- The main purposes of regulatory inspection and enforcement are to ensure that...(6) the operator is managing safety in a proper manner.

- (2) **BASIS:** GS-G-1.3 § 4.1 states that "To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Appropriate information and guidance should be provided to the inspectors and each inspector should be given adequate training in following this guidance. Consideration should be given to the extent to which this guidance should be made available to the operator or to the public. Appropriate subjects for guidance and instructions for inspectors could include:
 - (a) how to develop an inspection programme;
 - (b) the legal basis for regulatory inspection and the scope of the inspector's authority;
 - (c) the use of regulatory requirements, regulations and guides and industrial standards;
 - (d) implementation of the inspection programme, including:
 - —areas to be subject to inspection,
 - —method of inspection to be used,
 - —methods for selection of inspection samples,
 - —relevant technical information and questionnaires;
 - (e) reporting requirements and practices for inspectors;
 - (f) policies of the regulatory body as they may affect inspection;
 - (g) standards of conduct of inspectors;
 - (h) enforcement policy, procedures and practices.
- S19 <u>Suggestion</u>: UM BW should plan and schedule inspections outside the normal working hours (i.e., nights and weekends), and increase the number of such inspections.
- (1) **BASIS:** GS-R-1 § 5.18 states that "Enforcement actions are designed to respond to non-compliance with the specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance.
- S20 <u>Suggestion</u>: The BMU and UM BW should review the *enforcement tools* available to assure proportionality between enforcement actions and the safety significance of violations.
- (1) **BASIS:** GS-G-1.3 § 4.5 states that The regulatory body shall adopt clear administrative procedures and guidelines governing the use and implementation of enforcement actions. All inspectors and other staff of the regulatory body should be trained and should be knowledgeable about the procedures and guidelines.
- S21 <u>Suggestion</u>: UM BW should develop administrative procedures and guidelines for implementation of the enforcement process. UM BW inspectors and staff should be trained on the use and application of these documents.

7. DEVELOPMENT OF REGULATIONS AND GUIDES

7.1. THE HIERARCHY OF REGULATIONS AND GUIDES

The hierarchy of regulations and guides in Germany is described in detail in Chapter 1, together with the legislative framework. The essential points, with regards to the categorization of regulatory document and their legal status in the regulatory framework, can be summarized as follows:

• Legally and partly legally-binding documents:

- o Law (Gesetz) includes the Atomic Energy Act;
- Ordinances (Verordnung) needs a consensus between the government and the second chamber of the parliament ("Bundesrat"); and
- General administrative provision (Allgemeine Verwaltungsvorschriften) as an Ordinance, it needs a consensus between the government and the second chamber of the government (Bundesrat).

The two first categories of documents are legally binding, whereas the third category is only binding for the administration and is usually used to ensure harmonization of the work at different levels of government in Germany.

• Non-legally binding documents:

- o BMU regulatory documents;
- o RSK recommendations (Reaktor-Sicherheitskommission); and
- o KTA nuclear technical standards (Kerntechnischer Ausschuss).

There are two administrative processes to give these documents legal status in Germany. First, an Ordinance can refer to a regulatory document. Second, a regulatory document can be referenced in the licence or other supervisory measures, making it legally binding. It has to be noted that even if a regulatory document has no legal status, it can in many cases be recognized as binding by the court, according to the Paragraph 7 of the Atomic Energy Act that reads "…licence may only be granted if the necessary precautions have been taken in the light of the state of the art in science and technology to prevent damage resulting from the erection and operation of the installation."

7.2. PROCESSES FOR ISSUING REGULATORY DOCUMENTS

The key elements of the process for issuing regulatory documents and technical standards are described below based on limited discussions held on this subject.

7.2.1. Ordinances and general administrative provisions

Further to the information provided in Chapter 1, it is important to add here that, to adopt an Ordinance or an administrative provision, it is a common practice for BMU to first obtain an approval of the State Federal Committee (LAA). The approval has then to be reviewed by the BMU minister, and in some cases, by the cabinet in order to be recommended for approval by the second chamber of the parliament (Bundesrat) where all the Länder are represented. The

approval of an Ordinance renders it a legally-binding status. The approval of a general administrative provision constitutes its legally-binding status only for the administrations.

The government can theoretically submit a draft Ordinance to the Bundesrat for approval without agreement of LAA. In this case, however, it may be difficult to obtain the Bundesrat's approval without strong modifications of the proposed text.

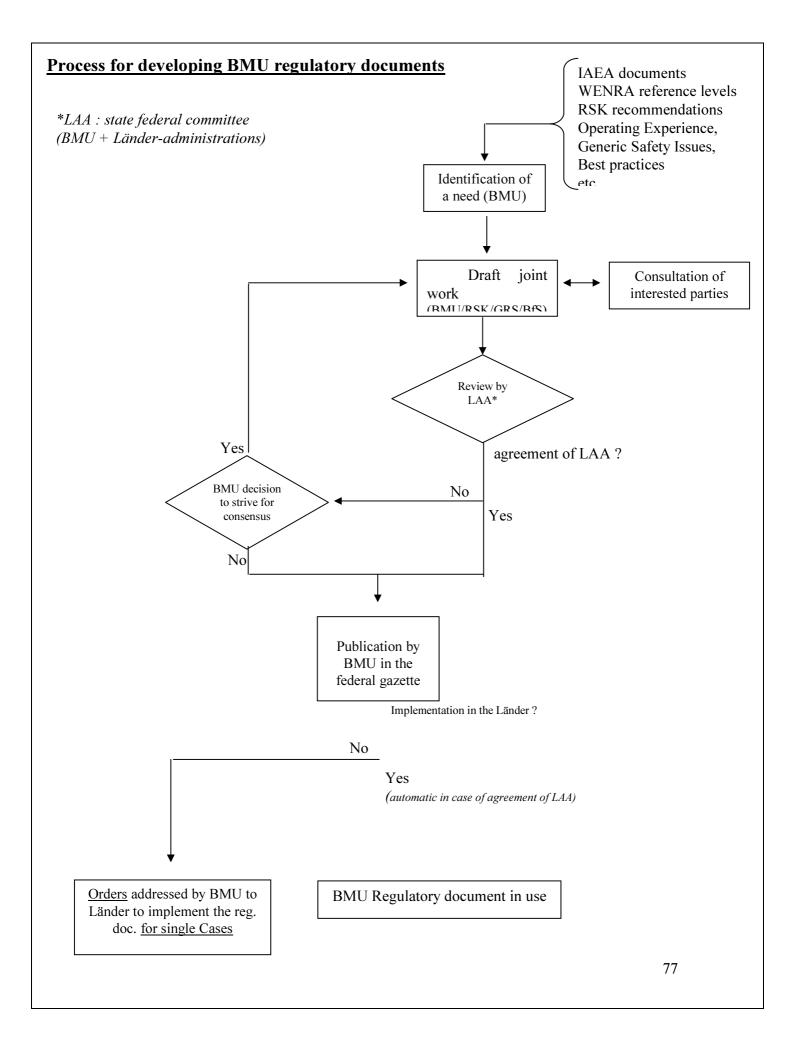
7.2.2. BMU regulatory documents

The process for the development of BMU regulatory documents is schematically illustrated in the figure below. It can be seen that the process starts from the need assessment. The assessment, however, is not carried out on a program basis. Rather, the document development process is initiated in response to specific issues such as a new development in science and technology, feedback from operating experience, or needs identified by operators or determined by the Länder.

After identifying the need and consulting interested parties, BMU provides a draft to the State Federal Committee (LAA) for the review and eventual approval. If LAA approves the document, it is published in the Federal Gazette and consequently becomes binding for all levels of government administration. Effectively it means that the document can be implemented in all Länder in order to establish new regulatory requirements. It should be noted, however, that the document has no binding legal status unless specified by the Länder in either the plant operating licence or other supervisory measures.

If LAA does not approve the document, BMU nevertheless has the possibility of publishing the document in the Federal Gazette. The Länder, however, are not administratively bound to enforce the document or some parts of it. In this case, BMU can only issue directives to the Länder to implement the document in a "single case rule". Further details on a legal meaning of a "single case rule" are provided in Section 1.

It can thus be seen that the LAA's role is essential in establishing the consensus between the Federation (BMU) and the Länder on the use of regulatory documents as legally binding requirements. However, there are no legislative and governmental mechanisms to ensure that regulatory documents are developed and approved in accordance with appropriate time-scales.



- (1) **BASIS:** GS-R-1 § 5.25 states that "The legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales."
 - R7 **Recommendation:** The existing administrative process to issue BMU regulatory documents should be reviewed and modified in order to ensure that regulations can be issued and implemented in a timely manner.

7.2.3. RSK recommendations

The RSK is commissioned and funded by BMU to assess specific safety and technical issues. The RSK membership is by invitation from the BMU Minister and lasts for a period of three years. The members are supported in their work by committees which are formed from external experts in addition to RSK members. The secretariat is provided by staff from the Federal Office for Radiation Protection (BfS), working from the BMU offices in Bonn.

BMU publishes RSK recommendations and guidelines, and generally distributes them through a generic letter to the Länder regulatory bodies. As in the case of BMU documents, there is no process in place to review and update the RSK recommendations on a regular basis.

7.2.4. KTA nuclear technical standards

KTA standards are based on striving for a strong consensus between regulatory bodies and licensees, expert organizations for safety assessment, manufacturers and operators. The KTA standards are aimed at providing technical solutions in order to reach safety objectives, more than to establish safety objectives themselves. The KTA consists of 50 expert members appointed by the BMU, 10 from each of the four following groups and 10 from other organizations via appointment by BMU:

- the manufacturers and builders of nuclear installations,
- the operators of nuclear installations,
- the federal and Länder regulatory bodies,
- the inspection agencies and advisory organizations and other authorities, and organizations and agencies concerned with nuclear technology.

The following subcommittees have been formed within KTA:

- Programme and Fundamental Issues Subcommittee (UA-PG),
- Plant and Structural Engineering Subcommittee (UA-AB),
- Operations Subcommittee (UA-BB),
- Electrical engineering and control technology Subcommittee (UA-EL),
- Mechanical components Subcommittee (UA-MK),
- Reactor core and system design Subcommittee (UA-RS), and
- Radiological protection Subcommittee (UA-ST).

Standards are drafted and reviewed in several working group, before being approved by the KTA. Approval requires a majority of member votes (specifically, 42 votes out of the 50 members). These standards are generally considered as a minimum safety level to be achieved, and are well recognized at a national level due to the strong consensus needed for their adoption. The Länder

have authority to apply the KTA standards as binding regulatory requirements if referenced in the licence or other administrative measures.

The KTA standards are reviewed every 5 years to account for the evolution of the state of the art in science and technology.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.28 states that "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."
 - G4 <u>Good Practice:</u> The process for developing KTA technical standards is very comprehensive and systematic. It covers a broad range of technical issues, taking into consideration state of the art in science and technology. The consultation process allows for consideration of comments from all interested parties. The documents are reviewed and, if necessary, revised every 5 years.

7.3. EXISTING REGULATORY FRAMEWORK FOR NUCLEAR SAFETY

The principle Ordinances regarding nuclear safety are the following:

- Radiation protection Ordinance;
- Nuclear Licensing Procedure Ordinance;
- Nuclear Safety Officer and Reporting Ordinance;
- Nuclear Reliability Assessment Ordinance;
- Nuclear Financial Security Ordinance;
- Cost Ordinance under the Atomic Energy Act;
- Ordinance Concerning Potassium Iodide Tablets;
- Nuclear Waste Transfer Ordinance;
- Repository Prepayment Ordinance.

The existing Ordinances do not specify regulations in relation to the plant design, operation, operating experience feedback, training and technical qualification of licensee staff, and some protective measures (e.g., shutdown and low power mode of operation). These aspects should be included in an Ordinance on nuclear safety (which has never been issued). It should be noted, however, that the Ordinance on radiation protection was intended to provide overarching provisions on nuclear safety by specifying the release limits for normal operation and design basis accidents. These limits are also specified in the plant operating license.

To date, BMU has issued over 60 regulatory guidelines and about 60 RSK recommendations in the field of nuclear safety. At the present, the majority of these documents are outdated and do not reflect the current state of the art in science and technology. They were issued in the 1970's and the 1980's and have not been updated.

In addition, about 90 KTA technical standards are currently in use, and 15 are in preparation. They generally account for the evolution of the state of the art in science and technology.

7.4. STRATEGY FOR THE DEVELOPMENT OF REGULATIONS AND GUIDES

The BMU conceptual approach to the development of regulations and guides is showed schematically in the figure below. The input is taken from screening of existing regulatory documents and modern international practices and experience. Once the need for a regulatory

document is identified, the document is developed in accordance with the processes described in Section 7.2.2. The document could be safety Ordinances, BMU regulatory document, or KTA technical standards. Two illustrative examples are shown in the figure below: the PSR guideline and the PSA technical standard.

BMU function Rule setting - Nuclear Safety RMI I task AtG IAEA Rules develop Safety Ordinance WENRA PSR Guidance to regulatory body RSK screening develop Operational Experience Supervision Technical document KTA develop PSA

Some strategic objectives for the development of regulatory documents are defined by BMU in the document entitled "Strategic Aims for 2008 of Directorate-General RS". The document defines, for instance, the general approach for identification of safety standards to be used in reviews and assessments of existing facilities, and supporting guidelines to be developed.

Nuclear Safety

It should be noted that this document is only for internal use in the BMU. Therefore, there is an urgent need to establish a federal strategy to modernize the existing regulatory framework by developing a comprehensive set of regulations and requirements consistent with international practice and experience. This framework should be developed in consultation with all Länder hosting nuclear power plants.

As a part of the federal strategy, the steering role of BMU in defining the strategic objectives and deciding on priorities should be clearly established to better co-ordinate document development processes and to optimize the use of available resources. BMU should also develop and implement a formal document review process to assure that the documents remain consistent with the current state of art in science and technology.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-G-1.4 § 3.1 states that "A systematic approach should be adopted for the production of regulations and guides, and the regulatory body's quality management should cover these activities"

- (2) **BASIS:** GS-G-1.4 § 3.26 states that "The regulatory body should follow a consistent procedure for establishing, revising and revoking regulations and guides....The procedure followed by the regulatory body for establishing regulations should include the following steps....."
- S22 <u>Suggestion</u>: A federal strategy should be adopted in consultation with all Länder hosting nuclear power plants for the production and the revision of regulations and guides, including all BMU and RSK documents. This strategy should include the following elements:
 - determination of the need for the new regulations or the revision of the existing documents, including all relevant information (IAEA, generic safety issues, operating experience, etc...);
 - setting the priority for development of the regulations;
 - determination of the scope of the proposed regulations or revisions; and
 - determination of the resources to be employed, depending on the resources available and on the time-scale for the preparation and establishment of regulations and guides

As a part of the strategy, the steering role of BMU should be strengthened. Furthermore, a formal document review process should be developed and implemented to assure that the documents remain consistent with the current national and international practice.

In developing the strategy, several essential elements of a regulatory framework should systematically be taken into account, in order to establish and maintain a modern and comprehensive set of regulatory requirements and guides. These elements, among others, should include considerations for:

- a nuclear safety Ordinance;
- supporting safety limits and criteria;
- consideration of risk insights to complement deterministic criteria;
- a process for reviewing and updating regulatory documents.

7.4.1. Nuclear safety Ordinance

In 2006, preparatory work was initiated to issue an Ordinance for nuclear safety that would include fundamental safety objectives and requirements in a manner consistent with the current state of the art in science and technology. The Ordinance should possibly describe the qualitative and quantitative safety goals and requirements to define the adequate, legally-enforceable level of safety for the existing nuclear power plants.

- (1) **BASIS**: GS-R-1 § 5.26 states that "The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations."
- (2) **BASIS:** GSG 1.4, §3.13. states that "The principal purpose in establishing a system of regulations is to codify safety requirements of general applicability. The development of any particular regulation will involve a balance between the need for flexibility (to permit easy adaptation of the regulation to developing circumstances

and technology) and the need to include detailed requirements (to facilitate determination of whether the requirements have been met)."

R8 **Recommendation:** An ordinance on nuclear safety should be adopted as soon as possible to provide a legally binding basis for the fundamental safety objectives and basic requirements corresponding to these objectives.

7.4.2. Safety limits and criteria

In 2003, BMU initiated a project to modernize the regulatory framework by revising the existing safety criteria and guidelines and by developing new requirements to ensure compliance with the state of the art in science and technology, as reflected by national and international practice and experience ("Sicherheitsanforderungen für KKW"). In particular, in the process of deriving the new requirements a comprehensive comparison was made against the current IAEA safety fundamentals, requirements and guidance documents such as NS-R-1, NS-R-2, NS-R-3 and GS-R-3. Also, the reference levels of WENRA were considered and to a large extent adopted. As a result, this document forms a comprehensive set of safety reference levels and criteria, reflecting the current state of the art in science and technology² which should be used to establish acceptable regulatory targets in a form of criteria, characteristics and practices that BMU could recommend on a case-by-case basis for meeting regulatory goals and requirements in the nuclear safety Ordinance (i.e., acceptable means of meeting regulations).

The approach used to develop the basis for these safety reference levels and criteria was very systematic and comprehensive (the mission makes no comments on the content of the document). The consultation process to invite comments from all interested parties was very transparent and far reaching.

A position paper was issued by BMU that outlines a three-step implementation plan to advise the Länder Regulators on the use of the proposed document in relation to a safety assessment of existing facilities. However, the approach does not appear to be detailed enough to provide sufficient guidance to the interested parties on implementation of the proposed safety reference levels and criteria, especially in relation to power plants of different ages.

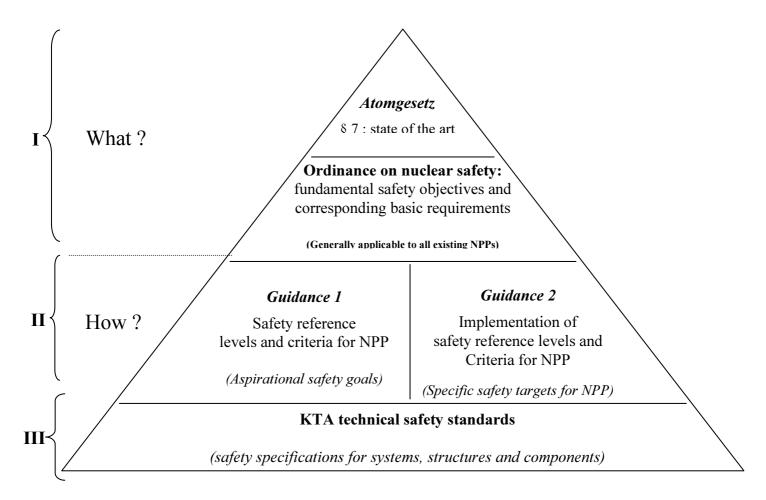
In a manner consistent with the hierarchy of regulations, the proposed document should have, for the time being, a status of a non-mandatory guidance instrument, providing a basis for inclusions of more detailed requirements and conditions for individual authorizations. Consequently, its title should be changed to, for example, "Guidance on Modern Safety Reference Levels and Criteria for NPPs". To assist with the interpretation and implementation of the proposed safety levels and criteria, it would be beneficial to prepare a more detailed process to further expand on the implementation plan. In particular, it should clearly be stated that for the existing facilities the proposed document defines aspirational safety goals, corresponding to the state of the art in science and technology, and not regulatory requirements to be used for the existing power plants. Furthermore, the implantation plan should provide a non-mandatory guidance on identification and disposition of any deviations, identified as a result of review of existing power plants against these aspirational safety goals, to establish regulatory targets which could legally be enforceable on a case by case basis. The plan should include a clear description of the process, including all factors that should be taken into consideration in the decision making, so that regulatory safety targets and any potential safety improvements to existing power plants could be identified in a consistent and

² It has to be noted that the IRRS Mission did not review the technical content of the proposed document and therefore is not in a position to comment on the adequacy of the proposed safety limits and criteria.

transparent manner.

- (1) **BASIS:** GSG 1.4, §3.13. states that "The principal purpose in establishing a system of regulations is to codify safety requirements of general applicability. The development of any particular regulation will involve a balance between the need for flexibility (to permit easy adaptation of the regulation to developing circumstances and technology) and the need to include detailed requirements (to facilitate determination of whether the requirements have been met)."
- S23 <u>Suggestion</u>: The proposed regulatory guide entitled "Sicherheitsanforderungen für KKW", outlining safety reference levels and criteria corresponding to the state of the art in science and technology should be used to define the fundamental safety objectives and basic requirements in the nuclear safety ordinance.
- S24 <u>Suggestion</u>: To assist with the interpretation and implementation of proposed safety reference levels and criteria to define regulatory safety targets and potential safety improvements to existing power plants, it should also be considered to issue a non-mandatory guide on identification and disposition of any deviations identified as a result of the safety review. Both documents should be issued and implemented in a timely manner.

The proposed structure for a revision of the legislative and regulatory framework for nuclear safety is illustrated below. The Ordinance defines safety objectives and goals for the existing facilities (i.e., what needs to be done?), the first guideline outlines safety limits and criteria which should be used to establish criteria, characteristics and practices for meeting regulatory goals and requirements (i.e. how it can be done in general?), the second guideline provides acceptable means on establishing case-specific safety targets in a form of criteria, characteristics and practices (i.e. how it can be done in specific cases?), and the KTA technical safety standards provide safety specifications for system, structures and components.



7.4.3 Risk-informed approach

The existing regulatory framework is largely based on deterministic consideration. The risk insights are not considered in the regulatory requirements and in the regulatory decision-making process to establish a proper balance between deterministic and performance setting safety objectives.

To assist with risk informing the existing regulatory framework, it is important to clarify the role of probabilistic safety assessment in the safety demonstration and decision making. The non-mandatory guide on the Periodic Safety Analysis (PSA) outlines the methodology which should be used, but there is little guidance on the use of the results. Some guidance, however, is provided in the proposed requirement document entitled "Sicherheitsanforderungen Fur KKW", which, to some extent, establish the role of PSA as a complementary tool to deterministic considerations. Specifically, the document states that, in addition to deterministic analysis, PSA shall be conducted to assess the safety impact of modifications proposed by an operator or new findings, if they are of safety relevance.

This proposed document will strengthen the role of PSA in the regulatory framework. It is therefore important to revise the PSA guideline accordingly. Nevertheless, further guidance should be provided on the use of risk insights in the regulatory decision making to achieve a proper balance between deterministic and performance based approaches. Also, a consideration should be given to the adoption of probabilistic safety goals, such as the Core Damage Frequency and the Large Released Frequency. Further discussion on this subject is provided in Section 5.2.

- (1) **BASIS:** GS-G1.4 §3.59 states that "As a complement to the deterministic approach, the regulatory body should require an evaluation of the risks arising from the facility."
- S25 <u>Suggestion</u>: A policy document should be developed on the use of risk insights in the regulatory framework and decision making to achieve a proper balance between deterministic and performance based approaches.
- (1) **BASIS:** GS-G-1.2 § 3.61 states that "...the insights 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 aspect should be given due consideration by a regulatory body reviewing a PSA."
- S26 <u>Suggestion</u>: The PSR and PSA guidelines should be reviewed and revised, as necessary, according to the policy document on the use of risk insights in the regulatory oversight, to clarify the role of PSA in the current regulatory framework.

7.4.4. Strategy for reviewing and updating regulatory documents

There is no supporting process in place for reviewing and updating the existing BMU regulatory documents or RSK recommendations. In consequence, the majority of the regulatory documents that have been issued since the 1970s is not up to date. Moreover, there is no process and supporting procedure in place to receive the feedback on the implementation of BMU regulatory documents. This feedback is essential for BMU to identify the necessary improvements on a regular basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.28 states that "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."
- (2) **BASIS:** GS-G-1.4 § 3.28 states that "The regulatory body should ensure that regulations and guides are kept up to date, and procedures should be established for their periodic review. Experience in implementing the regulations should be examined, and any problems or difficulties which may have arisen should be duly considered."
 - R9 **Recommendation:** The existing administrative process to issue and update BMU regulatory documents should be modified to include internal procedures to account for the feedback of experience from all interested parties, in relation to the use of regulatory documents.

Furthermore, it is suggested to perform an impact assessment of the proposed safety criteria and requirements on the existing regulatory framework. In particular, the documents that may require revision on the basis of the proposed requirements need to be clearly identified and an action plan developed for inclusion in the overall strategy for the development of regulatory documents, as described in Section 7.4 above. The priority for the revision of the documents should be set to ensure that bases for the safety assessment of existing facilities remain consistent and systematic. The high-priority

documents include, for example, the PSR and PSA guidelines, and RSK recommendations pertaining to ageing management.

- (1) **BASIS:** GS-G-1.4 § 3.2 states that "The establishment and periodic review of a system of regulations and guides tailored to the specific needs of a State entail a continuing effort.
- S27 <u>Suggestion</u>: It is suggested to perform an impact assessment of the proposed safety reference levels and criteria on the existing regulatory framework. In particular, the documents that may require revision on the basis of the proposed requirements need to be clearly identified and an action plan developed for inclusion in the overall strategy for the development of regulatory documents.

8. MANAGEMENT SYSTEM OF THE COMPONENT PARTS OF THE REGULATORY BODY

- This Chapter includes policy discussions on Knowledge Management
- This Chapter includes policy discussions on Regulatory Effectiveness

Management system requirements

The IAEA Safety Requirements publication GS-R-3, issued in 2006, defines the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements. This integration aims to ensure that safety is properly taken into account in all the activities of an organization in order to ensure the protection of people and the environment. The requirements are applicable on management systems for industrial nuclear facilities and activities as well as for regulation of such facilities and activities. GS-R-3 with its integrative approach, emphasis on safety culture promotion and strong focus on continuous improvement can be seen as an evolution of the earlier concept of quality management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-3 § 5.1 states that "The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved."
- R10 **Recommendation**: BMU DG RS and UM BW should incorporate the work identified in the suggestions and recommendations of all chapters of this report into their management systems.

BMU DG RS

Background

The management system description of the BMU DG RS is presented in common rules of procedures of the federal ministry (GO-BMU), description of the organization and its responsibilities, Quality Management (QM) manual of BMU DG RS and Emergency Preparedness handbook. The scope of the GO-BMU is the governmental functions such as law making, information of the Parliament and public as well as support functions such as the recruitment and the training of the personnel and documentation. The QM manual, which describes the regulatory activities of the BMU DG RS, first came into use in 2005. A process approach has been adopted in the development of this QM manual. The self assessment of the management system has been performed for the IAEA IRRS mission 2006/2007 by the senior management of BMU DG RS. The Federal Court of Audit (BRH) independently reviews the conduct of regulatory activities. The latest review was conducted in 2006/2007.

General requirements

As its part of a ministry the BMU DG RS has not seen any need to develop an integrated management system of its own covering all its activities. The GO-BMU procedures are binding to the BMU DG RS. However this does not prevent BMU DG RS from developing an integrated management system covering all functions important to the carrying out activities important to nuclear safety regulation. As an example, the human resource management and training procedures of the GO-BMU do not fulfil the requirements applied in the nuclear field. There are no instructions

to make project plans in spite of the fact that the major annual activities are carried out in the form of projects. There is no process in place for the management reviews.

Promotion and support of a strong safety culture

For a regulatory body it might be more appropriate to talk about a regulatory culture than a safety culture. How to apply the concept of safety culture on a regulatory body is elaborated to some extent in INSAG-4 and INSAG-15. Currently there is no mechanism in place at BMU DG RS to promote or assess the regulatory (safety) culture. A working climate survey was made in the Ministry of Environment in 2008. The results of this survey are not yet available. These surveys could be developed to assess the organizational culture of the BMU DG RS.

Grading the application of management system requirements

The graded approach of the management system requirements is reflected in the development of the QM manual especially devoted to regulatory activities.

Documents of the management system

The management system documents are in German. In the intranet there are: a policy statement, GO-BMU handbook, QM manual of BMU DG RS and the Emergency preparedness manual and the organization structure. The QM manual presents the processes of planning, quality management, international and national work reflecting the activities of a nuclear regulatory body. A table of regulatory activities described in the QM manual are presented in appendix zz. (picture from CNS report 2008 Figure 8 -6.

Management commitment

The management of the regulatory body is committed to development of the QM manual of BMU DG RS. The processes have been developed since the establishment of the system in 2005. However, with the present staffing levels and other work activities there have been difficulties to allocate resources to the quality discussions and the preparation of the procedures. Decision-making is described in the processes.

Satisfaction of the interested parties

BMU DG RS has a lot of interaction with the stakeholders in the nuclear field in Germany. In this interaction, BMU DG RS gains valuable information of the expectations of the stakeholders. However, systematic collection of the feedback could enable BMU DG RS to further enhance its processes and promote consensus building in the field of nuclear energy.

Organization policies

There is a statement presenting the strategic gaols of BMU DG RS and the principles to achieve quality are elaborated in the quality manual. However, the BMU DG RS would benefit from elaborating more on its nuclear safety and quality policies so that the expectations for the work performed are known and understood in a uniform way throughout the organization.

Planning

The cornerstone of the planning of the BMU DG RS is the list of strategic key objectives for the year. These objectives are a list of the most important tasks to be performed during the next year. There is no long term strategic plan. This is justified by the existence of the political steering of the ministry. However the enhancement of nuclear safety is a long term activity which should be carried out in a systematic manner. This is only possible by incorporating long term strategic planning and the related annual action plan. The only long term plan which has been made is the proposal for the recruitment of new personnel during the next 3 year.

A project plan is formed to accomplish each of the strategic key objectives. The annual planning does not include the standing duties of the BMU DG RS and the plan for the allocation of resources.

The progress of the projects is followed in management meetings, and the annual accomplishment of the projects is recorded.

Provision of resources

At the BMU DG RS a knowledge management system has been developed. However there has been no decision made on a general commissioning of this new system.

Human resources

Until now there has been no systematic approach in the BMU DG RS to the management of human resources and the competences needed by the organization. The training of the individuals is agreed in the annual discussions of the employees and manager. The training courses supplied by GRS are used. BMU DG RS is planning with GRS to develop a Training Academy. The competences needed for the accomplishment of the regulatory activities have not been described and evaluated. The management system does not have processes related to human resource management taking account of the practises in the nuclear field.

<u>Infrastructure</u> and the working environment

The assessment of the working conditions is part of the management work. In the Ministry of Environment a work climate questionnaire and survey was conducted in spring 2008. The results are not yet available. The record keeping system of the BMU is manual and common to the whole ministry. BMU DG RS sees that to change the system consensus would be needed in the ministry.

Development of processes

The QM manual presents the processes of planning, quality management, international and national work reflecting the activities of a nuclear regulatory body. There is no process in the management system to systematically assess the need for updating the regulations. The tools for the regulatory supervision of the Länder are based on event analysis and the review and assessment of selected license applications. Both instruments are applied on a case by case basis. The processes are based on independent analysis made by the BMU DG RS and its TSO.

The processes of the QM handbook are presented in the flowchart form, describing the interaction with involved parties as well as the inputs and outputs of the processes. There is no process in the management system for development and maintenance of the processes or describing the format and content requirements of the process descriptions.

Process management

An essential tool used to manage the processes in BMU DG RS is the annual discussions of the quality manager with the directorate heads. The results of the talks are summarized and the corrective actions decided at a management meeting. The procedures are approved by the director general.

All the described processes are under the control of BMU DG RS.

Control of the documents

The approval and the revision of QM procedures are described above. There is no support process in the QM handbook describing the development of the BMU DG RS processes.

Control of products

The process descriptions include the approvals needed at different levels of the organization. The verification of the work performed by authorized experts is in the responsibility of BfS.

Control of records

BMU has a manual system of controlling records which is fulfilling the federal requirements of record keeping. The system is supported by a database where identification data of the documents is

stored. Some simple searches can be made in the system by the record keepers. The current system can not provide the level of record management support needed to support the expert work of the BMU DG RS.

Purchasing

The purchasing of products is made according the procedures of BMU. The selection criteria are presented in the process.

Communication

Within BMU DG RS there are meetings of the management and delivery of the information inside the organization. BMU DG RS has a wide range of methods to inform the stakeholders and public. The participation in different types of co-operation is described in organization structure and the tasks. GO-BMU sets general requirements for internal communication. Public communication is included in the QM manual.

Managing organizational changes

Organizational changes must be justified although there is no formalized process to assess the effect of the change in safety. However, the effect of the change to the capability of BMU DG RS to perform its tasks is evaluated.

Measurement, assessment and improvement

The BMU DG RS measurement and improvement process relies heavily on the day to day management work and the quality discussions with the quality manager. There is no formal self assessment or auditing processes in place. The Federal Court of Audit (BRH) conducts regular independent audits. There is no system to collect non-conformances identified. The defined QM system of the regulatory processes is seen as a self-control system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-3 § 2.1 states that "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;
 - —Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."
 - (2) **BASIS:** GS-R-3 § 2.3 states that "The management system shall identify and integrate with the

requirements contained within this publication:

- —The statutory and regulatory requirements of the Member State;
- —Any requirements formally agreed with interested parties (also known as 'stakeholders' 7);
- —All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [8] and safety assessment [9];
- —Requirements from other relevant codes and standards adopted for use by the organization.

- (3) **BASIS:** GS-R-3 § 2.4 states that "The organization shall be able to demonstrate the effective fulfillment of its management system requirements."
- R11 **Recommendation:** BMU DG RS should continue in developing the management system using the IAEA safety requirements GS-R-3 in respect to the following aspects:
 - an integrated management system covering policy statements, description of the organization and the processes for regulatory functions of the BMU DG RS as well the support functions important for the management to achieve the goals of BMU DG RS;
 - incorporate into the management system a process describing the development and maintenance of the management system;
 - incorporate into management system a document describing the format and content of the management system descriptions; and
 - implement a transparent, systematic way of assessing compliance and effectiveness of the management system and looking for possibilities for improvements.
- (1) **BASIS:** GS-R-3 § 2.2 states that "Safety shall be paramount within the management system, overriding all other demands."
- (2) **BASIS:** GS-R-3 § 2.5 states that "The management system shall be used to promote and support a strong safety culture by:
 - —Ensuring a common understanding of the key aspects of safety culture within the organization;
 - —Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
 - —Reinforcing a learning and questioning attitude at all levels of the organization;
 - —Providing the means by which the organization continually seeks to develop and improve its safety culture.
- S28 <u>Suggestion</u>: BMU DG RS should consider on the basis of the good practice of international regulatory bodies and the experience of the UM BW to develop a method to assess its own safety culture.
- S29 <u>Suggestion</u>: BMU DG RS should review its safety goals and quality principles to take account of the recommendations of the IRRS review and then incorporate these, in the QM manual. The manual should include an explanation of how these goals and principles are expected to be implemented in the work and interaction of BMU DG RS with stakeholders.
 - (1) **BASIS:** GS-R-3 § 3.6 states that "The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."
- S30 <u>Suggestion</u>: BMU DG RS should collect, in a systematic manner, the expectation of its stakeholders, including Länder regulatory bodies, to improve its regulatory processes.

- (1) **BASIS:** GS-R-3 § 3.8 states that "Senior management shall establish goals, strategies, plans and objectives that are consistent with the policies of the organization."
- (2) **BASIS:** GS-R-3 § 3.9 states that "Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed."
- (3) **BASIS:** GS-R-3 § 3.10 states that "Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization."
- (4) **BASIS:** GS-R-3 § 3.11 states that "Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary."
- (5) **BASIS:** GS-R-3 § 4.1 states that "Senior management shall determine the amount of resources necessary and shall provide the resources9 to carry out the activities of the organization"
- R12 **Recommendation**: BMU DG RS should develop its long and short term planning processes so that:
 - a strategy plan is developed covering several years ahead along with the related programme of tasks to implement this plan; and
 - all the activities of the BMU DG RS, with the needed resources, are included in the annual plan.
- (1) **BASIS:** GS-R-3 § 4.2 states that "The information and knowledge of the organization shall be managed as a resource."
- S31 <u>Suggestion</u>: BMU DG RS should consider the commissioning of the appropriate knowledge management system and incorporate it into the QM handbook.
- (1) **BASIS:** GS-R-3 § 5.21 states that "Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable."
- S32 <u>Suggestion</u>: BMU DG RS should develop a records management system which supports their experts work.

UM BW

Background

UM BW started the development of the management system in 1997. The management system consists of a mission statement, oversight manual, organization manual and emergency preparedness manual. The oversight manual presents all the activities related to the regulatory activities of nuclear facilities. The contracting of the TSO and the activities of UM BW related to LAA and RSK are also presented in the manual. The oversight manual contains the description of the Oversight Concept. The manuals are available in the intranet. Some support activities such as record keeping and public communication are centralized in UM but the nuclear safety aspects are addressed in the organization manual.

The management system has been reviewed by external organizations in 2002 and 2006. The self assessment of the management system has been performed for the IAEA IRRS mission 2006/2007.

The Federal Court of Audit (BRH) reviews independently the conduct of regulatory activities. The latest review has been made in 1999/2000.

General requirements

The oversight manual presents instructions for authorizations, different type of reviews and assessments, and inspections and enforcement. In the organization manual the organization and the allocation of the tasks are presented. It includes a wide spectrum of topics related to regulatory activities, training, public communication and record keeping. The responsibility of planning and management as well as the development and maintenance of the management system has been allocated to individuals. However there are no processes describing the activities of the management.

Promotion and support of a strong safety culture

For a regulatory body it might be more appropriate to talk about a regulatory culture than a safety culture. How to apply the concept of safety culture on a regulatory body is elaborated to some extent in INSAG-4 and INSAG-15. UM BW conducted an internal workshop on safety culture/oversight culture after the ILK review in 2006 of the UM BW oversight practices. UM BW is now looking for a systematic way to promote and assess the regulatory (safety) culture.

Grading the application of management system requirements

The graded approach of the management system requirements is reflected. As an example the review and documentation and the use of TSO support is related to the safety significance of the issue.

Documents of the management system

The documentation of the management system is in German. In the intranet there are a policy statement, oversight manual, organization manual and the emergency preparedness manual and the organization structure. The content of the oversight manual is presented in *appendix zz*. (UM BW advance material AHB strucktogramme.ppt)

There is no uniform format in which the processes or procedures of the management system are presented. This is due to the system having been developed in a stepwise process.

Some of the processes or procedures are at a very general level and the role of different documents in the oversight manual is not obvious. As an example there is a legislative discussion of the evaluation of the application state of the standards. The responsibility of the evaluation is delegated to sections in coordination with the legal section. There is no description of systematic process of reviewing the changes in the regulations and guides and their implementation in the oversight. The overall documentation of the management system is innovative. However, this is made at the expense of a clear hierarchical structure of the management system.

Management commitment

The management of the UM BW has actively promoted the development of the management system and common understanding of the safety goals. The mission statement, vision and the safety goals have been develop with the organization.

Satisfaction of the interested parties

UM BW has a lot of interaction with the stakeholder of the nuclear field in Germany. In this interaction UM BW gains valuable information of the expectations of the stakeholders. However, systematic collection of the feedback could enable UM BW further enhances its processes and promotes the consensus building in the field of nuclear energy.

Organization policies

The organization policy of UM BW consists of the statement on compliance with the legislation, goal, requirements on quality, way of working, team working and relation to the TSOs, NPPs and the public. The policy statement has been developed in co-operation with the personnel of the UM BW.

Planning

There is no formal process of planning the activities presented in the management system. However in practice this process is in place. There is a strategic long term plan and annual plans. In the annual plan the standing and specific tasks of the year are presented. This plan also includes the allocation of the resources for the tasks.

Provision of resources

The activities of each section in UM BW are allocated to the staff members. The planning practice of UM BW also includes the allocation of the tasks to personnel. The competences needs are listed in the organization manual.

Human resources

The competences needed by UM BW are described in the organization manual. However, there is no systematic mapping of the competences in the organization. This should be included into the human resource processes of the management system.

Infrastructure and the working environment

The assessment of working conditions is part of the management work. This could be complemented with a work climate questionnaire. The IT support for the oversight activities is discussed below.

Development of processes

The activities in the oversight manual are presented in a flowchart form describing the interaction with involved parties as well as the inputs and outputs of the processes. There are plans to bring the organization manual into the same format as the oversight manual. The format and content of the process and procedure descriptions in the management system varies.

Process management

The responsibility of the management system is allocated to an expert in the general section of the UM BW. The decision of the development or update of a process is made during management meetings. The updated draft is reviewed by the section heads and the final version is approved by the division head. This process is not described in the management system.

All the processes described are under the control of UM BW.

Control of the documents

The approval and the revision of management system procedures is described above. There is no support process describing the development of the UM BW processes.

Control of products

The decisions are reviewed by a relevant expert and approved by the section head or the division head. The results of the review are documented.

Control of records

UM BW has a manual system of controlling records related to correspondence with the utilities. This system is fulfilling the official requirements of record keeping. The management system is documented in an electronic form. UM BW Division 3 has made an effort to persuade the ministry to modernize the record keeping system with no success.

Inspection program inspections are stored in the AGAVE database in electronic form. Data on reviews and assessments are entered into the AGAVE database by the inspectors. The inspectors can use the database to follow up on regulatory issues. There are requirements to enter specific data into the database. Some of the follow up data is entered on a voluntary basis. The manual official archive system does not support the AGAVE database. In the strategic action plan of UM BW there is an activity to improve this electronic system with respect to search capability and coverage of the AGAVE database.

Purchasing

The purchasing of TSO support is described in the oversight manual. The selection criteria are presented as is the bidding process. Conditions are included in the contracts. Reference to QM procedures of the TSO may be included in the contract.

Communication

In the organization manual there are requirements related to communication. Among other things, the requirements include goals for internal meetings, informing the minister and public, management meetings with operator, etc.

Managing organizational changes

Organizational changes must be justified.

Measurement, assessment and improvement

The UM BW measurement and improvement process relies heavily on the day to day management work. There are no formal self-assessment or auditing processes in place. There have been several external audits made. The Federal Court of Audit (BRH) independently reviews the conduct of regulatory activities. UM BW has plans to develop a procedure for management reviews. There is no system to collect information on identified non-conformances.

- (1) **BASIS:** GS-R-3 2.1 states that "'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;
 - —Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."
- (2) **BASIS:** GS-R-3 2.3 states that "The management system shall identify and integrate with the requirements contained within this publication:
 - —The statutory and regulatory requirements of the Member State;
 - —Any requirements formally agreed with interested parties (also known as 'stakeholders' 7);
 - —All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [8] and safety assessment [9];
 - —Requirements from other relevant codes and standards adopted for use by the organization."

- (3) **BASIS:** GS-R-3 2.4 states that "'The organization shall be able to demonstrate the effective fulfillment of its management system requirements."
- (4) **BASIS:** GS-R-3 2.10 states that "'The documentation of the management system shall reflect:
 - —The characteristics of the organization and its activities;
 - —The complexities of processes and their interactions."
- R13 **Recommendation:** UM BW should continue the development of its management system using the IAEA safety requirements document GS-R-3 in the following respect:
 - include the processes needed to manage the organization into the management system;
 - include the processes for the development and maintenance of the management system;
 - describe its strategic and annual planning process in the management system;
 - develop a standard format and content of the management system descriptions;
 - implement a transparent, systematic way of assessing compliance and effectiveness of the management system and looking for possibilities for improvements; and
 - develop a process for reviewing in regular basis the changes in the regulations and guides as well as implementing into the oversight.
 - (1) **BASIS:** GS-R-3 § 3.6 states that "The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."
- S33 <u>Suggestion</u>: UM BW should consider collecting in a systematic manner the expectation of its stakeholders, including the federal regulatory body, to improve its regulatory processes.
- (1) **BASIS:** GS-R-3 5.21 states that "Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable."
- Suggestion: UM BW should investigate in the AGAVE enhancement process possibilities to improve the interface with the official record keeping so that inspectors need to spend as little as possible time feeding record keeping data and that the requirements to the licensee can be easily followed.



APPENDIX I – LIST OF PARTICIPANTS

	INTERNATIONAL EXPERTS:			
1.	Mike WEIGHTMAN	Nuclear Safety Directorate Health and Safety Executive (HSE)	Mike.weightman@hse.gsi.gov.uk	
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APPENDIX II – MISSION PROGRAMME

	BONN, Sunday, 7 th September 2008		
→13:00	Arrival of the Reviewers at the MARITIM Hotel in Bonn	Reviewers	
13:50	Liaison Officers collect the Reviewers at the MARITIM	Reviewers	
14:00 - 18:00	Opening Team Meeting	IRRS Team, LOs	
	BONN, Monday, 8 th September 2008		
09:00 - 12:30	Entrance Meeting	Reviewers, LOs, CPs, W. Renneberg, O. Grözinger, GRS, BfS,	
13:30 - 18:00	Presentations of all modules	TÜV,	
18:15 - 19:00	•	IRRS Team, LOs	
	BONN, Tuesday, 9 th September 2008		
09:00 - 10:00	Plenary Meeting	IRRS Team, LOs	
10:00 - 12:30	Introduction and discussion of Regulatory Policy Issues	IRRS Team, LOs, CPs, W. Renneberg, O. Grözinger	
13:30 - 17:00	Interviews with CP's in 6 Groups (Group 3: starting on Wednesday,	10 th)	
	Group 1: Modules I and II	Reviewers, BMU: Schneider, Fischer, UM BW: Winter	
	Group 2: Modules III and VIII	Reviewers, BMU: Niehaus, Vorwerk, UM BW: Glöckle	
	Group 3: Module VII	Reviewers, BMU: Wassilew, UM BW: Wiesner	
	Group 4: Module IV	Reviewers, BMU: Ludwig, UM BW: Scheitler	
	Group 5: Module V	Reviewers, BMU: Engelhardt, UM BW: Korr	
	Group 6: Module VI	Reviewers, BMU: Sperling, UM BW: Wildermann	
14:30 - 17:00	GRS-Interview (with selected reviewers)	Reviewers, Los, GRS: Hahn, Liemersdorf, Teschendorff, Erven	
17:00 - 18:45	Daily Team Meeting	IRRS Team, LOs	
19:00	Transfer Group B and CPs (Module IV, V and VI) to Siegburg	Reviewers Group B, LO UM BW, BMU: Ludwig, Engelhardt, Sperling, UM BW: Scheitler, Korr, Wildermann	
20:11	ICE to Stuttgart		
22:09	Arrival Stuttgart		
	BONN, Wednesday, 10 th September 2008		

09:00 - 12:30	Group 1: Modules I and II (cont'd)	Reviewers, BMU: Schneider, Fischer, UM BW: Winter
	Group 2: Modules III and VIII (cont'd)	Reviewers, BMU: Niehaus, Vorwerk, UM BW: Glöckle
	Group 3: Module VII	Reviewers, BMU: Wassilew, UM BW: Wiesner
13:30 - 17:00	Group 1: Modules I and II (cont'd)	Reviewers, BMU: Schneider, Fischer UM BW: Winter
	Group 2: Modules III and VIII (cont'd)	Reviewers, BMU: Niehaus, Vorwerk, UM BW: Glöckle
	Group 3: Module VII (cont'd)	Reviewers, BMU: Wassilew, UM BW: Wiesner
18:30	Daily Team Meeting (Phone Conference with Stuttgart)	IRRS Team, LO BMU
	STUTTGART, Wednesday, 10 th September 20	008
09:00 - 09:30	Welcome and logistical aspects (rooms, equipment)	LO UM BW, Rauscher, Reviewers, BMU: Ludwig, Sperling, Engelhardt, UMBW: Scheitler, Korr, Wildermann
09:40 - 10.00	TSOs in BW	Scheitler, Reviewers, BMU: Ludwig, Sperling, Engelhardt, UMBW: Korr, Wildermann
10:00 - 12:30	Group 4: Module IV (cont'd)	Reviewers, BMU: Ludwig, UM BW: Scheitler
	Group 5: Module V (cont'd)	Reviewers, BMU: Engelhardt, UM BW: Korr
	Group 6: Module VI (cont'd)	Reviewers, BMU: Sperling, UM BW: Wildermann
	TÜV-Interview (with selected reviewers)	Reviewers, LO, Seibold, Brandes, Krüger
13:30 - 17:00	Group 4: Module IV (cont'd)	Reviewers, BMU: Ludwig, UM BW: Scheitler
	Group 5: Module V (cont'd)	Reviewers, BMU: Engelhardt, UM BW: Korr
	Group 6: Module VI (cont'd)	Reviewers, BMU: Sperling, UM BW: Wildermann

18:30	Daily Team Meeting (Phone Conference with Bonn)	IRRS Team, LO UM BW
	BONN, Thursday, 11th September 2008	
09:00 - 12:30	Group 1: Modules I and II (cont'd)	Reviewers, BMU: Schneider, Fischer UM BW: Winter
	Group 2: Modules III and VIII (cont'd)	Reviewers, BMU: Niehaus, Vorwerk, UM BW: Glöckle
	Group 3: Module VII	Reviewers, BMU: Wassilew, UM BW: Wiesner
13:30 - 17:00	Group 1: Modules I and II (cont'd)	Reviewers, BMU: Schneider, Fischer, UM BW: Winter
	Group 2: Modules III and VIII (cont'd)	Reviewers, BMU: Niehaus, Vorwerk, UM BW: Glöckle
	Group 3: Module VII (cont'd)	Reviewers, BMU: Wassilew, UM BW: Wiesner
17:00 - 18:45	Daily Team Meeting (Phone Conference with Stuttgart)	IRRS Team, LO BMU
	Transfer TL, TC, Addison and AL RS to Airport CGN → Be	erlin
19:00	Transfer Group A to Siegburg,	Review Group A, LO BMU, CPs UM BW
20:11	ICE to Stuttgart	
22:09	Arrival Stuttgart	
	STUTTGART, Thursday, 11th September 2	008
09:00 - 12:30	Group 4: Module IV (cont'd)	Reviewers, BMU: Ludwig, UM BW: Scheitler
	Group 5: Module V (cont'd)	Reviewers, BMU: Engelhardt, UM BW: Korr
	Group 6: Module VI (cont'd)	Reviewers, BMU: Sperling, UM BW: Wildermann
13:30 - 17:00	Group 4: Module IV (cont'd)	Reviewers, BMU: Ludwig, UM BW: Scheitler
	Group 5: Module V (cont'd)	Reviewers, BMU: Engelhardt, UM BW: Korr
	Group 6: Module VI (cont'd)	Reviewers, BMU: Sperling, UM BW: Wildermann
17:00 - 18:45	Daily Team Meeting (Phone Conference with Bonn)	IRRS Team, LO UM BW
	BERLIN, Friday, 12 th September 2008	

08:15 - 09:45	Discussion with Minister Gabriel	M. Weightman, G. Caruso, P. Addison, W. Renneberg und BM Gabriel
13:00	Arrival Airport Stuttgart	M. Weightman, G. Caruso, P. Addison
	STUTTGART, Friday, 12 th September 2008 - Neckarwesth	eim
08:00	Transfer to GKN	
09:00 - 12:30 and 13:30 - 14:45	Inspection GKN (conduct of a routine inspection: control room, containment, opening and final discussion with plant director)	Reviewers, CPs for Module VI, LOs
14:45 - 15:45	Transfer to Stuttgart	IRRS Team, LOs
	STUTTGART, Friday, 12th September 2008 - UMBW	
10:30 - 12:30	Reviewers who are not attending GKN-visit have the possibility to conduct further interviews with the CPs on request	IRRS Team
13:30 - 17:00	Reviewers who are not attending GKN-visit have the possibility to conduct further interviews with the CPs on request	IRRS Team
16:00 - 17:30	Discussion with UM BW Ministerin Gönner	M. Weightman, G. Caruso, P. Addison, O. Grözinger, T. Gönner
	STUTTGART, Saturday, 13 th September 2008	
09:00 - 12:30	Team Meeting	IRRS Team, LOs
13:30 - 17:00	Drafting Report	IRRS Team, LOs
	STUTTGART, Sunday, 14 th September 2008	
09:00 - 12:30	Team Meeting (cont'd) and Drafting Report (cont'd.)	IRRS Team, LOs
	STUTTGART, Monday, 15 th September 2008	
09:30 - 12:30	Regulatory Policy Issues (clarification of open issues, results, conclusions, notes of the reviewers)	Reviewers, LOs, W. Renneberg, O. Grözinger, CPs
09:30 - 12:30 13:30 - 17:00		W. Renneberg,
	conclusions, notes of the reviewers)	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg,
13:30 - 17:00	conclusions, notes of the reviewers) Final Discussions with CPs	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg, O. Grözinger, CPs TL, DTL, TC, LOs, GKN
13:30 - 17:00 14:00 - 16:00	conclusions, notes of the reviewers) Final Discussions with CPs Interview GKN-Management	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg, O. Grözinger, CPs TL, DTL, TC, LOs, GKN representatives
13:30 - 17:00 14:00 - 16:00	Conclusions, notes of the reviewers) Final Discussions with CPs Interview GKN-Management Daily Team Meeting	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg, O. Grözinger, CPs TL, DTL, TC, LOs, GKN representatives
13:30 - 17:00 14:00 - 16:00 19:00 - 23:00	conclusions, notes of the reviewers) Final Discussions with CPs Interview GKN-Management Daily Team Meeting STUTTGART, Tuesday, 16 th September 2008	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg, O. Grözinger, CPs TL, DTL, TC, LOs, GKN representatives Reviewers, LOs
13:30 - 17:00 14:00 - 16:00 19:00 - 23:00 09:00 - 12:30	Conclusions, notes of the reviewers) Final Discussions with CPs Interview GKN-Management Daily Team Meeting STUTTGART, Tuesday, 16 th September 2008 Drafting Report (cont'd)	W. Renneberg, O. Grözinger, CPs Reviewers, LOs, W. Renneberg, O. Grözinger, CPs TL, DTL, TC, LOs, GKN representatives Reviewers, LOs Reviewers, LOs

09:00 - 12:30	Finalization of the Report/ Highlight for Exit Meeting Preparation	Review Team
	CP-Review of Draft Report	CPs
13:30 - 18:00	Plenary Session	Reviewers, LOs, W. Renneberg, O. Grözinger, CPs
18:00 - 19:00	Preparation for the Exit Meeting	TL, DTL, TC, DTC, Addison
	Preparation of Press Release	LOs, PR Staff
	STUTTGART, Thursday, 18 th Septemb	oer 2008
09:00 - 12:30	Preparation for the Exit Meeting	TL, DTL, TC, DTC, Addison
13:15 - 14:15	Videoconference with London (NDF)	M. Weightman
14:15 - 17:30	Exit Meeting: Presentation of Report to BMU and UM BW (Hotel Le Meridien)	Reviewers, LOs, W. Renneberg, O. Grözinger, CPs, IAEA: P. Jamet, A. van Dongen
17:45	Transfer to Airport Stuttgart latest check-in: 18:35 to Berlin	TL. DTL, TC, P. Addison, P. Jamet, A. van Dongen, W. Renneberg, O. Grözinger, U. Winter
	BERLIN, Friday, 19 th September 2	008
08:00	Transfer to the press centre	TL, DTL, TC, P. Addison, P. Jamet, A. van Dongen, W. Renneberg, O. Grözinger, U. Winter
09:30	Press-Conference	BM Gabriel, T. Gönner, M. Weightman, P. Jamet
	Departure	all

APPENDIX III - MODIFICATION CRITERIA

Category	Criteria
A	 Criteria Modifications which can lead to a substantial increase or reduction of the activity release determined for the specified normal operation; modifications which can lead to an increase or a substantial reduction of the radiation exposure of the environment in case of accidents which the design of the plant is based on; modifications which lead to an increase of the so far licensed activity inventory of the plant; modifications which lead to an increase or substantial reduction of the maximum permitted thermal rate of the reactor; modifications concerning the design (basic design features) of the plant; substantial modifications in respect of the design concept of the plant and its operation in terms of malicious acts, disruptive actions by third parties, damages and operator errors; use of nuclear fuel exceeding the previous scope of the licence;
	 use of other radioactive materials exceeding the previous scope of the licence; structural measures subject to authorization according to the building regulations of the Land Baden-Württemberg which also concern safety-relevant installations or affect plant security.
В	 Modifications concerning the function or design features of installations or measures which are important in terms of nuclear safety or security; modifications which, when implemented or included in the plant operation, can impact the function or design features of installations or measures which are relevant in terms of nuclear safety or security; modifications of provisions laid down in the safety specifications which are relevant in terms of nuclear safety or security (e.g. design principles, design values and preset critical values) or in similar operating regulations relevant in terms of nuclear safety or security as far as these modifications are not of editorial character;
	• measures which are not subject to authorizations pursuant to the building regulations of the Land Baden-Württemberg and which also affect installations relevant in terms of nuclear safety or security. The measures concern for example modifications and additions related to structural and fire protection matters, or modifications of the emergency escape routes.
С	 Minor modifications in terms of plant safety, in particular the replacement or substitution of safety-relevant devices with equal or similar (slightly different) and at least equivalent devices as far as they are qualified according to the appropriate specifications and other safety-relevant operating rules; modifications of and additions to those documents of the safety documentation which do not belong to the safety specifications as far as the consultation of authorized experts is required according to the respective regulations.
D	• if none ob the criteria for categories A to C are applicable

APPENDIX IV – MISSION COUNTERPARTS

item	Subject Area	IRRS Experts	BMU	UM BW
I	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	Mr. WeightmanMr. AddisonMr. Park	Mr. SchneiderMr. Fischer	Mr. Winter
II	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	Mr. WeightmanMr. AddisonMr. Park	Mr. SchneiderMr. Fischer	Mr. Winter
Ш	ORGANIZATION OF THE REGULATORY BODY	Mr. JansenMs. L. Jaervinen	Mr. NiehausMr. Vorwerk	Mr. Glöckle
IV	AUTHORIZATION	Mr. Flury	Mr. Ludwig	Mr. Scheitler
V	REVIEW AND ASSESSMENT	Mr. SvabMs. Abe	Ms. Engelhardt	Mr. Korr
VI	INSPECTION AND ENFORCEMENT	Mr. McCreeMs. Mellado	Mr. Sperling	Mr. Wildermann
VII	REGULATIONS AND GUIDES	Mr. RzentkowskiMr. Kueny	Ms. Wassilew	Mr. Wiesner
VIII	MANAGEMENT SYSTEM FOR REGULATORY BODY	Mr. JansenMr. L. Jaervinen	Mr. NiehausMr. Vorwerk	Mr. Glöckle

APPENDIX V – RECOMMENDATIONS/SUGGESTIONS/GOOD PRACTICES FROM THE IRRS MISSION

 Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	R1	Recommendation: The German Government should make arrangements to establish adequate resources at a federal level in the future to ensure that it can discharge its determined and agreed roles and responsibilities for nuclear safety, in addition to those assigned by law.
		This Recommendation should be read in conjunction with recommendations and suggestions regarding the need to determine roles and responsibilities in Chapter 3.
AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R2	Recommendation: BMU DG-RS should develop its Federal Supervision Manual as it has proposed. The Supervision Manual should include arrangements for cooperation and interaction with the Länder in order to develop consensual processes (whether required by the law or voluntary) to continuously improve nuclear safety.
	S1	Suggestion: DG-RS and UM BW should ensure that their commitments to develop and share participation in international activities are included in their respective organization management manuals.
ORGANIZATION OF THE REGULATORY BODY	S2	Suggestion: UM BW division 3 should

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		introduce a near-term recruitment and staffing plan, as well as a long-term succession planning strategy. UM BW should develop a competence matrix to support the plan and strategy. These plans and strategies should be periodically reviewed and used to develop the training program. The process should be incorporated in the management system.
	G1	Good Practice: UM BW allows its regulatory body a 10% increase of staff in order to recruit new technical people in anticipation of retirement.
	S3	Suggestion: BMU and UM BW should execute their plans to acquire additional staff to supplement the current staff, thereby enabling management's flexibility to support advanced training, develop regulatory infrastructure, and benchmark best practices of other regulatory bodies.
	S4	Suggestion: BMU and UM BW should consider introducing means to adapt to market conditions to ensure that the required level of staffing is achieved and secured for the future.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	R3	Recommendation: BMU should introduce a near-term recruitment and staffing plan, as well as a long-term succession planning strategy. Both the plan and strategy should include a competence matrix based on the agreed roles and responsibilities. (as referenced in this and other chapters). These plans and strategies should be periodically reviewed, used to develop the training programme, and the process should be incorporated in the management system.
	S5	Suggestion: BMU should evaluate the assignments of tasks of the regulatory body at the federal level to further improve effectiveness and efficiency, and avoid unnecessary duplication.
	R4	Recommendation: In the interest of nuclear safety BMU DG RS and UM BW should cooperate in order to improve mutual trust by the development of an agreement at the LAA (possibly aided or led by a facilitator) to address all relevant topics, including:
		 clarification and understanding of the respective roles and responsibility of the BMU DG RS and the Länder, and the execution of these roles and responsibilities;

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		• identification of the means of communication between BMU DG RS and the Länder;
		 identification of the rules of the exchange of information regarding the supervision of nuclear safety. These rules should take regard of needs, in such a way that BMU DG RS has confidence in the data content and accuracy and it is able to: use the data without the need for further technical analysis; and assure itself that each Land is carrying out its regulatory responsibilities appropriately. Secondment of staff between BMU DG RS and the Länder to improve mutual understanding and experience. The establishment of a strategic nuclear safety research plan for the existing NPPs
AUTHORIZATION	S6	Suggestion: The UM BW should take into account probabilistic insights where
		appropriate, in addition to existing deterministic criteria, in decision-making on authorizations.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S7	Suggestion: For all categories of non-essential modifications, the UM BW should also include the bases and the rationale for the regulatory decisions in the documentation that is referenced in the authorization.
	S8	Suggestion: The UM BW should track all issues that require regulatory body action related to authorizations by using its instruments systematically. Also, for the lower level issues the use of an appropriate tracking tool should be mandatory and not be up to individual persons.
	R5	Recommendation: The BMU should initiate the development, in collaboration with the Länder regulators, of formal guidance to define how the operators categorize modifications and apply for the authorization of modifications. This should include all the criteria and definitions that are necessary.
REVIEW AND ASSESSMENT	S9	Suggestion: BMU and UM BW should agree on the information to be shared before UM BW's formal examination of a PSR report is completed. The PSR, including PSA, should be shared more timely to all the relevant organizations so that they will have a common view on the "current" state of safety of the plants.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S10	Suggestion: BMU DG-RS and UM BW should cooperate in progressing an agreement by the LAA of a process to ensure that the information required by BMU to fulfil its function regarding OEF, such as IRS and WL (Information Notice), is provided in a suitable format and content by each Land. The objective of this agreement should be to give DG-RS confidence in the data accuracy and to enable it to contribute more input and strengthen the OEF process within Germany. The agreement should include a mechanism to enable communications between DG-RS and each Land (including their respective advisory bodies) to clarify the details of the events.
	G2	Good Practice: The UM BW has implemented regulatory control of NPPs' human resources to ensure adequate staffing for safety at all times.
	S11	Suggestion: BMU should complete its action plan to develop the guide for ageing management.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S12	Suggestion: UM BW should develop an approach to the inspection and assessment process that facilitates a more systematic and consistent method to assess operator performance. In considering such an approach, due regard should be given to the benefits of using state of the art evaluative tools, including probabilistic safety assessment (PSA), to plan inspections, determine the safety significance of inspection findings, assess the significance of operational events and plant conditions.
INSPECTION AND ENFORCEMENT	G3	Good Practice: The approach for the systematic assessment and oversight of organizational and human factors (KOMFORT system) represents an innovative, structured and useful means of incorporating safety culture insights into the regulator's annual assessment process.
	R6	Recommendation: UM BW should review and enhance the enforcement system to ensure that deviations from, or violations of, requirements are documented in writing to the operator.
	S13	Suggestion: UM BW should review and expand the scope of the inspection programme, as appropriate, to assure that all areas of regulatory responsibility are covered.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S14	Suggestion: UM BW should develop more detailed procedures for inspection activities to enhance the consistency of inspections. Such detailed procedures would be particularly helpful in the context of a future work force that includes staff with less experience than the current staff.
	S15	Suggestion: UM BW should enhance the content of inspection reports to include reference to the applicable regulatory requirements associated with inspection findings.
	S16	Suggestion: UM BW should enhance the annual assessment process used to evaluate plant performance and define the inspection program for the upcoming year, such that it more clearly and systematically incorporates relevant performance information available to the regulator (e.g., the annual operator reports on the Safety Management System Performance, the KOMFORT system data, the results of inspections and enforcement, as well as performance indicators). Particular attention should be given to the schedule and activities for obtaining all relevant information to enable an integrated assessment.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S17	Suggestion: UM BW should review its performance indicators to confirm that the (72) safety indicators and the (8) safety culture indicators provide relevant and meaningful insights. The regulator should inspect the inputs used for the operators' performance indicators to verify their accuracy. The merits of a more frequent (e.g., quarterly) review and trending of the safety performance indicators should be considered to enable a more timely response to a declining trend in operator performance. In addition, UM BW should consider the merits of bench-marking the use of safety culture attributes of other regulatory bodies to optimize its approach to assessing safety culture.
	S18	Suggestion: UM BW should develop a procedure, that include criteria, for reactive inspections
	S19	Suggestion: UM BW should plan and schedule inspections outside the normal working hours (i.e., nights and weekends), and increase the number of such inspections.
	S20	Suggestion: The BMU and UM BW should review the <i>enforcement tools available to assure</i> proportionality between enforcement actions and the safety significance of violations.
	S21	Suggestion: UM BW should develop administrative procedures and guidelines for

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		implementation of the enforcement process. UM BW inspectors and staff should be trained on the use and application of these documents.
DEVELOPMENT OF REGULATIONS AND GUIDES	R7	Recommendation: The existing administrative process to issue BMU regulatory documents should be reviewed and modified in order to ensure that regulations can be issued and implemented in a timely manner.
	G4	Good Practice: The process for developing KTA technical standards is very comprehensive and systematic. It covers a broad range of technical issues, taking into consideration state of the art in science and technology. The consultation process allows for consideration of comments from all interested parties. The documents are reviewed and, if necessary, revised every 5 years.

 Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S22	 Suggestion: A federal strategy should be adopted in consultation with all Länder hosting nuclear power plants for the production and the revision of regulations and guides, including all BMU and RSK documents. This strategy should include the following elements: determination of the need for the new regulations or the revision of the existing documents, including all relevant information (IAEA, generic safety issues, operating experience, etc); setting the priority for development of the regulations; determination of the scope of the proposed regulations or revisions; and determination of the resources to be employed, depending on the resources available and on the time-scale for the preparation and establishment of regulations and guides As a part of the strategy, the steering role of BMU should be strengthened. Furthermore, a formal document review process should be developed and implemented to assure that the documents remain consistent with the current national and international practice.
	R8	Recommendation: An ordinance on nuclear safety should be adopted as soon as possible to

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		provide a legally binding basis for the fundamental safety objectives and basic requirements corresponding to these objectives.
	S23	<u>Suggestion</u> : The proposed regulatory guide entitled "Sicherheitsanforderungen für KKW", outlining safety reference levels and criteria corresponding to the state of the art in science and technology should be used to define the fundamental safety objectives and basic requirements in the nuclear safety ordinance.
	S24	Suggestion: To assist with the interpretation and implementation of proposed safety reference levels and criteria to define regulatory safety targets and potential safety improvements to existing power plants, it should also be considered to issue a non-mandatory guide on identification and disposition of any deviations identified as a result of the safety review. Both documents should be issued and implemented in a timely manner.
	S25	Suggestion: A policy document should be developed on the use of risk insights in the regulatory framework and decision making to achieve a proper balance between deterministic and performance based approaches.

 Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S26	Suggestion: The PSR and PSA guidelines should be reviewed and revised, as necessary, according to the policy document on the use of risk insights in the regulatory oversight, to clarify the role of PSA in the current regulatory framework.
	R9	Recommendation: The existing administrative process to issue and update BMU regulatory documents should be modified to include internal procedures to account for the feedback of experience from all interested parties, in relation to the use of regulatory documents.
	S27	Suggestion: It is suggested to perform an impact assessment of the proposed safety reference levels and criteria on the existing regulatory framework. In particular, the documents that may require revision on the basis of the proposed requirements need to be clearly identified and an action plan developed for inclusion in the overall strategy for the development of regulatory documents.
MANAGEMENT SYSTEM OF THE COMPONENT PARTS OF THE REGULATORY BODY	R10	Recommendation: BMU DG RS and UM BW should incorporate the work identified in the suggestions and recommendations of all chapters of this report into their management systems.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	R11	Recommendation: BMU DG RS should continue in developing the management system using the IAEA safety requirements GS-R-3 in respect to the following aspects:
		an integrated management system covering policy statements, description of the organization and the processes for regulatory functions of the BMU DG RS as well the support functions important for the management to achieve the goals of BMU DG RS;
		• incorporate into the management system a process describing the development and maintenance of the management system;.
		 incorporate into management system a document describing the format and content of the management system descriptions; and
		implement a transparent, systematic way of assessing compliance and effectiveness of the management system and looking for possibilities for improvements.

 Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S28	Suggestion: BMU DG RS should consider on the basis of the good practice of international regulatory bodies and the experience of the UM BW to develop a method to assess its own safety culture.
	S29	Suggestion: BMU DG RS should review its safety goals and quality principles to take account of the recommendations of the IRRS review and then incorporate these, in the QM manual. The manual should include an explanation of how these goals and principles are expected to be implemented in the work and interaction of BMU DG RS with stakeholders.
	S30	<u>Suggestion</u> : BMU DG RS should collect, in a systematic manner, the expectation of its stakeholders, including Länder regulatory bodies, to improve its regulatory processes.
	R12	Recommendation: BMU DG RS should develop its long and short term planning processes so that: • a strategy plan is developed covering several years ahead along with the related programme of tasks to implement this plan; and • all the activities of the BMU DG RS, with the needed resources, are included in the annual plan.

 Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	S31	Suggestion: BMU DG RS should consider the commissioning of the appropriate knowledge management system and incorporate it into the QM handbook.
	S32	Suggestion: BMU DG RS should develop a records management system which supports their experts work.

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
	R13	Recommendation: UM BW should continue the development of its management system using the IAEA safety requirements document GS-R-3 in the following respect:
		 include the processes needed to manage the organization into the management system;
		• include the processes for the development and maintenance of the management system;
		 describe its strategic and annual planning process in the management system;
		 develop a standard format and content of the management system descriptions;
		implement a transparent, systematic way of assessing compliance and effectiveness of the management system and looking for possibilities for improvements; and
		 develop a process for reviewing in regular basis the changes in the regulations and guides as well as implementing into the oversight.
	S33	Suggestion: UM BW should consider collecting in a systematic manner the

Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		expectation of its stakeholders, including the federal regulatory body, to improve its regulatory processes.
	S34	Suggestion: UM BW should investigate in the AGAVE enhancement process possibilities to improve the interface with the official record keeping so that inspectors need to spend as little as possible time feeding record keeping data and that the requirements to the licensee can be easily followed.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY BMU

BASIC PRINCIPLES

→ applying to the activities of authorized experts working under commission to federal authorities responsible for overseeing implementation of the Atomic Energy Act with respect to nuclear power stations, research reactors and other reactors (principles for authorized experts commissioned by federal supervisory authorities for nuclear power stations)

BMU GLOBAL AIMS

- → RS I
- → RS II
- → RS III
- → International Co-operation
- → Public Awareness

BMU PRESS RELEASE:

→ 222/07 on Safety Management

BMU QM HANDBOOK:

- → Central Document
- → Process description "Federal supervision licensing procedures"
- → Work instructions Order for advising, issued to the RSK/SSK

FRAMEWORK AGREEMENT:

* between BMU and GRS

FRAMEWORK GUIDELINE

- → on the Preparation of Expert Opinions in Nuclear Administrative Procedures
- → GRS Annual Report
- *→* 2005/2006

INFORMATION NOTICE

- → Information Notice on notifiable events in nuclear power plants in the Federal Republic of Germany (WLN 2006/06) "Incorrectly installed anchors in the Biblis nuclear power plant, Unit A"
- → Information Notice on notifiable events in nuclear power plants in the Federal Republic of Germany (WLN 2006/06a) Supplement to Information Notice 2006/06 "Incorrectly installed anchors" in the Biblis nuclear power plant, Unit A (KWB-A)

RULES OF PROCEDURE of the BMU (GO-BMU),

- *→* Chapter 01 Introduction / Principles
- → Chapter 02 Organization / Personnel Requirements
- → Chapter 04 Internal cooperation within the Ministry / Business routine
- *→* Chapter 05 Correspondence / Records Management
- → Chapter 06 Information and publications / Dealings with bodies outside the BMU
- → Chapter 09 Cabinet and parliamentary matters / Legislative procedures
- → Chapter 10 Budget matters / Procurement
- → Chapter 12 Project Planning / Research

SAFETY REQUIREMENTS FOR NUCLEAR POWER PLANTS (DRAFT REVISION B):

→ Module 1: Fundamental Safety Requirements

- * Module 2: Requirements for the Design of the Reactor Core
- → Module 3: Events to be Considered in Pressurised and Boiling Water Reactors Core
- → Module 4: Requirements for the Design of the Reactor Coolant Pressure Boundary, the Pressure-Retaining Walls of the External Systems and the Twin-walled Containment System
- → Module 5/1: Requirements for Instrumentation and Control
- → Module 5/2: Requirements for Electrical Energy Supply, Accident Instrumentation
- → Module 6: Requirements for Safety Demonstrations and Documentation
- → Module 7: Requirements for Accident Management
- → Module 8: Requirements for Safety Management
- → Module 9: Requirements for Radiation Protection
- → Module 10: Requirements for the Design and Safe Operation of Plant Structures, Systems and Components
- → Module 11: Requirements for the Handling and Storage of the Fuel Elements

SELF-ASSESSMENT

- → MODULE I Legislative and Governmental Responsibilities
- → MODULE II Responsibilities and Functions of the Regulatory Body
- *→ MODULE III Organization of the Regulatory Body*
- → MODULE IV Authorization by the Regulatory Body
- **→** MODULE V Review and Assessment
- → MODULE VI Inspection and Enforcement
- → MODULE VII Development of Regulations and Guides
- → MODULE VIII Management System

OTHER DOCUMENTS

- → Joint Rules of Procedure of the Federal Ministries
- → List of Regulatory Research Issues of BMU
- → Principles Regarding the Awarding of Subcontracts by Authorized Experts
- → Promulgation of the Federal Chancellor's organizational directive of 27 October 1998
- → Report to the Ministry of Economics acc. to § 88 para 2 Federal Budget Code "Safety Research for Nuclear Facilities"
- → Strategic aims for 2008 of Directorate-General RS
- Supplement to the Information Notices (Weiterleitungsnachrichten) WL 14/92 and 14A/92 with regard to notifiable events in nuclear power plants abroad (WL 14B/92) "Clogging of sump suction strainers of the emergency core cooling systems due to inadvertent opening of a safety valve in the Barsebäck-2 nuclear power plant (Sweden) on 28th July 1992"
- → Supplement to the Information Notices WL 14/92, WL14A/92 and WL 14B/92 on events on foreign nuclear power plants (WL 14C/92) "Blocking of sump suction strainers of the emergency cooling systems due to inadvertent opening of a safety valve in the Barsebäck-2 nuclear power plant (Sweden) on 28th July 1992"
- → Training of Authority Staff in Germany
- → Update of regulatory guidelines: Extracts from resource synopsis
- → *Update of regulatory guidelines: Extracts from the documentation of international regulations*
- *→ BMU Emergency task force organization*
- → Action Plan

APPENDIX VII – REFERENCE MATERIAL PROVIDED BY UM BW

EXAMPLES OF OVERSIGHT PRACTICE

- → Findings at fastenings in KKP2
- → Findings fire protection at GKN I
- → Findings in the documentation room of KKP 1
- → Increased PSA application
- → Increased steam moisture
- → Increased temperature of the main water inlet
- Introduction safety management system
- → Personnel planning
- → Remote monitoring system KFÜ
- → Weak points barrier concept

SELF-ASSESSMENT

- *▶ MODULE III Organization of the Regulatory Body*
- → MODULE VIII Management System

OTHER DOCUMENTS

- → Action Plan
- Activity Report by the Nuclear Supervision, Environmental Radioactivity Division of UMBW
- → Additional requirement for the operating management of the Neckarwestheim Nuclear Power Plant (Unit II)
- → Administrative agreement between the Federal States of Baden-Württemberg, Hesse and Bavaria of July 5, 1999 (ILK)
- → Concept for regulatory oversight of nuclear power plants in Baden-Württemberg ILK Report on the Assessment of Nuclear Oversight Activities of the Ministry of Environment, Baden-Württemberg
- → License for the operation of the shared-ownership nuclear power plant Neckar Unit II (4th partial license)
- → Manual for the organization of Division 3 "Nuclear Supervision, Environmental Radioactivity" (Organizational manual OHB)
- → Mission Statement for the Division Nuclear Supervision, Environmental Radioactivity of UMBW
- → Nuclear power plants in Baden-Wurttemberg (Chapter 7 of Department's Report) Oversight Manual UM BW
- → Schedule of Responsibilities UM BW
- * Strategic Approach and Objectives of the Division Nuclear Supervision, Environmental Radioactivity of UMBW
- → TÜV SÜD Energietechnik: Organisational Chart

APPENDIX VIII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1.] IAEA SAFETY STANDARD SERIES GS-R-1 Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety
- [2.] IAEA SAFETY STANDARD SERIES GS-G-1.1 Organization and Staffing of the Regulatory Body for Nuclear Facilities
- [3.] IAEA SAFETY STANDARD SERIES GS-G-1.2 Review and Assessment of Nuclear Facilities by the Regulatory Body
- [4.] IAEA SAFETY STANDARD SERIES GS-G-1.3 Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
- [5.] IAEA SAFETY STANDARD SERIES GS-G-1.4 Documentation for use in Regulation of Nuclear Facilities
- **[6.] IAEA SAFETY STANDARD SERIES GS-R-2** Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements
- [7.] IAEA SAFETY STANDARD SERIES GS-R-3 Management System for Facilities and Activities
- [8.] IAEA SAFETY STANDARD SERIRES GS-G-3.1 -
- [9.] IAEA SAFETY STANDARD SERIES NS-R-1 Safety of Nuclear Power Plants: Design Safety Requirements
- [10.] IAEA SAFETY STANDARD SERIES NS-R-2 Safety of Nuclear Power Plants: Operation Safety Requirements
- [11.] IAEA SAFETY STANDARD SERIES NS-R-4 Safety of Research Reactors
- [12.] IAEA SAFETY STANDARD SERIES NS-G-4.1 Commissioning of Research Reactors

APPENDIX IX – ORGANIZATIONAL CHART BMU

(aus Datenschutzgründen vorläufig nicht abgebildet)

APPENDIX X – ORGANIZATIONAL CHART UM BW

(aus Datenschutzgründen vorläufig nicht abgebildet)