

**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
MISSION
TO
THE NETHERLANDS**

The Hague, The Netherlands

3-13 November 2014

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



Integrated
Regulatory
Review Service

IRRS

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

The Netherlands





Integrated
Regulatory
Review Service

IRRS

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE NETHERLANDS

Mission date: 3-13 November 2014
Representatives of the regulatory body: Ministry of Economic Affairs (EZ)
Ministry of Infrastructure and Environment (I&M)
Ministry of Health, Welfare and Sport (VWS)

Location: The Hague, the Netherlands

Regulated facilities and activities: Nuclear power plants, research reactors, fuel cycle facilities, waste management and storage facilities, radiation sources in industrial and medical facilities, emergency preparedness and response, transport, decommissioning, control of medical exposure, environmental monitoring, control of discharge and public exposure

Organized by: International Atomic Energy Agency (IAEA)

IRRS REVIEW TEAM

| | |
|---------------------------|-------------------------------------|
| STRITAR Andrej | Team Leader (Slovenia) |
| REGIMBALD Andre | Deputy Team Leader (Canada) |
| ALTORFER Felix | Reviewer (Switzerland) |
| BODIS Zoltanne | Reviewer (Hungary) |
| DONALD John | Reviewer (United Kingdom) |
| FIGUEIRA DA SILVA Eduardo | Reviewer (Brazil) |
| FISCHER Bernhard | Reviewer (Germany) |
| FOUCHER Laurent | Reviewer (France) |
| HOWE Allen | Reviewer (United States of America) |
| JAERVINEN Marja-Leena | Reviewer (Finland) |
| KAMENOPOULOU Vasiliki | Reviewer (Greece) |
| KILOCHYTSKA Tetiana | Reviewer (Ukraine) |
| MADDEN Jack | Reviewer (Ireland) |
| MALHOTRA Reeta Rani | Reviewer (India) |
| MULLER Alan | Reviewer (South Africa) |
| PATHER Thiagan | Reviewer (South Africa) |
| PELCHAT John | Reviewer (United States of America) |
| SERENAITE Dovile | Reviewer (Lithuania) |
| VAN WONTERGHEM Frederik | Reviewer (Belgium) |
| ZAGRAJEK Marcin | Reviewer (Poland) |

| | |
|-------------------------|--------------------------------------|
| HULSMANS Mark | Observer (EC) |
| PAGAR Sunil | Observer (India) |
| KOBETZ Tim | IRRS Coordinator (IAEA) |
| MANSOUX Hilaire | IRRS Deputy Coordinator (IAEA) |
| BRUNO Gerard | IRRS Review Area Facilitator (IAEA) |
| LUX Ivan | IRRS Review Area Facilitator (IAEA) |
| SALINAS MARIACA Rodrigo | IRRS Review Area Facilitator (IAEA) |
| REBIKOVA Olga | IRRS Administrative Assistant (IAEA) |

IAEA-2014

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

CONTENTS

| | |
|--|-----------|
| EXECUTIVE SUMMARY | 9 |
| I. INTRODUCTION | 11 |
| II. OBJECTIVE AND SCOPE | 12 |
| III. BASIS FOR THE REVIEW | 13 |
| 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | 15 |
| 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY | 15 |
| 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY | 16 |
| 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE | 17 |
| 1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY | 18 |
| 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK | 19 |
| 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS | 20 |
| 1.7. PROVISIONS FOR DECOMMISSIONING AND MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL | 20 |
| 1.8. COMPETENCE FOR SAFETY | 21 |
| 1.9. PROVISION OF TECHNICAL SERVICES | 22 |
| 1.10. SUMMARY | 22 |
| 2. GLOBAL NUCLEAR SAFETY REGIME | 24 |
| 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION | 24 |
| 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE | 25 |
| 2.3. SUMMARY | 26 |
| 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | 27 |
| 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES | 27 |
| 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES | 29 |
| 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY | 30 |
| 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS | 32 |
| 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES | 33 |
| 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL | 33 |
| 3.7. SAFETY RELATED RECORDS | 34 |
| 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES | 34 |
| 3.9. SUMMARY | 35 |
| 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY | 36 |
| 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM | 36 |
| 4.2. MANAGEMENT RESPONSIBILITY | 37 |

| | |
|--|----|
| 4.3. RESOURCE MANAGEMENT | 38 |
| 4.4. PROCESS IMPLEMENTATION | 38 |
| 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT | 38 |
| 4.6. SUMMARY | 39 |
| 5. AUTHORIZATION..... | 40 |
| 5.1. GENERIC ISSUES..... | 40 |
| 5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS | 40 |
| 5.3. AUTHORIZATION OF RESEARCH REACTORS..... | 43 |
| 5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES..... | 44 |
| 5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES..... | 44 |
| 5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES | 44 |
| 5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES..... | 46 |
| 5.8. AUTHORIZATION OF TRANSPORT..... | 46 |
| 5.9. SUMMARY | 47 |
| 6. REVIEW AND ASSESSMENT | 48 |
| 6.1. GENERIC ISSUES..... | 48 |
| 6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS..... | 53 |
| 6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS | 53 |
| 6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES..... | 53 |
| 6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES..... | 53 |
| 6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES..... | 54 |
| 6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES | 54 |
| 6.8. REVIEW AND ASSESSMENT FOR TRANSPORT..... | 54 |
| 6.9. SUMMARY | 55 |
| 7. INSPECTION..... | 56 |
| 7.1. GENERIC ISSUES..... | 56 |
| 7.2. INSPECTION OF NUCLEAR POWER PLANTS..... | 59 |
| 7.3. INSPECTION OF RESEARCH REACTORS | 59 |
| 7.4. INSPECTION OF FUEL CYCLE FACILITIES..... | 59 |
| 7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES | 60 |
| 7.6. INSPECTION OF RADIATION SOURCES FACILITIES..... | 60 |
| 7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES | 61 |
| 7.8. INSPECTION OF TRANSPORT | 61 |
| 7.9. SUMMARY | 62 |
| 8. ENFORCEMENT | 63 |
| 8.1. ENFORCEMENT POLICY AND PROCESSES | 63 |
| 8.2. ENFORCEMENT IMPLEMENTATION..... | 63 |
| 8.3. SUMMARY | 65 |
| 9. REGULATIONS AND GUIDES..... | 66 |
| 9.1. GENERIC ISSUES..... | 66 |
| 9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES | 68 |

| | |
|---|-----|
| 9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES | 68 |
| 9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES | 68 |
| 9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES | 69 |
| 9.6. REGULATIONS AND GUIDES FOR TRANSPORT | 71 |
| 9.7. SUMMARY | 72 |
| 10. EMERGENCY PREPAREDNESS AND RESPONSE..... | 73 |
| 10.1. GENERAL EPR REGULATORY REQUIREMENTS | 73 |
| 10.2. FUNCTIONAL REGULATORY REQUIREMENTS | 75 |
| 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE..... | 77 |
| 10.4. ROLE OF REGULATORY BODY DURING RESPONSE..... | 78 |
| 10.5. SUMMARY | 79 |
| 11. ADDITIONAL AREAS..... | 80 |
| 11.1. CONTROL OF MEDICAL EXPOSURES | 80 |
| 11.2. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION | 83 |
| 11.3. SUMMARY | 86 |
| 12. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT | 87 |
| 12.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY..... | 87 |
| 12.2 TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT | 89 |
| 12.3 PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT | 91 |
| 12.4 CONCLUSIONS BY REVIEWED AREAS..... | 92 |
| APPENDIX I – LIST OF PARTICIPANTS | 98 |
| APPENDIX II – MISSION PROGRAMME..... | 100 |
| APPENDIX III – SITE VISITS..... | 102 |
| APPENDIX IV – LIST OF COUNTERPARTS..... | 103 |
| APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)..... | 106 |
| APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT | 113 |
| APPENDIX VII – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW | 116 |
| APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW | 132 |

EXECUTIVE SUMMARY

At the request of the Government of the Netherlands, an international team of senior safety and radiation protection experts met with representatives of the Ministry of Economic Affairs (EZ), the Ministry of Health, Welfare and Sport (VWS) and the Ministry of Infrastructure and Environment (I&M) of the Netherlands from 3 to 13 November 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of the Netherlands's national regulatory framework for nuclear and radiation safety. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the national framework for safety of the TEPCO-Fukushima Daiichi accident.

The IRRS mission covered all nuclear and radiological facilities and activities regulated by the Netherlands. The review compared the Netherlands regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Dutch counterparts in the areas covered by the IRRS.

The IRRS team consisted of 20 senior regulatory experts from 17 IAEA Member States, five IAEA staff members, one IAEA administrative assistant and two observers. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; occupational exposure control of nuclear facilities, development and content of regulations and guides; emergency preparedness and response; medical exposure control; public and environmental exposure control; transport, and waste management and decommissioning.

In addition, two policy issues were discussed. These were the Dutch approach of implementing safety requirements through licence conditions rather than regulations, and the separation of inspection of regulated facilities and activities from those of policy making, the development of legislation and licensing activities.

In preparation for the IRRS mission the Netherlands conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material. Team members also observed regulatory activities and conducted interviews and discussions with management and staff from the Directorate of Nuclear Installations and Safety (NIV) and the Netherlands Enterprise Agency (RVO) from the EZ; management and staff from KFD, TAN, HGS of the Inspectorate for Human Environment and Transport from the I&M and representatives from the VWS. IRRS team members observed inspections at various facilities.

Throughout the mission, the IRRS team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The possible implications of the TEPCO Fukushima Daiichi accident on nuclear and radiation facilities in the Netherlands were well recognized by the Dutch regulators in the past, and the IRRS team did not find any unresolved important related issue.

The IRRS team observed that all Dutch counterparts were committed to provide as good as possible regulatory functions covering a small but complex and diverse nuclear programme and a diverse range of activities with radioactive sources in the country. The most significant challenge at the time of the mission was a complexity of regulatory responsibilities divided among many administrations within several ministries.

The IRRS team found that the main challenge that faces the Netherlands over the next several years is a consolidation of several authorities into the single independent administrative authority.

The IRRS team identified two good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards.

The good practices identified by the IRRS team are the Dutch system for protection from orphan sources of ionizing radiation in scrap metal and the regulatory body's initiative to create an international forum of nuclear regulators of countries operating nuclear power plants of German origin.

The IRRS team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system. Most important are:

- National policies on nuclear and radiation safety, radioactive waste management and associated financial provisions for decommissioning and disposal should be consolidated with a special emphasis on assuring sustainability of human resources in the future.
- The new regulatory body should ensure that its structure and organization promote a common safety culture which will enable regulatory functions to be discharged in an integrated and coordinated manner.
- The regulatory body should be assured independence from undue political influence. The communication and cooperation between different parts of the regulatory body should be enhanced. Sufficient resources should be made available.
- The integrated management system of the regulatory body should be finalized and should include descriptions of all relevant processes, systematic training and qualification of regulatory staff, consolidation of the various safety-related records systems and document management systems.
- The regulatory body should further develop and periodically review regulations and guides to improve consistency, clarity and transparency in the licensing processes of the different facilities and activities and to strengthen the regulatory framework in the area of emergency preparedness and response as well as patient and public protection.
- Inspections should be systematically planned and prioritized. Inspection findings should be effectively tracked and the effectiveness of enforcement should be periodically reviewed.

The IRRS team noted that the Dutch Council of Ministers decided on 24 January 2014 that the expertise in the area of nuclear safety and most of the expertise on radiation protection will be brought together in a single new administratively independent authority in the course of 2015. Once in place the new regulatory body will be the Authority for Nuclear Safety and Radiation Protection (ANVS) under the I&M. Therefore, the Netherlands has already begun to address several of the recommendations and suggestions identified by the IRRS team.

The IRRS team findings are summarized in Appendices V and VI.

An IAEA press release was issued at the end of the IRRS Mission.

I. INTRODUCTION

At the request of the Government of the Netherlands, an international team of senior safety experts met representatives of the EZ, I&M and VWS of the Netherlands from 2 to 13 November 2014 to conduct an IRRS mission. The purpose of the IRRS mission was to perform a peer review of the Netherlands's national regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the Netherlands in August 2012. A preparatory mission was conducted on 13-14 May 2014 at the EZ Headquarters in the Hague to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the existing facilities and activities regulated in the Netherlands.

The IRRS team consisted of 20 senior regulatory experts from 17 IAEA Member States, five IAEA staff members, one IAEA administrative assistant and two observers. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; medical exposure control, public and environmental exposure control, transport, waste management and decommissioning. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the national framework for safety of the TEPCO-Fukushima Dai-ichi accident.

In addition, two policy issues were discussed. These were the Dutch approach to implement safety requirements through licence conditions rather than regulations and the separation of inspection of regulated facilities and activities from policy making, the development of legislation and licensing activities.

The Netherlands conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from the NIV and the RVO from the EZ; and management and staff from KFD, TAN and HGS of Human Environment and Transport Inspectorate from the I&M; and representatives from the VWS. IRRS team members performed direct observation of inspections at the NRG/HFR Research Reactor in Petten, the URENCO Fuel Cycle Facility in Almelo, the EPZ/KCB Nuclear Power Plant and COVRA Interim Waste Storage Facility in Borssele, the Anthony van Leeuwenhoek Hospital in Amsterdam, and the Applus RTD NDT applications in Rotterdam.

All through the mission the IRRS team received excellent support and cooperation from NIV, RVO, KFD, TAN, VWS and all the other counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Netherlands' radiation and nuclear safety regulatory framework and activities to evaluate its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated in the Netherlands, with the exception of the control of occupational exposure (however, the inspection activities on occupational exposure at the nuclear installations were included) and the interface between safety and security. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in the Netherlands and other Member States from the knowledge gained and experiences shared between the Netherlands regulatory staff and IRRS reviewers and through the evaluation of the effectiveness of the Netherlands regulatory framework for nuclear safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response by:

- Providing the Netherlands and NIV, RVO/TSB, KFD, TAN and VWS, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing the Netherlands and NIV, RVO/TSB, KFD, TAN and VWS, with a review of their regulatory programmes and policy issues relating to nuclear and radiation safety and emergency preparedness;
- Providing the Netherlands and NIV, RVO/TSB, KFD, TAN and VWS, with an objective evaluation of the regulatory framework for radiation and nuclear safety and emergency preparedness and response within the Netherlands with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key NIV, RVO/TSB, KFD, TAN and VWS, staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing the Netherlands and NIV, RVO/TSB, KFD, TAN and VWS, with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Netherlands, a preparatory meeting for the IRRS was conducted from 13 to 14 May 2014. The preparatory meeting was carried out by the appointed Team Leader Mr Andrej Stritar, the Deputy Team Leader Mr Andre Regimbald and the IRRS IAEA Team representatives, Mr David Graves, Mr Tim Kobetz, IAEA coordinator, Mr Hilaire Mansoux, IAEA Deputy Team Coordinator and Mr Rodrigo Salinas, IEC Representative. At that time the IRRS team members were notified that the Dutch Council of Ministers decided on 24 January 2014 that the expertise in the area of nuclear safety and most of the expertise on radiation protection will be brought together in a single new administrative Authority in the course of 2015. Once in place the new regulatory body will become the ANVS, as an independent administrative authority under the Minister of Infrastructure and the Environment. However, since the IRRS mission would take place before the transition took place the IRRS mission would only review the regulatory framework that was in place at the time of the mission.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of NIV, KFD, RVO and TAN. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Research Reactors;
- Fuel cycle facilities;
- Waste Management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport;
- Emergency Preparedness and Response
- Control of medical exposure;
- Inspection of occupational exposure at nuclear installations;
- Public and Environmental exposure control;
- Regulatory implications of the TEPCO Fukushima Dai-ichi accident; and
- Selected policy issues.

Representatives of NIV, RVO/TSB, KFD, TAN and VWS, made presentations on the national context for nuclear and radiation regulatory framework and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in the Netherlands in November 2014.

The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Netherlands Liaison Officers for the IRRS mission were confirmed as Mr Aad Sedee from NIV and Mr Robert Jansen from KFD.

The liaison officers provided IAEA (and the review team) with the advance reference material for the review in October 2014 including the self-assessment results. In preparation for the mission, the IAEA review team members performed a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. A more complete list of IAEA publications used as the reference for this mission is given in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting was conducted on Sunday 2 November 2014 in The Hague by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues 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 the evaluation among all reviewers. They also presented the agenda for the mission.

In addition, the Team Leader and IAEA staff provided refresher training to the IRRS team to ensure a common understanding of the IRRS process, methodology, report preparation. The refresher training included the expectations for reviewing the module on the “Regulatory implications from TEPCO-Fukushima Dai-ichi Accident”. The reviewers also reported their first impressions of the advance reference material.

The Liaison Officers were present at the opening IRRS team meeting, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 3 November 2014, with the participation of NIV, RVO/TSB, KFD, TAN and VWS, senior management and staff. Opening remarks were made by Ms Jenny Thunnissen, Inspector General, from the Ministry of Infrastructure and Environment, Mr Andrej Stritar, IRRS Team Leader. Mr Barto Piersma (NIV) gave an overview of the Netherlands context, and Ms Andrea Niederländer, KFD, gave an overview of the facilities and activities existing in the country, the main regulatory activities and the action plan prepared as a result of the self-assessment.

During the mission, a review was conducted for all the review areas to the Netherlands with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Thursday 13 November 2014. The opening remarks at the exit meeting were presented by Mr Aad Sedee, Liaison Officer, and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Andrej Stritar. Thereafter the minister of Economic Affairs of the Netherlands, Henk Kamp, which is primarily responsible for the Nuclear Energy Act and its regulations, accepted the report from Andrej Stritar. Closing remarks were made by Mr James E. Lyons, Director, Division of Nuclear Installation Safety, IAEA.

An IAEA press release was issued at the end of the exit meeting.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Dutch government has developed a radiation protection and nuclear safety strategy aimed at the protection of humans and the environment against the risks of radiation. This strategy is set out in several policy papers and other documents (e.g. letters to Parliament) as part of the legal framework that encompasses the protection against ionizing radiation, nuclear safety and management of radioactive waste and spent fuel. The strategy also extends to the transport of radioactive materials, fuels and ores, the response to radiation incidents, decommissioning, nuclear safeguards and the security of radioactive sources and nuclear facilities.

Other important elements of the strategy are transparency, a graded approach, consideration for ALARA and continuous improvement of safety. A graded approach is taken towards the development and design of the radiation protection and nuclear safety policy including the relevant legislation and the supervision thereof. The graded approach is expressed in the legislation through the application of three concepts: exemptions, notification requirements and technical requirements that are commensurate with the potential radiation risk. The graded approach extends to all functions of the regulatory framework, including licensing, assessment, supervision and enforcement. All authorized parties are required to apply ALARA principle and ensure that the doses are as low as reasonably achievable. Licence holders of nuclear facilities are required to continuously, systematically and verifiably examine, assess and improve the safety of their facilities.

While there are many policy documents in place, as part of the regulatory framework, the IRRS team found that some of these documents are not up to date. For example, the policy for the management of radioactive waste and spent fuel was adopted in 1984.

Policy documents are amended from time to time through letters to Parliament in order to maintain the policy up to date. Recently the Government sent to Parliament an outline document consolidating the present policy on nuclear safety, security and radiation protection. A process for periodic review and a consolidated and overarching documentation under which all policies would be derived is missing. In addition, the IRRS team believes that the need and provision for human and financial resources, as well as a framework for research and development should be addressed in a policy document.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Policy documents exist, but some are not up to date. They are amended from time to time through letters to Parliament (e.g. the waste policy). However a consolidated, overarching policy documentation is missing including human and financial resources, as well as a framework for research and development.

(1)

BASIS: GSR Part 1 para. 2.3 (d,e) states that *“National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following: ...*
(d) The need and provision for human and financial resources;
(e) The provision and framework for research and development;

(2)

BASIS: GSR PART 5 Requirement 2 states: *“To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste”*

R1

Recommendation: The government should provide a consolidated, overarching national policy and strategy for safety, including radioactive waste management and disposal, and including human and financial resources, as well as a framework for research and development.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal foundation for radiation protection and nuclear safety is specifically reflected in the Nuclear Energy Act, established in 1963, and in the legislation and licences based on it. The Nuclear Energy Act is an integrated law on radiation protection and nuclear safety, which encompasses the protection of workers, patients and the environment, the transport of radioactive and fissionable materials, radioactive waste management, radiation incident response, security and safeguards. While the Nuclear Energy Act has been amended more than 50 times, a comprehensive review is anticipated by the regulatory body since it has never been fundamentally updated.

The Nuclear Energy Act is supplemented by associated Decrees and Regulations. The designation of powers with regard to the regulatory activities is fixed in mandates and a regulation under the Nuclear Energy Act clearly allocates responsibilities. The most relevant of these Decrees are the Radiation Protection Decree, the Nuclear Installations, Fissionable Materials and Ores Decree, and the Transport of Fissionable Materials, Ores and Radioactive Substances Decree. In addition to these Decrees, there are several regulations covering further aspects of safety and security, such as the regulation implementing the Radiation Protection Decree 2013 and the regulation on Justification of uses of Ionizing Radiation. The regulations are supplemented with safety guides and other international documents.

Financial and human resources for policy-making, implementation, supervision and enforcement are made available by the various ministries. These resources are set in the state budget for a period of several years. A small part of the costs is recovered by (annual) fees.

All the costs for radioactive waste management are borne by the parties responsible for the generation of the waste. This includes all costs incurred by the state-owned radioactive waste management organization COVRA for collection, conditioning, storage and disposal of the waste. These costs are charged back to the waste generators through COVRA's fees. A disposal fund has been established, to which waste generators contribute.

For nuclear reactors, the licence holder is required to make available adequate financial resources for decommissioning at the moment that these are required. While the licence holder is free to choose the form of the financial provision, this must however be submitted to the regulatory body for approval.

There is currently no requirement for financial provision by operators of facilities other than nuclear power plants, research reactors, owners of high-activity sealed sources (HASS) sources and operators of larger scrap metal facilities. For example, there is no requirement for financial provision for nuclear fuel cycle facilities (e.g., URENCO) and radioactive waste facilities (e.g., COVRA).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body has the legal power to require financial provisions for decommissioning from licence holders of nuclear power plants, research reactors, HASS and scrap metal facilities. However, there is no legal provision to require such provisions for others nuclear facilities, including fuel cycle facilities.

- | | |
|-----|---|
| (1) | <p>BASIS: GSR Part 1 para. 2.5 (16) states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:...</i></p> <p><i>(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities.</i></p> |
| (2) | <p>BASIS: GSR Part 6 requirement 9 states that <i>“Responsibilities in respect of financial provisions for decommissioning shall be set out in national legislation. These provisions shall include establishing a mechanism to provide adequate financial resources and to ensure that they are available when necessary, for ensuring safe decommissioning.</i></p> <p><i>(Para 6.2) The cost estimate for decommissioning shall be updated on the basis of the periodic update of the initial decommissioning plan or on the basis of the final decommissioning plan. The mechanism used to provide financial assurance shall be consistent with the cost estimate for the facility and shall be changed if necessary.</i></p> <p><i>(Para 6.3) If financial assurance for the decommissioning of an existing facility has not yet been</i></p> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----------|--|
| | <i>obtained, adequate financial resources shall be put in place as soon as possible. Approval of a renewal or extension of the authorization for operation of the facility shall include provisions for financial assurance.</i> |
| R2 | Recommendation: The government should make legal provisions to require financial provisions for nuclear and non-nuclear facilities, for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities. |

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

In the Netherlands, the minister of EZ is the primary responsible authority for carrying out the regulatory process under the Nuclear Energy Act and for the main functions of the regulatory body. At present the regulatory body is composed of separate entities residing within different ministries. However, the expertise in the area of nuclear safety and most of the expertise on radiation protection will be brought under a single independent new administrative authority in the course of 2015. The new regulatory body, the ANVS, will be positioned within the Ministry of Infrastructure and the Environment.

The current regulatory body presently consist of several entities embedded within different ministries, each of whom has its own responsibilities and powers:

- The Minister of EZ is responsible for the protection of humans and the environment against ionising radiation, nuclear safety, radioactive waste and spent fuel management, radiation incident response, the transport of radioactive and fissile materials, the security of facilities and radioactive sources and safeguards. This Minister is also responsible for the implementation of and compliance with the Nuclear Energy Act, which means the Minister is primarily accountable to Parliament and responsible for ‘legislative maintenance’. The Minister of EZ is also responsible for radiation safety on or in facilities in the oil and gas extraction and mining industries and for product and food safety.
- The Minister of I&M is responsible for the general environmental policy and legislation, including policy and legislation on Environmental Impact Assessments, soil, surface water and drinking water.
- The Minister of Social Affairs and Employment (SZW) is responsible for the policy on the protection of workers against the risks of ionizing radiation.
- The Minister of VWS is responsible for healthcare and the protection of patients against the risks of ionizing radiation.
- The Minister of Security and Justice (V&J) is responsible for disaster and crisis management and is therefore involved in all steps of emergency management, from prevention to recovery. If a disaster or crisis has to be escalated to the national level, the Ministerial Crisis Management Committee must be involved, chaired by the Minister of V&J, or the Prime Minister if he/she so wishes.
- The Minister of Defence is responsible for military radiation applications, including applications governed by a secrecy requirement. It should be noted that these particular applications were out of the IRRS mission scope.
- The Minister of Finance is responsible for insurance and liability issues, including those related to liability for accidents involving nuclear facilities.
- The Minister of Foreign Affairs coordinates the relevant foreign policy, particularly where it concerns non-proliferation and nuclear issues, and Euratom and IAEA matters.

The separate entities that form the regulatory body operate with working agreements under the responsibility of the minister of Economic Affairs (EZ).

Within the Ministry of EZ,

- The NIV, is responsible for the preparation of legislation, formulating policies (on nuclear safety, radiation protection and related security and emergency preparedness and response; excluding energy policy), regulatory requirements and licensing and related review and assessment.

- The RVO/TSB is mandated to grant licences under the Nuclear Energy Act, excluding licences for nuclear installations and licences for the larger transports of nuclear fuel, which are issued by NIV.

Within the Ministry of I&M,

- KFD is responsible for the independent supervision (review and assessment, inspection and enforcement) of licence holder compliance with the requirements related to nuclear safety, nuclear waste and transport safety, radiation protection, security and non-proliferation (safeguards). The KFD is embedded in an organizational division of the Human Environment and Transport Inspectorate (ILT) and operates under the general responsibility of the Minister of EZ via mandate.
- ILT transport departments (Rail and Road Transport Inspectorate “HGS”, Civil Aviation Authority Netherlands, Netherlands Shipping Inspectorate) are responsible for supervision of the requirements of the Modal Transport Regulations.
- The TAN deals with the executive part of the emergency preparedness and response and advises the NIV on policy items.

In addition to KFD, there are other authorities (national and local) contributing to the supervision of the activities of the licence holders.

Each of the entities especially NIV, RVO/TSB, KFD and TAN has its own set of responsibilities and tasks, related to the Nuclear Energy Act.

The EZ is also responsible for the nation’s energy policy, but this topic is handled by a different directorate. The IRRS team found that the position of the regulatory body within EZ may be perceived to be a conflict of interest for the ministry. This may put into question the independence of the regulatory body.

In January 2014 the Dutch council of Ministers decided to transfer the regulatory functions today held in the ministries of EZ and I&M (NIV, RVO/TSB, KFD and TAN) into a single independent organisation (ANVS). The new administratively independent organisation will fall under the responsibility of the ministry of I&M. This move will require an amendment to the Nuclear Energy Act, which is envisaged in 2015. As an intermediate step, until such time as the Nuclear Energy Act is amended, the NIV, RVO/TSB, KFD and TAN will work together under the responsibility of the ministry of I&M from 1 January 2015 onward. The IRRS team supports this move as a means to strengthen the independence of the regulatory body. Nevertheless, interdependencies between different authorities will still remain. And a further review after the formation of ANVS should be considered.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The position of the regulatory body within the Ministry of EZ that is also responsible for the nation’s energy policy may be perceived to be a conflict of interest for the ministry. This raises concern regarding the independence of the regulatory body.

| | |
|------------|--|
| (1) | BASIS: GSR Part 1 para. 2.8 states that <i>“To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities.”</i> |
|------------|--|

| | |
|-----------|--|
| R3 | Recommendation: The government should separate the regulatory body from the ministry that has responsibility in respect of the facilities regulated by the regulatory body or responsibility for energy policy. |
|-----------|--|

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

The principle of prime responsibility for safety is not explicitly mentioned in the Nuclear Energy Act. However, the conditions that stipulate the responsibilities for safety through all stages of lifetime are described in the legal

framework. The licence holder is responsible for the application of all regulatory requirements related to its installation. Article 70 of the Nuclear Energy Act states that the licence is personal and not transferable without permission of the Minister. Consistent with the IAEA Safety Fundamentals and the European Directive on Nuclear Safety, the responsibility of authorized parties is enduring and cannot be delegated. The regulatory body has the authority to require demonstration of compliance with requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The fundamental principle of prime responsibility for safety is currently not explicitly stated in the legal framework.

| | |
|-----|--|
| (1) | BASIS: Safety Fundamentals SF-1, Principle 1 states that <i>“The prime responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.”</i> |
| (2) | BASIS: GSR Part 1 para. 2.14 states that <i>“The legal framework for safety shall be established in such a way that the authorized party retains the prime responsibility for safety throughout the lifetime of facilities and the duration of activities, and shall not delegate this prime responsibility.”</i> |
| S1 | Suggestion: The government should consider explicitly stating in the legal framework that the fundamental principle of prime responsibility for safety rests with the person or organisation responsible for facilities and activities, that give rise to radiation risks. |

1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

The legislation clearly defines the duties and responsibilities of the various authorities having responsibilities to ensure safety. Coordination processes are partly determined by the laws and regulations such as the General Administrative Act and the General Provisions Environmental Law Act.

The IRRS team found that KFD produces inspection reports and, in addition to the licence holder, distributes them to a number of groups within their parent organisation (ILT) and to other agencies. If necessary, the Minister is informed too. However, they do not actively share their reports with NIV. The IRRS team recognised that KFD policy emphasises the separation of policy making and licensing activities from the supervision of regulated facilities. Nevertheless, inspection reports should be distributed to the branches of the regulatory body responsible for licensing and policy making to ensure that feedback from regulatory inspections is shared.

The planned reorganisation of the regulatory body into a single entity should facilitate the sharing of information, such as inspection reports. However, as some regulatory responsibilities, i.e. occupational radiation protection and health care and protection of patients, will remain outside ANVS, the need for communication and coordination between the authorities remains a challenge. The IRRS team concluded that restricted communication between branches of the regulator (both within the organisation and with other, external regulatory authorities) could hamper the effectiveness of the regulatory body. Coordination, cooperation and horizontal communication between licensing and supervision activities on all levels should be encouraged by management of the regulator, to assist in achieving consistency and in enabling authorities to benefit from each other’s experience.

The IRRS team was shown a new regulatory intelligence tool that enables sharing and analysis of enforcement and inspection performance data between multiple regulatory bodies. Only some of the nuclear and radiation safety regulators in the Netherlands currently input to and access this tool, but it appears to have potential to improve coordination between and within the different regulatory authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Restricted communication and cooperation between and within the regulatory bodies appear to hamper the quality and effectiveness of the regulatory activities.

| | |
|-----|--|
| (1) | <p>BASIS: GSR Part 1 para. 2.18 states that “Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.</p> <p><i>This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other’s experience.</i></p> |
| (2) | <p>BASIS: GS-G-1.3 Paragraph 4.33 states that “Inspection reports should be distributed according to established procedures in order to provide for the following information to regulatory staff responsible for the development of requirements for authorization or new regulations”</p> |
| R4 | <p>Recommendation: The government should make provisions to foster the effective coordination of and collaboration between and within the regulatory authorities.</p> |

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

The Euratom HASS Directive has been implemented in the Radiation Protection Decree to reduce the risks associated with unregulated sources. Financial provisions are provided by the authorized parties for the removal of HASS.

If an orphan source (or something which is suspected to be an orphan source) is found, the Nuclear Energy Act stipulates it should be reported to the mayor of the municipality, who in turn reports it to KFD. If the responsible party for the source (e.g. licence holder who has lost the source) cannot be identified, the cost of the seizure and waste management is assumed by the State. KFD is continuously available for reports and requests for assistance at any time. If necessary KFD will also seek assistance from other specialized parties. Eventually, it is declared as waste and stored at COVRA.

There are legal requirements for the operation of larger facilities where scrap metal is stored, processed, treated or trans-shipped. The requirements include i.a. radiation safety program, detection and documentation of radiation measurements, notification to regulatory authorities, the qualification of responsible staff and financial security for removal of contaminated metal. Some scrap metal facilities have been granted an authorisation. There exists a good regulatory interaction between KFD and the other scrap metal facilities in the Netherlands.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Specific and comprehensive regulatory provisions are in place regarding detection and safe management of radioactively contaminated metal scrap.

| | |
|-----|---|
| (1) | <p>BASIS: GSR Part 1, Requirement 9 states that “The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.</p> |
| GPI | <p>Good Practice: The specific and comprehensive regulatory provisions in place allows for effective control of contaminated scrap metal and safe management of the contaminated material.</p> |

1.7. PROVISIONS FOR DECOMMISSIONING AND MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL

The Nuclear Energy Act requires the licence holder to be responsible for decommissioning. According to new regulation, in force since April 2011, a nuclear facility shall be decommissioned directly after final shut down. The

BKSE Decree requires the licence holder to have and periodically (every five years) update a decommissioning plan during the lifetime of the facility. The plan requires approval by NIV every time it is updated. The decommissioning plan serves as the safety-basis for all the activities carried during the decommissioning phase, and provides the basis for the financial provisions for the decommissioning costs. During decommissioning, the licence holder is obliged to act according to the decommissioning plan.

The Dutch national policy on radioactive waste management and spent fuel management is based on a report presented to parliament in 1984. There have subsequently been a number of letters to Parliament over the years that have successively updated the national position over time. There has not however been a consolidation of the various changes in policy into a single coherent and consistent document reflective of current national position on the subject. The IRRS team has previously addressed this in Recommendation 1. The IRRS team has been informed that a waste policy will be described in a National Waste Programme as required by the EURATOM waste directive and will be ready by beginning 2015.

The Dutch national approach to radioactive waste management entails long term (100 years plus) above ground storage of radioactive waste at a centralised facility COVRA with the possibility of geological disposal at the end of this period. The policy envisages that all types of radioactive waste will be disposed in a single geological repository.

COVRA is wholly owned by the government and charges a fee for the acceptance of radioactive waste. Upon receipt of the required fee and acceptance of the waste all liabilities regarding future management of the radioactive waste are transferred from the waste generator to COVRA.

Establishment of the geological repository for radioactive waste is envisaged to be ready around 2130. It is anticipated that development review and societal acceptance of the financial and technical aspects associated with the geological disposal will be completed during this period. At present there is no specific regulation on disposal facilities available and development of such regulation is also not foreseen in the near future.

The IRRS team concluded that the policy and approach adopted by the Netherlands allows that society will have the freedom of choice between a continuation of the storage for another 100 years, to realise the final disposal, or to use new techniques or management options that may become available during the period of interim storage.

In 1993 the government adopted, and presented to Parliament, a position paper on the geological disposal of radioactive and other highly toxic wastes. This formed the basis for further development of a national radioactive waste management disposal policy. The new policy requires that any geological disposal facility be designed in such a way that each step of the process is reversible. The IRRS team was informed that in response to a question from the Parliament, the Minister EZ confirmed that retrievability of the waste will only be possible prior to closure of the disposal facility.

The Netherlands presently has not established specific milestones (e.g. a programme) for implementation of geological disposal. In the view of the IRRS team, a programme that identifies the necessary steps for research, site selection, design, construction, commissioning, operation, closure and post-closure of the disposal facility, would facilitate further implementation of the national waste management strategy. This could contribute to avoiding undue burdens on future generations and to making effective use of the current knowledge about radioactive waste management in the Netherlands.

1.8. COMPETENCE FOR SAFETY

There appears to be no clear commitment in the national policy and strategy for safety to make provisions for the necessary professional education and training for maintaining the competence of a sufficient number of suitably qualified and experienced experts in nuclear and radiation safety. However, the government supports research by means of regular commissions to the National Institute for Public Health and the Environment (RIVM) for radiation protection research. It also provides a research grant to the Nuclear Research and consultancy Group (NRG) for nuclear and radiation protection research and it co-finances the OPERA research program on the final disposal of radioactive waste.

The IRRS team found that the regulatory body currently has competent staff, who are trained in the field of nuclear safety, radiation protection and the relevant legislation. Further development of the staff is obtained by participating in (national and international) working groups, study and attendance of customized training.

Concern has been expressed by the regulatory body that it cannot fulfil all of its functions in depth due to currently limited human resources (see also subsection 3.3). The IRRS team believes that a more detailed human resources development plan would strengthen the long-term competence of the regulator. The IRRS team therefore concluded that the government should make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety and increase its resilience. Licence holders are required to provide a system of training and verification of competence of personnel in accordance with the importance of the work they perform. The Dutch system of radiation protection provides a framework for the issue of a licence for expert training of selected personnel, which requires regulatory approval. The quality of the expertise depends on the application and on the risk and is extensively regulated under the Radiation Protection Decree, the Ordinance Radiation Protection EZ and in the licences. The licence holder is required to ensure that a sufficient number of qualified personnel is present to guarantee radiation protection.

The building of competence is required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. However, as discussed in section 1.1 this not reflected in the current policy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There is no sufficient commitment in the national policy and strategy for safety to make provisions for the necessary professional education and training for building and maintaining the competence of a sufficient number of suitably qualified and experienced experts in nuclear and radiation safety and increasing its resilience.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1, Requirement 7, para. 2.34 states that <i>“As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.</i> |
| (2) | BASIS: GSR Part 1 para. 2.36 (b) states that <i>“ The government (b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety.</i> |
| R5 | Recommendation: The government should, as an essential element of the national policy and strategy for safety, make provisions for the necessary professional education and training, research and development to build and maintain the competence of a sufficient number of suitably qualified and experienced experts in nuclear and radiation safety and increase its resilience. |

1.9. PROVISION OF TECHNICAL SERVICES

The National Dose Registration and Information System (NDRIS) has been established for the dose registration for exposed workers, which is under the responsibility of the NRG. A calibration laboratory is available in the VSL Dutch Metrology Institute.

The RIVM has a signalling and a supporting role in environmental monitoring. The National Radioactivity Monitoring Network (NMR) continuously monitors the radiation levels at various points in the Netherlands. Its measurement results are available on its website.

The IRRS team concluded that the elements explicitly mentioned in GSR Part1, para 2.41 are in place and that no further technical services are to be provided.

1.10. SUMMARY

The IRRS team found that policy documents exist, but some are not up to date. They are amended from time to time through letters to Parliament (e.g. in the case of the Waste Policy). Consolidated, overarching documents and policy papers regarding provision for human and financial resources, as well as a framework for research and development are missing. There appears to be no commitment in the national policy and strategy for safety to make

provisions for the necessary professional education and training, research and development to build and maintain the competence of a sufficient number of suitably qualified and experienced staff.

The position of the regulatory body within the ministry that is also responsible for the nation's energy policy may be perceived as a conflict of interest for the ministry, and may inhibit the independence of the regulatory body. The existing restricted communication between and within the regulatory bodies appears to hamper the quality of the regulatory activities. The regulatory body has the legal power to require financial guarantees for decommissioning from licence holders of nuclear power plants, research reactors, owners of HASS and scrap metal facilities. However, there is no legal provision to require such guarantees for others facilities including fuel cycle facilities.

The IRRS team considered the specific regulatory provisions in place regarding detection and disposal of radioactively contaminated metal scrap as a good practice.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Netherlands is a party to, and has implemented the obligations of the:

- Convention on Nuclear Safety (CNS)
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (JC)
- Paris Convention on Nuclear Third Party Liability and the Brussels Supplementary Convention, and related protocols
- Treaty on the Non-Proliferation of Nuclear Weapons (NPT)
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency
- Convention on Early Notification of a Nuclear Accident
- OSPAR Convention
- Convention on the Physical Protection of Nuclear Material (CPPNM)

The Dutch Government has committed itself to both the Code of Conduct on the safety and the security of radioactive sources and the Code of Conduct for Research Reactors. The Netherlands is represented at the periodical review meetings of the CNS and the JC.

The Netherlands actively participates in the IAEA safety standards committees and most of the IAEA safety standards for NPPs have been transposed into nuclear safety rules (NVRs).

The Netherlands participates in several international organizations (e.g. OECD/NEA, ENSREG, HERCA, WENRA and ERDO) and their related working groups and specific committees.

International (IAEA) review-missions are an integral part of the supervision-strategy of the KFD of the RB. Recent examples are SALTO-missions (2009, 2012 and 2014), IPSART-missions (2009 and 2013), Waste safety appraisal (2009) and OSART missions (2005 and 2014). The IRRS team acknowledged that national emergency preparedness and response topics are planned to be reviewed through an IAEA EPREV mission.

KFD has for many years had a Memorandum of Understanding (renewed in 2013) with the USNRC, giving them insight into their regulatory experience. It is the intention of the RB to increase the exchange with foreign regulators on a bilateral or multilateral basis in the future. First steps have been taken in 2014 to start cross-inspections with Belgium and France.

The Dutch regulator has taken the initiative to start a “KWU regulator group” (KWUREG), bringing together regulators from all countries (Brazil, Germany, the Netherlands, Spain, and Switzerland) where Siemens/KWU NPP are in operation. KWUREG shall promote closer cooperation of those countries to cope with the effect of the phase-out in Germany, which is expected to slowly reduce its importance as a source of operating and regulatory experience.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Dutch regulator has taken the initiative to start a KWUREG.

- | | |
|-----|--|
| (1) | BASIS: GSR Part 1 para. 3.2 states that “(e) Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections.” |
| (2) | BASIS: GSR Part 1 para. 3.4 states that “The regulatory body shall established and maintain a means for receiving information from other states and from authorized parties as well as a means for making available to others lessons learned from operating experience and regulatory experience. ...” |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|--|
| GP2 | Good Practice: The Dutch regulator has taken the initiative to start a KWUREG. KWUREG is expected to harmonize experience from all countries with Siemens/KWU reactors i.e. for long term operation and to promote closer cooperation of those countries to cope with the effect of the phase-out in Germany. |
|-----|--|

The IRRS team acknowledged that the Netherlands has a high level of international cooperation, especially taking into account their limited resources as a small country. The IRRS team concluded, that the regulatory body fully fulfils the international obligations by participating in the relevant international arrangements, including international peer reviews, and by promoting international cooperation to enhance safety globally.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Operating Experience Feedback (OEF) is required in the Netherlands by the Nuclear Safety Regulation implementing the EU Directive 2009/71/EURATOM (“Regeling implementatie richtlijn nr. 2009/71/EURATOM inzake nucleaire veiligheid”, article 2.2). According to article 2 of the regulation, the licensees are required to continuously assess and evaluate in a systematic manner the nuclear safety of the installation, taking into account relevant developments and insights regarding nuclear safety of similar installations at home and abroad.

The KFD supervises the OEF programmes of the licensees to ensure that programmes to collect and analyse operating experience are established, the results obtained and the conclusions drawn are acted upon and that existing mechanisms are used to share important experience with international bodies and with other operating organizations and regulatory bodies. Notification to the KFD of events by the licensee has been required since the 1970’s. Since the 1980’s the KFD has been reporting annually to Parliament about these events and since 2013 KFD has been publishing notifications of events at all nuclear installations on its website.

The KFD annually produces a summary document about national operating experience that is provided to Parliament. In 1994 KFD created its own permanent OEF Working group to follow up national and international events. At present the activities of the working group have been significantly reduced due to the assignment of the limited resources, mainly to Fukushima related activities. Thus only a limited number of major incidents, decided on a case-by-case basis, are followed up. The biannual reports by KFD on incidents with radioactive materials or in non-nuclear installations have been stopped in 2011 due to resource limitations.

The KFD is the national contact point for the international reporting systems NEWS, IRS, IRSRR and FINAS and the national INES-coordinator. As a member of the EC JRC Clearinghouse, KFD receives all OEF reports from the Clearinghouse. As part of the contract with the German TSO GRS, KFD is informed about relevant nuclear incidents or findings in Germany.

Feedback of regulatory experience is also performed in the context of international working groups and bilateral arrangements (see 2.1) where NIV and KFD are active members. NIV seems to have no complete access to OEF collected and analysed by KFD and so cannot take it into account during licensing. The dissemination of information on measures taken to prevent recurrence, especially those resulting from incidents abroad is not done in a structured way.

The IRRS team concluded that most of the necessary elements of operational and regulatory experience feedback are in place, although activities related to operating and regulatory experience feedback at the RB are currently not deployed in a structured and systematic way in line with international practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Activities related to operating and regulatory experience feedback at the regulatory body are currently not deployed in a structured and systematic way.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 Requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and</i> |
|-----|--|

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

for their use by authorized parties, the regulatory body and other relevant authorities”.

R6

Recommendation: The regulatory body should organize activities related to operating and regulatory experience feedback (e.g. exchange of information including experience from other countries, analysis and reporting) in a structured and systematic way. This should also include feedback on measures taken in response to information received.

2.3. SUMMARY

The IRRS team acknowledged that the Netherlands has a high level of international cooperation. The IRRS team concluded, that the regulatory body fulfils the international obligations by participating in the relevant international arrangements, including international peer reviews, and by promoting international cooperation to enhance safety globally.

Most of the necessary elements of operational and regulatory experience feedback are in place, although activities related to operating and regulatory experience feedback at the regulatory body are not deployed in a structured and systematic way in line with international practices.

The Dutch regulator’s initiative to start a “KWU regulators group” to harmonize experience from all countries with Siemens/KWU reactors and to promote closer cooperation is regarded as a good practice.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The regulatory body is implemented across several ministries. Organizations acting on behalf of the minister of EZ are NIV, KFD, RVO and TAN. Within the EZ, NIV is responsible for licensing, regulations and policy-making. NIV is an organisation consisting of project groups and two coordination areas. Within the same ministry RVO/TSB is a small team of 13 persons licensing radiation sources and non nuclear applications and transport except for transport of nuclear fuel.

Embedded within the I&M within one of the directorates of the ILT, the KFD is responsible for the oversight of the compliance by the authorized parties with the requirements on nuclear, waste and transport safety, radiation protection, security and non-proliferation. These functions are carried out in two departments.

The unit TAN deals with executive part of emergency preparedness and response. It was originally a separate unit embedded within the ministry of Infrastructure and Environment, but has been merged into KFD in October 2014. There are three experts working at TAN.

There are several other inspectorates responsible for conduction nuclear and radiation safety inspections. HGS resides in the ILT Domain of Rail- and Road transport. There are some part time inspectors responsible for the oversight of rail- and road transport. Also I-SZW, IGZ, and SodM are responsible for inspections, but I-SZW and SodM are out of the scope of this IRRS mission.

The budgets of NIV, RVO and KFD are agreed upon with the EZ. The budgets are part of the state budget and the final decision on budget allocation is made by the parliament. The agreement for the licensing conducted by RVO/TSB is made by NIV. The management agreement defines the main issues and the budget, which in turn defines the resources.

The state budgeting process includes the estimated need for the next 5 years. However, NIV, RVO/TSB, KFD and TAN are independent in their decision-making concerning the annual planning of the activities. The IRRS team recognised areas where there are insufficiency of resources. These areas are discussed in more detail in section 3.3.

The NIV and KFD both report to the Minister of EZ, who in turn reports to the parliament when needed. Independent interviews of the RVO and NIV staff as well as of KFD inspection staff revealed the existence of organization policy barriers that restrict technical discussions at the staff level between the inspection and, regulation, policy licensing making and licensing groups. These organizational barriers require that any feedback and or suggestions for improvements to be funnelled upward to a special unit within the ILT before technical information can be exchanged or discussed. Both licensing and inspection staff indicated that this inhibited exchange of information flowing from both review and assessment as well as inspections. Likewise this restricted the sharing of licensee feedback between the respective organizations. A similar policy of limiting contacts to the licensing and policy authority is not in place in between other inspectorates overseeing radioactive sources.

The planned merging of several authorities into the new ANVS after 1 January 2015 could remove some of inter-organisational communication barriers. However, the IRRS has noticed from the Advance Reference Material and from the interviews Dutch situation about the role distinction might be a risk that could lead to the limiting or controlling the free communication and cooperation between the policy making and licensing functions and inspection functions of the new organisation. The IRRS team encouraged the regulatory body to ensure that there is strong and effective interaction and exchanges of information between the various functional units in line with the guidance provided in IAEA safety standard GS-G-1.1 para 3.4.

The annual inspection plans and the inspection reports of the medical facilities with radioactive sources are shared by KFD, labour safety inspectorate I-SZW and the inspectorate of the VWS. The planning and conduct of inspections with several inspectorates is discussed in more detail in the subsection 11.1.

The manager makes the decisions of the authorizations in NIV responsible for authorization of the nuclear installations. The Minister grants the authorizations such as long-term operation of the nuclear power plant. The manager responsible for licensing can decide whether it is desirable that the Minister should sign the licence. At KFD, the inspector has authority to make the decisions. However, a second independent review of the decision is

made by a second inspector. At RVO/TSB the team manager or the team coordinator grants the licences. The appropriate experts review the notifications.

The IRRS team was informed that in January 2014 the Council of Ministers decided to consolidate several parts of the regulatory body (NIV, RVO/TSB, KFD, TAN) together into a single organization to form the ANVS, to be within the ministry of Infrastructure and Environment. The organizational structure of the new regulatory body will be implemented on 1 January 2015 and all divisions of the new ANVS will move into the same building. The Nuclear Energy Act is to be revised during 2015 to reflect the changes implemented. The new structure is to enhance the functions of the regulatory body. During the time of the IRRS mission the organizations were in the preparation phase for the transition.

A policy issue discussion took place during the mission on the separation of regulatory functions. Currently, regulatory functions are separated between NIV and RVO/TSB on one side (policy making, regulations, licensing, review and assessment) and KFD on the other side (inspection, enforcement and corresponding review and assessment). The separation of functions and the independence of inspection is a dominant issue in the Netherlands extending beyond the nuclear sector. It was triggered by past events not related to nuclear or radiation facilities. This has resulted in a policy within the ILT to separate the inspection functions of facilities and activities from the regulation and licensing function. With the creation of ANVS, all these functions will be combined into a single organization for the nuclear sector. However, the Netherlands is still discussing how to optimize cooperation of the various regulatory functions.

During the policy discussion the IRRS team members shared the experiences of their regulatory bodies. Overall, whether licensing and inspection function are conducted by the same or separate entities within the organization, there is always a significant amount of interactions between the functions. It was recognized by all team members that inspectors have extensive knowledge of the facilities and radioactive sources they inspect. It is crucial that this knowledge is shared with the licensing officers who may need to amend licence conditions, or even regulations, based on the experience of inspectors enforcing those regulations. Similarly, inspectors should be involved in the licensing process in order to be able to properly inspect facilities and check compliance with licences. The IRRS team noted that discussions at working level and managerial levels are necessary between licensing and inspections organization units to facilitate common understanding of information, databases, and facility history records. There was also a clear consensus among the team members on the need to properly organize the internal coordination and cooperation and to identify how and when management needs to be involved in the decision making process. The importance of a strong internal leadership was also recognized as a key factor for successful coordination without overlap of responsibilities. Roles and responsibilities are different but all regulatory staff, regardless of their specific functions, need to develop the same integrated safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Regulatory functions have been distributed to several organizations resulting in a fragmented distribution of the responsibilities and unnecessary organisational boundaries reducing the effective implementation of the regulatory functions. The new ANVS will start operation on 1 January 2015. Following this, continuation of the policy of limiting or controlling the free communication and cooperation between the policy making and licensing part and inspection part of the new organisation would be likely to continue to reduce effectiveness.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 req. 16. states that <i>“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”</i> |
| (2) | BASIS: GSR Part 1, req. 19, par. 4.15.(3) states that <i>“The management system of the regulatory body...is to foster and support a safety culture in the regulatory body through the development and reinforcement of leadership, as well as good attitude and behaviour in relation to safety on the part of individuals and teams”</i> |
| R7 | Recommendation: The regulatory body should ensure that its structure and organisation enable effective fulfilment of its statutory obligations and there are no restrictions to the |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----------|--|
| | exchange of information between policy making, developing regulations and guides, licensing, review and assessment, inspection and enforcement functions at all levels. |
| R8 | Recommendation: The regulatory body should develop and implement policies and practices to promote common safety culture. |

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The NIV and RVO/TSB are embedded in the organizational divisions of the Ministry of Economical Affairs. They have a mandate and independence in their decision-making related to their regulatory responsibilities. The KFD is separate from the authorization and the policy-making bodies NIV and RVO/TSB. There is at ILT a policy that describes the contacts between KFD and NIV. The budget of KFD is allocated by the EZ. NIV and KFD independently determine how their annual plans are executed. NIV makes an annual agreement on the tasks and budget of the RVO/TSB. There is no evidence that the independent decision making of NIV, RVO/TSB and KFD has been compromised by the EZ. The regulatory body is independent making decisions on nuclear and radiation safety.

In the Netherlands there is an integrity policy as obliged by the Civil Servant Act. If new inspectors are recruited from the licence holder's organization or from the activity overseen there is a practice that the inspector does not inspect the licence holder or activity for a certain period. However this practice is not documented. KFD has started the policy of rotating managers, inspectors and the lead site inspector at the beginning of this year and the implementation of this policy is just starting. The change of the enforcement policy three years ago was made to emphasise the impartiality of the inspectors. The policy has been well communicated inside the inspectorate. The communication to other parts of the regulatory body and nuclear facilities and activities is discussed in section 3.5. The licensing of the nuclear facilities and activities dealing with radioactive sources is transparent and open for public comments. There are barriers in place to prevent conflict of interest in regulatory decision-making. The integrity of the staff is ensured by the recruitment process and applied policies.

The NIV and KFD report to the EZ. The minister reports regularly to the parliament on the nuclear safety, radiation protection and Nuclear Energy Act issues. The Parliament can request the minister to report on any specific issue. The annual report of ILT, of which KFD is part, is sent to the Dutch parliament. The decisions of the regulatory body are public. NIV, RVO/TSB and KFD websites serve as platform for information on nuclear facilities as well as radiation and nuclear safety. The minister signs the regulations and guidance. Thus NIV itself is not able to impose mandatory binding generic requirements. The independence of the regulatory body is discussed in Section 1.

The IRRS team has been informed that ANVS will be reporting to the ministry of Infrastructure and Environment. The update and the maintenance of the Nuclear Energy Act will be shifted to the I&M. In the new proposed structure the energy policy making and regulatory oversight are separated. The ANVS is going to be an independent administrative body in the governmental structure. If the ministry of Infrastructure and Environment does not agree on the budget of ANVS it has to justify its position to the parliament.

The Dutch government in 2006 signed an agreement (Covenant) with the owners of the Borssele NPP, which allows for operation until the end of 2033, provided that the requirements of the operating licence and additional requirements specified in the Covenant are met. The Borssele Benchmark Committee (BBC) was established to assess whether Borssele NPP meets an additional requirement of performing in the top 25% in safety of the fleet of water-cooled and water-moderated reactors in the EU, Canada, and the United States. The committee will report every 5 years whether or not Borssele NPP continues to be in the top 25% of the facilities. The first report was published in September 2013 before the LTO licence for extension of its operation until 2033. KFD has no interface with the BBC. The IRRS team concluded that such agreement has not interfered with the independence of the regulatory body.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of personnel and competency needs of the various regulatory bodies have been reviewed several times during the past few years. NIV and KFD each have about 40 people, TAN has three persons and in HGS some people work part time with respect to the control of transport of radioactive materials. Furthermore, the RVO/TSB team has 13 persons. The support processes such as finance, purchasing and external communication are supported by the central organizations within the ministries of EZ and I&M. As the new regulatory body is starting its operation there is planned to be 120 persons.

The core competence is to be in-house. However TSOs such as GRS, TÜV, NRG and RIVM are used for the in-depth analysis or measurements. There are framework agreements with the major TSO organizations. Lloyd's Register serves as authorized inspection body supervised by KFD. The licensees order the inspection of the pressure equipment directly from the authorized inspection body.

The long term planning of the human resources is made by 5 years plans. This planning is to ensure sufficiency and competence of the staff. NIV, RVO/TSB and KFD have assessed its needs for competences. However a systematic structured development of the knowledge management and the competences in house is currently under development. KFD has a knowledge management process, which was started in 2014. Annually the need for the resources and training is assessed in June. The strategic planning based on the future scenarios on regulatory controlled areas for longer time perspective than 5 years would be helpful to ensure availability of competent resources in the regulatory body.

The RVO/TSB has had a systematic development programme since the year 2007 as the decision was made to shift from administrative organization into an expert organization. At TAN the training is basically on the job.

There are basic training and annual training programmes as well as the recording of the training in place. NIV, RVO/TSB and KFD have a personal training plan, but it is not formalized or structured. KFD and NIV provide new employees with initial training. KFD and NIV require its inspectors to qualify as radiation safety officers along with systems training for installations. KFD management on the basis of their judgement of inspector competences takes a decision regarding readiness of inspector to conduct field inspections. There is no formalized process supporting this system. KFD provides a training of various applicable legal base to its own personnel. This training includes information on transport regulations and transport safety.

The IRRS team observed that at NIV, RVO/TSB or KFD there is no systematic and structured training of inspectors or other staff members to become formally qualified for the regulatory activities. NIV and RVO/TSB have decided to use on the job training by following the system used for radiation protection experts. There is an intention to start this activity in the new ANVS organization. The integrity aspects of the inspectors and possible grace periods have not been laid down in the documentation of the organizations.

At the time of IRRS mission the inspection plan of KFD was found to be based on the number of existing persons in the organization rather than the oversight needs. The development of the Integrated Management System is restricted by the availability of resources. Some technical competencies such as neutrons assessment for research reactor necessary for in depth safety assessment are not available within NIV or KFD and are not supported by a TSO. The international operating experience is not fully utilized to enhance oversight due to allocation of resources.

Recent new tasks involving registration of experts, assessment of experts with foreign qualifications, recognition of radiation protection education programs and personal dosimetry services require specific knowledge and expertise. These are not all available within the regulatory body at the moment and require proper attention in the 2015 work plan of ANVS.

In several places in the report the issue of resources is mentioned and should be considered as contributing to the recommendation of this section.

For the establishment of the new organization a study has been made of the needed resources to fulfil obligations of the regulatory body and the international conventions. In that study it has been concluded that there is lack of resources. The IRRS team has identified regulatory functions where additional staff would bolster the quality of the oversight. These functions comprise licensing and inspection during construction and commissioning phases of nuclear facilities, international operating experience, management system, HF and transport. For some areas, i.e.

management system, reactor physics, only one dedicated expert is available. ANVS will need additional staff to provide support functions such as planning, human resources, financing, which now are being provided by the ministry. The assessment of the sufficiency of the resources should be done as part of establishment of ANVS and appropriate measures taken.

The pre-licensing phase is an informal phase during which most of the review and assessment work for a licence application is performed by the regulatory body. During the pre-licensing phase, the regulatory body (NIV) does not receive any funding from a prospective applicant. Only when a licence application has been formally introduced, a specific licensing fee must be paid by the applicant to cover the expenses of the regulatory body (and its TSOs where applicable). When a project is cancelled or put on hold indefinitely during pre-licensing, no funding of the regulatory body for the review and assessment work is provided.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The planned resources of the ANVS are equal to the current personnel of the NIV, RVO/TSB and KFD plus 20 persons for the support, legal and communication functions. In the planning of the new ANVS it has been estimated that the need for resources is higher. However, the actual need for the resources can only be made after the establishment of the new organization. Several gaps in the fields of expertise were identified during the mission. There is in use a pre-licensing process for which there is no mechanism to cover the costs of the regulatory review and assessment by the potential licence applicant if the project is cancelled or put on hold for an indefinite time.

| | |
|-----|---|
| (1) | BASIS: GSR Part 1 Reg 16 states that <i>“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”</i> |
| R9 | Recommendation: The regulatory body should assess its resources and competency needs, against the strategies and regulatory functions and take the measures to ensure it has sufficient resources to fulfil its statutory obligations. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NIV, RVO and KFD have training programmes and annual planning of the training needed by the staff. However no systematic, formalised and structured training programme is in place for NIV, RVO/TSB and KFD staff to become qualified regulatory personnel. Also there is no formal maintenance of qualifications of the staff members. The efficiency of the training programme of NIV, RVO/TSB or KFD has not been evaluated. Some technical competencies necessary for in depth safety assessment are not available within NIV or KFD and are not supported by a TSO.

| | |
|-----|---|
| (1) | BASIS: GRS part 1 Requirement 18 states that <i>“The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.”</i> |
| (2) | BASIS: GSR part 1 Para. 4.11 states that <i>“The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.”</i> |
| (3) | BASIS: GSR part 1 Para. 4.12 states that <i>“The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements”</i> |
| R10 | Recommendation: The regulatory body should develop a systematic, structured and formalised training programme for current and new staff involved in the management and implementation of the regulatory activities. In particular the verification of adequate |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

competence of certified inspectors should be included. The efficiency of the programme should be verified periodically.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

At the moment there is an advisory body related to the environmental impact assessment process in Netherlands. The use of advisory bodies by NIV has not been common practice since the mid 1990's due to absence of major regulatory issues and lack of independent experts in the Netherlands. There is an Advisory Committee for Radiation Protection established in 2013; the members are nominated by decision of the EZ. The tasks of the Committee are to advise in registration of radiation experts, approval of education institutes of radiation protection and the assessment of the foreign radiation protection qualifications. The term of the Committee has started 1st January 2014. The possibility to have an advisory body for AVNS has been discussed.

The NIV and KFD often ask IAEA for advice. By example specially invited IAEA groups give advice on Dutch Safety requirements in 2013, on the new Regulatory Body and its independency in 2013 and 2014, as well as advice on the safety of the HFR in 2009 and 2010.

German organizations GRS and TÜV, national TSOs RIVM and NRG are used as TSO organizations. The NIV and KFD define the work to be made by the TSO and they assess the output. In the agreements there are arrangements to ensure impartiality. For larger contracts with a TSO an European bidding procedure must be followed. In 2012 at NIV and in 2013 at KFD measures were taken to select technical organizations and consultants by applying this European bidding procedure. In this procedure requirements regarding legal aspects, administration, security and technical/non-technical expertise were defined. This bidding procedure doesn't guarantee the continuous or durable involvement of a specific TSO. Due to the complexity of technical issues and the importance of historic knowledge of the safety assessment this point could be considered as a possible weakness. This issue is partly resolved by the fact that KFD and NIV appropriate themselves with the deliverables of a TSO and the technical contents of these deliverables. All project documents from the review and assessment done by a TSO are therefore given to the contracting party (NIV or KFD), as the regulatory body owns the products of the TSO. For example, all documents and programs related to the new analysis simulator will be transferred to the regulatory body in the near future. There has been, however, no audits made to the TSOs and the possibility checking of the conflict of interests have not been considered. NIV, RVO/TSB and KFD have the capability and knowhow to contract technical support needed by regulatory body and act as an intelligent customer.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NIV and KFD do not have Advisory bodies. Advice have been asked on case-by-case based from international organizations. Beside of that RVO/TSB has an Advisory body for the registration of radiation experts.

| | |
|-----|---|
| (1) | BASIS: GSR part 1 Reg. 20 states that <i>“The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.”</i> |
| (2) | BASIS: GSR part 1 para. 4.20 states that <i>“If this is not possible domestically, then the necessary advice or assistance shall be sought from organizations in other States or, as and where appropriate, from international organizations which have no such conflicts of interest.”</i> |
| (3) | BASIS: GSG – 4 para. 2.7 states that <i>“The following list covers most of the main sources of advice, but is not intended to be all inclusive: — Sources of advice from within the State include: • Advisory bodies: many governments and regulatory bodies appoint experts in the form of an advisory committee to assist and provide advice. Such experts may be from other States, but should be appointed in accordance with clearly defined terms of reference that include criteria for their selection (see Ref. [4], paras 3.30–3.32).”</i> |
| S2 | Suggestion: The regulatory body should consider establishing an advisory body or bodies to |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

give technical or other expert professional advice as necessary in support of regulatory functions. The regulatory body should consider inviting participation of international experts to such Advisory body/bodies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NIV, RVO/TSB or KFD use national and international TSO organizations. These organizations are on the approved supplier list. There are in the agreements provisions concerning the impartiality. However NIV, RVO/TSB or KFD have not audited these organizations.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 para. 4.20 states that “Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.” |
|-----|--|

| | |
|----|---|
| S3 | Suggestion: The regulatory body should consider making arrangements to ensure and verify that there is no conflict of interest in its technical support organisations. |
|----|---|

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There are various means used to inform authorized parties in use; letters, by official communications, publications of the NVRs, website and meetings. The IRRS team noted that the NVRs are not easily accessible.

The NIV has holds meeting with the licence holders before the application and during the licensing process. The management of NIV holds regularly scheduled conferences with the management of authorized parties or the stakeholders.

The KFD has written decisions and inspection reports. The meetings are held in between KFD and licensees such as: progress meetings, directors meetings and meetings with the platform of directors of nuclear installations. With non-nuclear stakeholders there are meetings, as needed. In the field of transport KFD and HGS have not established communication mechanism with transporters. HGS plans to start communication with large transport organizations. KFD has no resident inspector, but coordination is provided by leading site inspectors. At the beginning of the year 2014 the policy of rotating the leading site inspectors has been taken in place.

The RVO has made survey of the organization of the licensing of the radiation sources in 2009 and in 2012.

A survey of the licensees regarding the NIV and KFD functions was made in 2014. Three years ago KFD changed its oversight strategy to enhance the impartiality of the inspectors and emphasises that the licensee has the prime responsibility for safety. The change of the strategy was communicated well inside the inspectorate but not so extensively to NIV and RVO/TSB and the licence holders. The survey shows that there is room for improvement of the communication of the KFD inspection and enforcement policies.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The regulatory requirements are laid down in the Nuclear Energy Act and related decrees and regulations. The Dutch approach is based on the individual licences were licence conditions are tailored according to the type of the installation. NVRs are attached as licence conditions. However at the time of the IRRS mission there were only NVRs to nuclear power plant. The participation of the licensees and the registered organizations is included in the development of legislation and regulations. The regulations and guidance is published in the Governments Gazette and on the regulatory body’s website. The coverage of the regulations and guidance is discussed in Section 9.

The licensing, review and assessment and the inspections and enforcement are based on the legislation and regulations. The oversight is based on legislation, regulations and licences. The licence conditions are tailored to the nuclear installations. The authorizations of the nuclear installation for which there are no guidance available is discussed in Section 5. The IRRS team considers that the establishment of the structured set of regulations and guidance for all types of facilities would enhance the predictability of the regulatory control. The licences are available on the regulatory bodies website.

The regulatory body has regular meetings and contacts with the major regulated organizations. The regulatory policies are communicated in these meetings.

3.7. SAFETY RELATED RECORDS

According to the Dutch law the regulatory body shall keep the records of licences, applications and review documents of these applications. The NIV has DOMUS system for safety related records. The KFD safety related records for nuclear installations are currently stored permanently. The KFD has the Holmes system where the inspection findings, review and assessment findings, incidents and enforcement actions are stored. The RVO/TSB has Terra ICT system for its licensing of sources. The Terra system is available for KFD access. More information is provided in the section 6.

The RVO has a database called TERRA, which contains all the non-nuclear licences. The licences contain the total activity that was requested in the licence application and the maximum number of radiation sources licensed. A register of HASS sources has been developed by RVO but licensed sources under the HASS exemption threshold are not included. There is no register for sources other than HASS. The RVO/TSB holds a register of radiation protection experts. The use of HASS register and radiation protection expert register is to start at the beginning of 2015. The register for the workers doses is held by NRG.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NIV, RVO/TSB and KFD have several different document management systems and safety related registers that do not communicate with each other. There is a plan to review and assess all the ICT systems and safety related registers in use and make an overall planning of the ICT systems and registers to be utilized by ANVS in support of the regulatory functions.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 Reg. 35 states that <i>“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.”</i> |
| (2) | BASIS: GSR Part 1, Requirement 35 states that <i>“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities. The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: —Registers of sealed radioactive sources and radiation generators⁹ ...”</i> <i>The regulatory body specifies which sources are to be included in the registers and inventories, with due consideration given to the associated risks.</i> |
| R11 | Recommendation: The regulatory body should consolidate and improve its systems for keeping all records relating to the safety of facilities and activities, including registers and documents related to administrative support. |
| S4 | Suggestion: The regulatory body should consider including all authorized radiation sources in the national source register. |

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The NIV formulates a communication strategy for each project and each authorization at national and local level. The draft licences are available for a period for six weeks for public comments on the NIV website. All members of the public are free to express written opinion on the draft decisions and to ask for a hearing. Also the major licences of the RVO/TSB are available for public comments on their web site. The IRRS team noted that the period of public comment on the revised licence to be issued to COVRA closed in the week of the IRRS mission.

The KFD has formulated a plan within the communication strategy to develop regular meetings with the interested parties and the public in the vicinity of nuclear installations and at national level. There are annual meetings with the local authorities.

All new legislation is published on the Internet and the Governments Gazette. Also the announcement of draft new regulations is published on the Internet and the Governments Gazette. RVO/TSB has an extensive web site

instructing the licensees in preparing the applications and reports. RVO/TSB has so called TopDesk software where all the questions and answers from public, potential applicants and licence holders are stored.

Different means of informing stakeholders is used: press releases, reports web site and meetings with interested parties and the public. The Regulatory Body issues a regulatory report and fulfils the international obligations of conventions.

The KFD has started putting event reports on its website in mid 2013.

3.9. SUMMARY

At the time of the IRRS mission the Dutch radiation and nuclear safety regulatory body functions were comprised of several distinct organizations. There has been made a decision to form a new regulatory body at the beginning of 2015 where the functions of NIV, RVO/TSB, KFD and TAN are consolidated. The new regulatory body ANVS will be under the ministry of Infrastructure and Environment. The establishment of ANVS, its organization and regulatory functions and update of the Nuclear Energy Act to reflect this are to be made in 2015. As of 1 January 2016 it is anticipated to become an independent administrative authority. There are challenges related to establishing a common regulatory culture, adequate resources, systematic qualification of the staff and improvement of the safety related records of the regulatory body. The regulatory body should consider establishing Advisory bodies and appropriate arrangements to ensure the independence of the technical support it uses.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The Dutch Regulatory Body for radiation protection and nuclear safety currently consists of various separate institutions within different ministries, each of them having their own responsibilities and competences. KFD, NIV and RVO/TSB are the main entities in the Regulatory Body, at present they are each working on their own Management System. However, at this moment the system is not yet completed, and it is separated for NIV, RVO/TSB and KFD.

Based on the government decision in January 2014 to form a single regulatory authority, an ANVS Management System will be established. All the regulatory and support activities will be documented in the ANVS Management System.

Some elements of the management system are already in place and defined by documented processes.

The MAVIM system is currently used by KFD, NIV and RVO/TSB to document the management system.

Currently, KFD's document management system does not fully satisfy the needs for managing documents for all regulatory functions. E.g. letters which are not related to inspections cannot be incorporated to this system. KFD is working on a more comprehensive system.

For KFD, NIV and RVO/TSB safety is paramount as it is clearly reflected in their mission statements. KFD, NIV and RVO/TSB have started elaborating and executing a Safety Culture development process but it has not yet been completed.

For each process and every function, national and international requirements have been identified and described by the KFD. However for NIV and RVO/TSB it has only partly been done.

The management system of NIV and RVO/TSB has not yet been completely implemented. RVO/TSB's legal tasks and other requirements are periodically checked and evaluated by an independent party. KFD uses a Plan-Do-Check-Act cycle for monitoring the adequacy of the management system.

All the three main entities in the Regulatory Body apply graded approaches in the performance of their activities. All KFD activities are prioritized commensurate with the risks involved. For NIV, the graded approach is part of the legislation on nuclear safety and radiation protection, part of the strategic policy document and part of the Annual plan. A graded approach is also taken into account by RVO/TSB when it performs its legal tasks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body in The Netherlands has not completely established and implemented an Integrated Management System. Some elements of a management system are already in place and defined by documented processes. In January 2015 KFD, NIV and RVO/TSB will be merged into one single authority called ANVS.

KFD, NIV and RVO/TSB have started elaborating and executing a Safety Culture development process.

The Management System of the regulatory body is not adequately documented. Identification and documentation of the processes are under development. NIV and RVO/TSB have developed about half of their processes in the new system, and KFD has developed the core processes but not yet all of the supporting processes.

NIV and RVO/TSB have not elaborated the complexities of processes and their interactions. KFD has elaborated its processes and the interactions between them, but not for all the processes.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1, R. 19 states that “The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.” |
| (2) | BASIS: GS-R-3; para 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.” |
| (3) | BASIS: GS-R-3; para. 2.5. states that “The management system shall be used to promote and |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|--|
| | <p><i>support a strong safety culture by:</i></p> <ul style="list-style-type: none"> —<i>Ensuring a common understanding of the key aspects of safety culture within the organization;</i> —<i>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;</i> —<i>Reinforcing a learning and questioning attitude at all levels of the organization;</i> —<i>Providing the means by which the organization continually seeks to develop and improve its safety culture.”</i> |
| (4) | <p>BASIS: GS-R-3; para 2.8. states that “<i>The documentation of the management system shall include the following:</i></p> <ul style="list-style-type: none"> —<i>The policy statements of the organization;</i> —<i>A description of the management system;</i> —<i>A description of the structure of the organization;</i> —<i>A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;</i> —<i>A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.”</i> |
| R12 | <p>Recommendation: The regulatory body should complete its program for establishing and implementing an Integrated Management System. This should include development of all processes, description of interactions between processes, internal procedures to perform different tasks and promotion and support of strong safety culture in the organisation.</p> |

4.2. MANAGEMENT RESPONSIBILITY

The management of the merging organisations is convinced of the importance of the Management System. This is shown by the leading role of the current management in the different phases of the execution of the Management System. In the NIV Annual Plan 2014 the management system is described as a separate project with resources. The management of the KFD has had a leading role in the different phases of realization of the Management System.

The senior management of the regulatory body takes the expectations of stakeholders into consideration in the activities and processes. KFD and NIV had frequent and regular meetings with stakeholders. NIV involves stakeholders on a regular basis in its activities.

Within NIV and RVO/TSB, communication is done during team meetings, on paper or through the intranet. With external stakeholders, communication is mainly done through the website, on paper and by meetings.

The KFD has an external communication strategy which has not yet been fully implemented. For safety and health, the ILT has information for staff members on the intranet.

The KFD, NIV and RVO/ TSB have developed and documented the policies.

The senior management has developed goals, strategies, plans and objectives that are consistent with the policies of the Regulatory Body. The goals and strategy for NIV and RVO/TSB are incorporated in the Annual Plans of NIV and RVO/TSB. KFD has incorporated these in Policy documents in the Management System.

The senior management reviews the implementation of the plans regularly against the organizational objectives. Each year the ILT makes a plan on inspection of that year, and KFD has a sub section in this plan. The KFD has recognized the need to review the prioritisation of inspection activities to ensure a proper coverage of important inspection areas. The KFD uses a “Balanced score card” for the monthly review The NIV and RVO/TSB Annual Plans are reviewed every three months.

Above mentioned issues are addressed with the recommendation 11 in subsection 4.1.

4.3. RESOURCE MANAGEMENT

Senior management of the Regulatory Body cannot yet allocate all necessary resources to establish, implement and continually improve the management system.

The KFD has estimated the necessary resources (staff) to reach the goals and objectives. The NIV and RVO/TSB determined the resources and provided some resources in the Annual Plan and the action plan. These are not all available at the moment.

Senior management of the Regulatory Body has ensured that individuals are competent to perform their assigned work. For each role or position within the KFD, competences have been defined. The NIV has made an analysis of who performs what tasks and what competences are needed to perform these tasks well. At NIV and RVO/TSB, a personal development plan is created for each employee and progress is discussed periodically. Every year, an educational or training plan is established, composed of basic training for new staff and retraining for the existing staff.

This subject is also covered in subsection 3.3 of this report.

The team notes that there may not be enough human and financial resources foreseen for development and maintenance of the Management System of the new ANVS.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|--|
| Observation: The human and financial resources’ of the merging organizations are not sufficient to establish, implement, assess and continually improve the management system. | |
| (1) | BASIS: GS-R-3 para. 4.1 states that <i>“Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.”</i> |
| S5 | Suggestion: The regulatory body should consider allocating sufficient resources to establish, implement, assess, maintain and continually improve the management system. |

4.4. PROCESS IMPLEMENTATION

The regulatory body in the Netherlands has not completely established and implemented a Management System. The regulatory body has not adequately implemented management system processes necessary to fully achieve goals, and all regulatory responsibilities. All tasks and activities of the KFD have been identified and described. The operational and supporting processes are developed. NIV and RVO/TSB are together working on the establishment and implementation of a Management System and also on identification and documentation of their processes. All the described processes are documented and are filed within the MAVIM web based system, which is used by NIV, RVO/TSB and KFD.

The regulatory body does not have a complete overall process for the control of documents. The KFD has a process for the control of documents that uses the ISO methodology Plan-Do-Check-Act cycle.

The NIV uses the document management system DOMUS for official documents. RVO/TSB uses the document management system TERRA. The governmental organization has general processes for organizational changes. Within the EZ (NIV and RVO/TSB) and within ILT a guideline for reorganisations is available. Within NIV, RVO/TSB and KFD senior management has their own mandate for smaller organizational changes. However, these processes and documents do not explicitly address the relationship between organizational changes and safety.

Above mentioned shortcomings are addressed with the recommendation 11 in subsection 4.1.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Self-assessment to evaluate the performance of work has not been performed at all levels of the organisation. Within the KFD, there are self-assessments for the management system, but there are no formalized self-assessments for other activities, tasks or functions within the KFD.

Within NIV/TSB, there are non-formalized self-assessments, which are often organized with an external independent facilitator. NIV, KFD and RVO/TSB employees can also give their findings in the employee satisfaction studies, which are carried out every couple of years. The regulatory body does not have arrangements for independent assessments.

The regulatory body does not monitor and / or does not measure the effectiveness of its management system because the Regulatory Body as a whole has not yet a fully operating integrated Management System. However the KFD does have an operating Management System of which the effectiveness is already partly measured and monitored by the use of performance indicators. The management system of NIV and RVO/TSB is still under construction and therefore the effectiveness is not measured yet.

The regulatory body as a whole does not have arrangements for the management of non-conformances within its management system as that it is under development. The KFD-document 'Procedure preventive and corrective measures' describes the process for handling non-conformances. The management system of RVO/TSB and NIV is under construction and arrangements for non-conformances are not yet prepared.

The regulatory body as a whole has not yet arrangements in place for the improvement of its management system. The KFD uses the Plan-Do-Check-Act Cycle for improvement of the management system.

For NIV/TSB, the PDCA cycle will be one of the leading principles of the management system, but this is under construction.

Above mentioned shortcomings are addressed with the recommendation 11 in subsection 4.1.

4.6. SUMMARY

The regulatory body in the Netherlands has not completely established and implemented an Integrated Management System. In January 2015, KFD, NIV and RVO/TSB will be merged into one authority called ANVS and, consequently, a new management system will be established.

Some elements of the Management System are already in place and defined by documented processes.

Since the regulatory body is constituted of various entities in a number of ministries, different sets of documents are used for the management system of the regulatory body. Identification and documentation of the processes are under development.

The KFD, NIV and RVO/TSB have started to elaborate and execute a Safety Culture development process.

The senior management of KFD, NIV and RVO/TSB should provide the appropriate amount of resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The national legislative framework provides the generic nuclear safety and radiation protection objectives that apply to all nuclear installations. In order to perform any activity (use, processing, storage, disposal, transport) involving fissile material, radioactive materials, or any source of ionizing radiation (whether artificial or naturally occurring), it is required to obtain an authorization issued under the Nuclear Energy Act or the Radiation Protection Decree.

The authorization process in the Netherlands covers all the life stages of nuclear installations and is supported by a comprehensive legal framework. The framework incorporates the principles of a graded approach and transparency of decision making, including public consultation.

The licences for nuclear facilities and for the transport of fissile materials are granted by NIV. The RVO/TSB has the mandate to grant licences for non-nuclear facilities using radioactive sources or generators and for the transport of radioactive materials (excluding the larger transports of fissile materials). Some authorizations, in particular regarding the approval of nuclear pressure equipment have been designated to a notified body (Lloyd's Register Netherlands BV).

The licence holder, who is the operator of the facility but may be different from the owner of the nuclear installation, is assigned the responsibility for safety.

In the authorization process both NIV and KFD rely on their own experts and can be supported by TSO such as GRS and NRG for review and assessment. No standing advisory board on nuclear safety exists or is consulted during the licensing procedure.

The procedure to grant a licence follows the generic administrative process described in the General Administrative Act. This procedure provides for a public involvement in the licensing process. As part of a licence application for a nuclear facility, it is often also compulsory to conduct an Environmental Impact Assessment (EIA).

Transparency is a key item of the licensing process. During the licensing process, information is provided to the public on the government gazette, on the internet, and on occasion, in public hearings. Any person can request information related to administrative matters as contained in documents held by public authorities or companies carrying out work for a public authority.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Licensing of all nuclear facilities (nuclear power plants, research reactors, fuel cycle and waste management facilities) follows the same regulatory process described in the Nuclear Energy Act.

The basic principles and generic guidelines for licensing of nuclear facilities and transport of fissile materials are being described in a Dutch Licensing Policy document. A first version of this Dutch Licensing Policy was approved in October 2014 by the NIV management for its licensing activities (related to nuclear facilities and transport of fissile materials). This Dutch Licensing Policy document is based on past experience and describes the current practices on licensing activities and gives guidance on the review and assessment of licence submittals. The Dutch Licensing Policy prescribes that the licence conditions should be goal-oriented as already stated in the Nuclear Energy Act. NIV plans to make this Dutch Licensing Policy public and available to applicants and licensees.

The Nuclear Energy Act stipulates that a licence must be obtained to construct, commission, operate, modify or decommission a nuclear facility. The different types of licences given by the NIV to nuclear facilities are construction licences, commissioning and operating licences, decommissioning licences, modification licences and revision licences.

The regulatory body is not directly involved in the decision of general siting of new nuclear facilities. For nuclear energy production, three possible sites were pre-selected by the Government. A specific "siting" licence is not included in the Dutch nuclear licensing system. The licensing procedure for new nuclear installations includes an EIA in which the impact of the nuclear facility on the surrounding environment is assessed. The impact of the site on the nuclear facility is dealt within the nuclear licensing procedure. Hence NIV has the authority to establish site-

related conditions for a facility or can reject a construction licence based on siting concerns. A reassessment of the site related effects is also performed during periodic safety reviews of nuclear facilities.

In the licensing of nuclear facilities, two procedural options exist:

- A long version which includes stakeholder consultation of a draft decision issued by the regulatory body. The formal period to decide upon the application is six months. This long procedure is always used when an EIA is made.
- A short version where the final decision is directly issued by the regulatory body. The formal period to decide upon the application is 8 weeks. The regulatory body can opt for this short procedure when the modification does not imply greater adverse effects on the environment than is tolerated under the existing licence.

In the last decades, all licence applications were modifications to existing nuclear facilities and no new nuclear facilities have been licensed, constructed or commissioned. Little or no experience remains within the regulatory body to deal with the licensing and inspection activities during construction and commissioning phases. As the pre-licensing phase of the new research reactor PALLAS is scheduled to be started in the immediate future, this is a point of attention for the regulatory body. It is foreseen that a construction licence will contain hold-points and witness-points where an approval or intervention by the KFD will be necessary. Before nuclear or radioactive material is introduced in the nuclear facility (hot commissioning), a “commissioning and operating licence” must be granted which will also identify additional hold and witness-points to be checked by KFD. NIV assesses the contents of the Safety Analysis Report before operation is permitted. The regulatory body is developing a strategy for new build.

The Minister of EZ is responsible for the entire licensing process including its coordination. This coordination includes the consultation of all relevant advisory bodies during the public consultation of the draft decision. Licences have an integral character, this means that licence conditions also contain prescriptions based on other regulations next to the Nuclear Energy Act. For example it has general prescriptions to protect the environment (conventional aspects). NIV recently hired a consultant to report on the state of the art “conventional and environmental” aspects (fire safety, storage of chemicals). This report serves as an input for the establishment of required documents in a licence applications and possible related licensing conditions. During the licensing process, certain governmental authorities (province, local community, Water State Authority) can give advice on draft licences and thus ensure that these conventional aspects are adequately treated. This should ensure consistency with the licences of non-nuclear facilities. On a general level, further expertise is being developed within the NIV on these conventional issues.

The maximum time to issue a licence is by law limited to six months (so called “long licence procedure”). If needed, the NIV can extend this period based on a justification (such as the complexity of application, the large numbers of stakeholder comments to be addressed). This strict time limit does not allow enough time for a thorough review and assessment for some more complex licence applications.

Therefore for these complex licence applications, the regulatory body has been pro-active by organising an informal pre-licensing phase with applicants to exchange information on the design of the project and make the review and assessment work more efficient. This pre-licensing phase is considered a commendable practice. This pre-licensing phase is not required by law and no rights can be acquired from it by the applicant. This pre-licensing phase can take up to several years and has no definite time limit. An internal guidance (“Roadmap for pre-licensing of complex licence applications”) is being drafted for the new ANVS to ensure a consistent approach for this pre-licensing. Some recent or planned examples of pre-licensing projects include the new build Pallas research reactor, the Oyster project for the Delft research reactor and the Long Term Operation (LTO) project for the Borssele NPP.

The minimum contents for licence applications are described in the Nuclear Facilities, Fissionable Materials and Ores Decree: description of the site and installation, Safety Analysis Report (SAR), Probabilistic Safety Analysis Report. The licence application file is checked on its completeness and acceptability by NIV, using a checklist. A number of requirements (for example contents of a SAR and safety demonstration) will be regulated in more detail when the Dutch Safety Requirements for nuclear reactors (in particular section 5) come into force.

After an independent technical review and assessment of the licence application by NIV, a draft licence decision is made public for stakeholder comments together with the NIV evaluation of the safety aspects of the licence application. For larger projects a separate NIV Safety Evaluation Report is published.

Before the final licence is granted, the enforceability and the feasibility of the draft decision are evaluated by the entity responsible for inspections (KFD). A specific “Feasibility and enforceability test” by the KFD is included in the licensing process.

Taking these views into account, a final licence might be granted by NIV. The licence decision contains a detailed justification why and how the decision was made. Every stakeholder comment or view is to be addressed in the final licence decision (evaluation if the comment is applicable, how it was taken into account in the licence conditions). Licences are granted for an indefinite time period, but a periodic safety review is required for nuclear facilities.

After the final licence is granted, it is published and open for public scrutiny, including the licence conditions and the “Safety Report” (see below). Any stakeholder (licensee, member of the general public) who can prove an interest can lodge an appeal at the Administrative Court within a period of 6 weeks.

Typical licence conditions or limitations which are imposed through the licence are reactor power and fissionable materials limits, emission limits to water or air, organisation and operational requirements. Similar licence condition topics are used for different nuclear facilities. The licence refers to the “Safety Report” (which is a summary of the SAR with all main safety parameters) which was used during the licensing process for stakeholder involvement. This document could be several hundred pages long but is not considered a living document and is used for licensing purposes and public information.

Due to the small number of nuclear facilities and their variety the regulatory body has chosen not to develop a general regulatory framework and prefers to specify precise safety requirements in the individual licences (so-called “Dutch approach”). This is considered by the Dutch authorities a more effective and practical way than drawing up extensive regulations and guides for specific types of facilities. This means that a relatively large number of nuclear safety issues are regulated through the licence requirements rather than in generally binding regulations.

The NIV has developed for the Borssele NPP a set of NVRs that consist of IAEA Safety requirements and guides that are slightly adapted to the specific Dutch situation. These NVRs will be made public. The licence of the NPP include requirements that the NVRs must be followed by the licensee (which makes them binding). In this way specific requirements on subjects such as ageing management, severe accident management and licensing of plant personnel are covered. For other nuclear facilities (research reactors and fuel cycle facilities), the licence does not refer directly to NVRs but reference is made to specific IAEA Safety standards and guides. Actions are foreseen to develop and implement more specific guidance for these facilities, for example on ageing management of research reactors (Suggestion S13 in Section 9 addresses this issue).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Due to the small number of nuclear facilities and their variety the regulatory body has chosen not to develop a general regulatory framework and prefers to specify precise safety requirements in the individual licences (so-called “Dutch approach”).

The operating licence of the Borssele nuclear power plant refers to the Dutch NVR-guides which form an integral part of the licence. However for other types of nuclear facilities, no similar NVR-guides exist, in some cases reference is made to specific IAEA Safety standards and guides, in other cases no such reference is made.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 para. 4.28 states that “ <i>There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties</i> ”. |
| R13 | Recommendation: The regulatory body should enhance the consistency of different licences by using similar reference documents in the licences of all nuclear facilities (NVR and/or IAEA Safety standards and guides). |

The KFD is in charge of analyzing licensee proposals for modifications and decides whether these modifications require a modification of the licence or not. This is done based on an assessment of the possible impact on the “Safety Report” which is referred to in the licence and on the impact of the content of the licence. There is no KFD

and NIV common evaluation on the impact of a modification on the existing licence. In case of doubts whether a licence modification is needed, KFD will discuss this with NIV.

If the licence or any document which is referred to in the licence (such as the “Safety Report”) are to be changed, a formal application must be introduced to the NIV which will do the further review and assessment. If no licence modification is needed, the KFD will do the review and assessment of the modification and follow up on its implementation.

When a licence for a modification to an existing nuclear facility is requested by a licensee which has already different licences, NIV can stipulate that a revision licence must be requested by the licensee to have an updated general overview of the licensing situation. A licensee can also voluntarily request a revision licence. A revision licence gives the opportunity to combine all previously granted licences into one coherent, easily readable licence, and is to be considered a commendable practice. A revision licence application must go together always with the application of a modification of the licence. It is suggested that the regulatory body should consider developing an internal strategy or overall planning when a revision licence application will be requested to the different licensees. There is not a specific link between the revision licence process and periodic safety reviews. For example the last revision licence for the Borssele NPP and the Delft research reactor dates from the '90s.

The NIV has the possibility to change a licence because of technical advances, based on operational experience or new possibilities to protect the public. Examples of this prerogative of the regulatory body are additional licence conditions for the NRG facility to enhance the disposal of accumulated historical waste.

A licence cannot be suspended by the regulatory body. However, the regulatory body (KFD) has the authority to shut down an installation if needed. Further, the regulatory body (NIV) can revoke a licence. This is usually used as a means of termination of the licensee's period of responsibility.

A licence pursuant the Nuclear Energy Act is personal and its transfer to a new licence holder is subject to specific requirements (prior approval by the regulatory body through a new licence, assessment of security provisions, competency, solvability of the new licence holder). NIV will check the organisational aspects of the (new) licence holder. No specific internal guidance exist for this transfer evaluation, but where needed the NIV will consult other governmental bodies (for example the Ministry of Finances to check the solvability of a licence holder). The KFD will check that the key management staff are compliant with the applicable personnel requirements (as defined in the licence, the Safety Report and applicable NVRs).

Any member of the public can apply to the minister of Economic Affairs to amend a licence of a nuclear facility in the interest of nuclear safety and environment. The regulatory body (NIV) decides whether such a request fulfils the criteria stated in the Nuclear Energy Act and action should be taken to amend the licence.

In 2013 a licence under the Nuclear Energy Act was granted to Borssele NPP to extend its lifetime to 2033. The NIV performed a review and assessment of this LTO licence application. Specific licence conditions dealing with ageing management programmes, maintenance and inspection programmes were included in this licence. Taking into account the extended design life of 60 year, as a licence condition the licensee was required to submit an implementation plan for improvement measures to the ageing management system, which were based on the results of the assessment by NIV and the results of the 2012 IAEA SALTO mission.

The KFD is involved in the certification of personnel which are assigned to a designated safety related position at nuclear power plants. For nuclear power plants, control room operators must pass written exams and a specified period of simulator training before they are submitted to an oral examination. KFD inspectors and licensee management are members of the examination board. KFD will assess whether the examination process was correctly performed and will co-sign the certificate given to the control room operators.

Further requirements on the competence of the personnel and on management and organization of the licensee can be specified in the licence of nuclear facilities. The adequate qualification and training of safety related personnel is in the scope of inspections performed by KFD at all nuclear facilities.

5.3. AUTHORIZATION OF RESEARCH REACTORS

Licensing of research reactors follows the same regulatory process described in section 5.2. The presence of experimental devices or experiments, and possible core configurations are to be described in the SAR. It is also

expected that the SAR for research reactors will include a description of the licensee's way of grading or waiving of a certain requirement (in line with Annex No. 6 of the Dutch Safety Requirements) and provide its justification in a traceable manner.

One of the results of the last PSR of the Delft RR is the requirement to develop an ageing management program. This requirement will be included in a future revision of the licence.

For research reactors, a formal certification of control room operators by the KFD is not required by the licence. Certification for these operators is done by an internal licensee process.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

Licensing of fuel cycle facilities follows the same regulatory process described in section 5.2

New rules and regulations have recently been drafted, establishing the requirements for new reactors (nuclear power plants and research reactors), known as the 'Dutch Safety Requirements' (DSRs), which will be used by NIV when assessing changes to existing installations. However, these rules are not currently drafted as to encompass fuel cycle facilities. On the other hand, the IRRS team identified the plan of NIV determining the parts of the DSR and the Management & Organisation requirements that will be applicable to fuel cycle facilities (See also Suggestion S14 in Section 9).

For fuel cycle facilities the KFD is not involved in the certification of personnel.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Licensing of radioactive waste management facilities follows the same regulatory process described in section 5.2.

In line with the national policy on radioactive waste management, a centralised facility for predisposal management of all radioactive waste has been established. Within this facility several facilities are operated for the predisposal management of the various types of waste produced in the Netherlands. The COVRA site includes facilities for the treatment and conditioning of low and intermediate level waste treatment (AVG), the storage of low and intermediate level waste (LOG), the storage of high level waste (HABOG), the storage of NORM waste (COG) and the storage of depleted uranium (VOG).

These facilities are all authorised under the licence issued to COVRA. The COVRA licence conditions include a requirement for a periodic safety review every ten years. Furthermore, a less detailed safety reassessment is required every five years. The regulatory body has identified the need to improve the authorisation conditions related to management system, periodic testing and inspection and the contingency plan and arrangements of COVRA. Consequently the regulatory body is in the process of amending the current licence (including also a revision of the licence) issued to COVRA. It was noted that this process included a public consultation and consultation with the KFD.

There is currently some historical waste stored at the site of the research facility at Petten. This is licensed under the authorisation issued to NRG. It is intended that this waste will be transferred to COVRA by 2020. Options for the conditioning of the waste prior to transfer are being investigated.

Based on the approach of long term storage (100 years plus) at COVRA the Netherlands has not established any requirements related to siting, design and authorisation of waste disposal facilities. The IRRS team also noted that there is currently no intention to develop regulations related to radioactive waste disposal in the near future. A programme that identifies the necessary steps for research, site selection, design, construction, commissioning, operation, closure and post-closure of the disposal facility would facilitate the further implementation of the national waste management strategy. This would contribute to avoiding undue burdens on future generations and to making effective use of the current knowledge about radioactive waste management in the Netherlands.

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES

The legal foundation for radiation protection and nuclear safety in the Netherlands is based on the Nuclear Energy Act and a number of associated decrees and regulations based on this Act. In accordance with Article 29 of the Nuclear Energy Act, practices with radioactive sources and generators require a licence. The graded approach is applied through the concepts of exemption, notification and authorization.

The RVO issues the authorization for all practices involving radiation sources. Minimum requirements for application documents are indicated in Regulation Implementing the Radiation Protection Decree and in RVO Standard Documents and in a large set of application forms. In assessing all applications, RVO considers justification of the practice, optimisation of the protection of workers, patients and the environment, compliance with dose limits for workers and the general public and the qualifications of radiation protection qualified personnel. As part of this decision making process, RVO has drafted different model licences for many common applications of ionising radiation which contain licence conditions that ensure adequate implementation of the ALARA principle.

The licences for radiation sources are usually granted for indefinite periods of time and are free of charge. Licence conditions and restrictions are specific to the licensed practice and currently some 28 different standard models have been established covering a range of different practices. In drafting specific licence conditions, RVO may consult with the relevant Inspectorates such as KFD, I-SZW, IGZ, SodM as to verify the workability or enforceability of the proposed conditions and to ensure that the conditions are clear and unambiguous.

The procedures to obtain a licence for radiation sources must follow guidelines set down in the General Administrative Act and these provide for public involvement in the licensing process. In a case of radiation sources this process involves 8 weeks for licensing and 6 weeks for objection by stakeholders.

The licensing authority is required to be notified by the licensee of all minor and major changes in the activities including termination of practices of the licensee. Reuse and/or recycling of radiation sources is compulsory, if reasonably possible. This is a general requirement that applies to all practices and work activities, and is laid down in the Radiation Protection Decree.

The RVO has a database called TERRA which contains, amongst other information, documentation about the total activity of radiation sources that they have authorised. TERRA only contains the total activity that was requested in the licence application and there is no information about the actual number of radiation sources involved. A register of HASS has been developed by RVO. Sources under the HASS threshold are not included. The IRRS team suggested to extend the national register to include all authorized radiation sources in the Netherlands as addressed by Suggestion S4 in section 3. For the HASS, the financial security for the long term management of the source is checked and the records of the source are maintained.

The process of notification of a change in the licensed activity (amendment of a licence) is treated in a manner similar to that of a licence application. Licences can be revoked on request by the licence holder, based on termination of practices. They can also be revoked by RVO if the licence has not been used for a period of at least 2 years and also as a consequence of enforcement action.

Transfers of radioactive sources to/from other EU Member States are conducted in accordance with the EU Regulation 1493/93/Euratom. Apart from radiopharmaceutical products and consumer products, the import of radiation sources into and the export out of the EU does not form part of the Authorization system, but is covered by a notification process. The import/export of high activity sealed radioactive sources is not covered by an authorisation process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Under the Dutch system, the import/export of high activity sealed radioactive sources is not covered by an authorisation process.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1, Requirement 23 states that <i>“Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process”</i> . |
| (2) | GS-G-1.5 para 3.29 states that <i>“In principle, a licence should be required for the higher risk or more complex practices, including those for which the radiation protection depends significantly or largely on human performance, as with some medical applications (e.g. radiotherapy) and industrial radiography, for example”</i> . |
| S6 | Suggestion: The regulatory body should consider extending the scope of authorisation to include the Import/Export of high activity sealed radioactive sources. |

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The licensing of decommissioning activities follows the same regulatory process described in section 5.2. Decommissioning of a facility is seen as a distinct phase in the facility lifecycle and requires authorisation by the regulatory body. This is effected as a modification/amendment of the operating licence. Furthermore, an EIA is required for decommissioning of nuclear facilities.

In principle the licensee is responsible for all aspects of decommissioning. New legislation, introduced in April 2011, requires that a nuclear facility shall be decommissioned directly after final shut down.

The regulatory body has identified improvement possibilities for aspects of the management system, documented programmes for maintenance, testing, surveillance, inspection and ageing, the safety case and contingency plans and arrangements. Such improvements are scheduled to be implemented in 2016.

Currently the legislation in place does not contain provision for retaining regulatory body key staff. As far as staffing of the regulatory body is concerned as well as the maintenance and transfer of competences and knowledge, the findings given in section 3.3 on the general staffing and competence of the regulatory body, are also applicable.

The Shutdown and Decommissioning regulations and the BkSe Decree contain requirements relating to the need to retain appropriate qualified expertise for purpose of decommissioning, at nuclear installations. These requirements should be extended to all other regulated facilities, including non-nuclear facilities.

5.8. AUTHORIZATION OF TRANSPORT

The regulatory responsibilities for the safe transport of radioactive material are primarily allocated to the various ministries making up the Regulatory Body through the Nuclear Energy Act. Additional authorities and requirements are specified by various topical decrees including the Radiation Protection Decree; the Import, Export and Transit Decree; and, the Fissionable Materials, Ores and Radioactive Materials Transport Decree. The transport of radioactive materials by road, rail, air, and waterborne modes is regulated in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) and the relevant modal instruments (ADR, RID, ICAO, ADN and IMDG).

Under the Ministry of Economic Affairs, NIV and RVO regulate the transport of radioactive material through the assessment of applications for transportation licences and the associated technical documentation for licensing. NIV licences transport associated with nuclear reactors including the transport of fresh and spent nuclear fuel as well as the transport of fresh and irradiated targets. Likewise, RVO licences radioactive material transport for non-nuclear activities and fuel cycle-related activities. Licences may be issued to the Consigner, the Carrier or the Consignee and any one of these licensed parties is required to be the licensee of record for a particular shipment taking sole responsibility for ensuring that the transportation of radioactive material is accomplished safe and in compliance with applicable regulatory requirements.

In general, the authorization process for licensing the transportation of radioactive material takes a graded approach. Specific authorization is required for the shipment of all fissionable materials, including fissile materials, radiopharmaceuticals, certain consumer goods, and shipments requiring special arrangements (regulatory exemptions). Other shipments of radioactive materials only require prior notification of the appropriate regulatory body depending on the form and quantity of radioactive material involved and the transport mode being used for the shipment. Two exceptions to the graded approach were noted where the transportation of depleted uranium requires a licence whereas the transport of a high activity sealed source only requires notification. It was noted that the latter example will soon change so that all high activity sealed source shipments will require a licence, rather than notification.

Both RVO and NIV make transport licence applications and supporting guidance material publically available to prospective applicants via the internet. All aspects relevant for the safety of the shipment must be included in the documents submitted in approval request. The transport application documents are reviewed for conformance with the requirements of the Nuclear Energy Act, topical decrees and review guidance. NIV provides guidance describing the information to be submitted with the application on line and as appropriate is incorporated in the application. Some guidance for completion of RVO transport licences applications is contained in the application form and an additional guidance brochure is under development by RVO and NIV staff and is scheduled for

publication in 2015. Applications can be made electronically using dynamic PDF or PDF forms. Safety documentation submitted by an applicant is compared with legal requirements for the design of type-approval and shipment. Licences incorporate documents and procedures submitted with the application as a legally binding component of the licence. Radioactive transport licences are processed in accordance with the Netherlands General Administrative Act.

Regulatory provisions exist and are implemented by NIV to license special arrangement shipments of radioactive material when unique circumstances exist that would prevent compliance with existing transportation requirements. NIV reviews the justification for exemptions from specific regulatory requirements and, taking the form and quantity of radioactive material involved into consideration, issues a new short term transport licence with special conditions to provide an equivalent level of nuclear and radiation safety during the shipment.

Independent interviews of the RVO and NIV licensing staff as well as of KFD inspection staffs revealed the existence of organisational policy barriers that prohibit technical discussions at the staff level between the inspection and licensing groups. Recommendation 7 in Section 3 addresses this issue.

5.9. SUMMARY

The IRRS team concludes that the authorization process in the Netherlands covers all the major life stages of nuclear installations and is supported by a comprehensive legal framework. It implements a graded approach and benefits of an extensive transparency policy. The administrative bodies involved in delivering authorization are related to their domain of competency provided by the regulatory framework.

Due to the small number of nuclear facilities and their variety the regulatory body has chosen not to develop a general regulatory framework and prefers to specify precise safety requirements in the individual licences (so-called “Dutch approach”). The IRRS team recommends the regulatory body to enhance the consistency of different operating licences by using similar reference documents in the licences of all nuclear facilities. The regulatory body has been pro-active by organising an informal pre-licensing phase with applicants of nuclear facilities, which is considered a commendable practice by the IRRS team.

A programme that identifies the necessary steps for research, site selection, design, construction, commissioning, operation, closure and post-closure of the disposal facility would facilitate the further implementation of the national waste management strategy. This would contribute to avoiding undue burdens on future generations and to making effective use of the current knowledge about radioactive waste management in the Netherlands.

Decommissioning is seen as a distinct phase in the facility lifecycle and requires authorisation by the regulatory body. This is effected as a modification/amendment of the operating licence.

For radioactive sources, a graded approach is applied through the concepts of exemption, notification and authorization. The IRRS team suggests to extend the national register to include all authorized radiation sources in the Netherlands. The regulatory body should also consider extending the scope of authorisation to include the Import/Export of high activity sealed radiation sources.

The IRRS team concludes that transport of radioactive material in the Netherlands is well established and an appropriate governmental, legal and regulatory framework for the safety of transport of radioactive material is in place.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The regulatory framework provides the generic nuclear safety and radiation protection objectives that apply to all nuclear installations. The review and assessment of licence applications and compliance verification encompasses all radiation risks associated with the installation and follows a graded approach whereby the depth and scope of review and assessment of the facility is commensurate with the radiation risks. The conduct of technical review and assessment occurs at different stages of the times throughout the lifetime of installations and involves mainly staff within NIV and KFD, in addition to experts from different organizations outside the regulatory body.

As the Netherlands has a limited number of nuclear installations, the regulatory body has chosen to implement regulatory requirements by way of site-specific, tailor-made licence conditions rather than through generic, performance-oriented regulations and general safety documentation.

Responsibility for the review and assessment

NIV and KFD have shared responsibilities for review and assessment of nuclear installations. Primarily, NIV is involved with licence-related review and assessment, mostly during:

- the pre-licensing phase,
- the licensing phase, and
- any licence modification or update

Before issuing a licence, NIV consults with KFD in order to ensure that the proposed licence conditions and requirements are clear, unambiguous and enforceable.

The inclusion of new requirements for existing installations is done through licence updates which entail a complete review of the requirements or through licence modifications that deal with updating requirements related to what might be encompassed by a given modification of licence conditions. The Dutch “existing right principle” stipulates that the requirements can in principle only be related to the modification, though this concept is itself balanced with the “continuous improvement principle” that is also in the Dutch regulation. In practice, this notion is understood extensively.

The IRRS Team found that some licence requirements are not consistent across the different installations due to the infrequent licence revisions and differences in the availability of regulatory reference documents for the different nuclear installations. For instance, NIV issued a life-time extension licence modification for the Borssele NPP but not for any of the other nuclear installations.

The KFD is responsible for conducting the review and assessment necessary to assess the licence holder compliance with requirements on nuclear safety, security and non-proliferation. Safety assessments are conducted by KFD in order to verify the consistency of technical and organisational modifications implemented by the licence holder in compliance with licence conditions. Safety management aspects are also reviewed during periodic safety reviews or audits.

Scope of review and assessment

The scope of review and assessment conducted by NIV and KFD encompasses all radiation risks. For NIV, the safety goals to be fulfilled by licensees are discussed on a case-by-case basis between NIV and the licensee to account for actual state of the art or on the basis of existing references. These requirements are formalized into a letter to the operator before the beginning of the licensing procedure, and are then usually included in the licence.

The KFD has the responsibility to verify compliance with the licensing basis, so their assessments are bounded by the licence conditions, and other regulatory requirements, and related documentation (mostly the justification of the safety case by the operator). As part of the review process, KFD holds periodic internal Inspector Group meetings where the results of review and assessment can be discussed and can therefore feed into the inspection planning process.

As mentioned earlier in this report, KFD and NIV review and assessment functions will merge together in 2015 under the new single regulatory body ANVS.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Prioritization of the workload regarding review and assessment

Modifications proposed by licence holders are required to be categorized according to their safety significance and require prior approval by the regulatory body before their implementation. The licence holders follow a graded approach with regard to the impact on safety or implementation schedule.

At NIV, the prioritization of tasks is made by the management; for licence application the general goal is to manage demands within a 6 month period as far as practicable, whereas KFD activities regarding review and assessment are part of a multi-year plan prepared on the basis of significance of the risk posed. The review and assessment processes are described in internal documents through a generic process for review and assessment and specific internal instructions.

For important modifications to the licence, the important new requirements will be implemented progressively through a transition period, while others will have a non binding status and will be implemented as far as reasonably achievable.

Monitoring (tracking) of the review and assessment process and document control system

Both NIV and KFD are structured into teams dealing with different areas such as nuclear facilities, radiation protection, etc., in a project orientated management mode. For review and assessment of licence applications, NIV organises each licensing activity into a project, each of which is validated by management who allocates resources based on a NIV project plan. Each project is implemented by a document that defines and allocates tasks to staff from a review and assessment pool. The leader of the project is an experienced staff member who reports to the management.

Similarly, at KFD two teams deal with ongoing inspection, review and assessment of modification applications and periodic safety reviews, while other topics like radiation protection and transport are dealt with in different teams. In collaboration with the management, each team produces an annual work plan that identifies activities and deliverables. KFD management validates the annual work plans and allocates resources and competencies to each team. Management undertakes monthly monitoring of progress against the defined deliverables.

Each significant activity is organised and managed on a project based approach. Projects are conducted by technical personnel under the supervision of management. At KFD, the project management and reporting system uses an information system (HOLMES) that collects and organises each information flow for the project and identifies each deliverable to be produced, including those from TSOs.

The HOLMES database is used by management and the project managers and limits access to information only to people who require it. HOLMES is also used for task allocation, information distribution and reporting. HOLMES is an important contributor to quality assurance since it records the validation steps by each contributor and allows open issues and pending projects to be easily identified.

On completion of a project, the licence holder is notified of the conclusions. Any issues are then integrated by the licence holder into an action plan that is followed up by KFD.

The KFD does not have a specific system for the management of technical documentation; ie, historical technical knowledge of the nuclear installation and documentation on technical issues important for safety evaluation. KFD has limited local technical paper archives and relies on the national archive system to retrieve information.

Quality control of review and assessment processes and documents

At both NIV and KFD, the quality of deliverables is verified through the use of peer review, the “four eyes principle”, which requires that a document compiled by one person is validated by another person. The NIV has developed a list of persons authorised to validate documents based on their competencies. Similarly, at KFD, the reviewer (or Inspector) and the person who validates the document are not the same person and they must also have the required competencies.

For each step of the review and assessment process there is also the option to organise an internal peer review by a panel.

Staff specific competence and training in the area of review and assessment

Following a review by NIV and KFD of the required staff competences for review and assessment, it was concluded that some competencies are missing for the in-depth assessment of safety for some relevant subjects. Scarce reviewer working hours are shared by different project managers and arbitration between projects is made by the management. On this basis, the technical staff is organized in such a way as to concentrate on the more safety significant issues.

The IRRS Team noted that this type of arbitration for the allocation of internal or external resources is difficult having regard to the level of safety required for nuclear installations.

This issue is addressed also in the subsection 3.3.

6.1.2. MANAGEMENT OF REVIEW AND ASSESSMENT

Availability of internal guidance for review and assessment

The NIV has developed an internal organisational review plan and a technical review plan both of which are used as internal guidance for review and assessment. These two documents form together the Dutch review plan and will be made available to the public and licence holders.

A draft NIV document Organisational review plan (“Guidance on organisational tools and prerequisites for the review of the Safety Analysis Report as part of Nuclear Reactor Licensing in the Netherlands”) gives guidance on the organisational aspects of the NIV review process for licence applications (for example the use of the “four-eyes” principle for review of work).

A technical Review Plan (“Review Plan for the Safety Analysis Report as part of Nuclear Reactor Licensing in the Netherlands”) is being developed by NIV for the review and assessment of new nuclear reactors. At the moment this review plan is focussed on the design stage of new reactors and modifications. The main objective of the technical Review Plan is to ensure a high quality review in which the technical experts manage their review activities according to the safety-significance of the issue being considered. In addition it aims to ensure a uniform and transparent review process so that all applicants are treated equally. This technical Review Plan could form the basis for project specific review and assessment plans for all types of nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The basic principles and generic guidelines for licensing are described in a NIV document “Dutch Licensing Policy” which is not yet made public. A draft NIV document “Organisational Review Plan” gives guidance on the organisational aspects of the NIV review process. A draft NIV document “Technical Review Plan” contains more detailed review recommendations and gives more detailed guidance on the required contents of a Safety Analysis Report in support of an operating licence application.

(1) **BASIS: SSG-12 para. 2.26 states that** *“The regulatory body should develop regulations for the licensing process of nuclear installations and should provide guidelines for applicants in order to provide clarity and transparency in the licensing process.”*

(2) **BASIS: GSR Part 1 para. 4.34 states that** *“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization.”*

S7 **Suggestion: The regulatory body should consider finalizing and publishing the “Dutch Licensing Policy”, “Organisational Review Plan” and “Technical Review Plan” in order to provide clarity and transparency in the licensing process.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: A draft Dutch Review Plan is being developed by NIV for the review and assessment of reactors (nuclear power plants and research reactors). At the moment this review plan is focussed on the design stage of new reactors and modifications. As several new-build projects are foreseen in the near future (Pallas research reactor, Oyster project), a need will arise for the regulatory body to clarify its procedures and guidance for “construction, commissioning and operating” licence applications and related review activities during construction and commissioning.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|--|
| (1) | BASIS: SSG-12 para. 2.26 states that “ <i>The regulatory body should develop regulations for the licensing process of nuclear installations and should provide guidelines for applicants in order to provide clarity and transparency in the licensing process.</i> ” |
| (2) | BASIS: GSR Part 1 para. 4.34 states that “ <i>The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. ...</i> ” |
| (3) | BASIS: GSR Part 1 para. 4.29 states that “ <i>Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). ...</i> ” |
| S8 | <p>Suggestion: The regulatory body should consider extending the scope of the “Dutch Review Plan” to give guidance on the licensing and review and assessment for</p> <ul style="list-style-type: none"> • other types of nuclear facilities (including fuel cycle facilities and waste management facilities) • all stages of the life cycle of the nuclear facility (siting, design, construction, commissioning, operation and decommissioning). |

The NIV works with two information systems (a historical one, ATLAS, and a recent one, DOMUS) to access its own archive and to access structured project documentation. The use of these information systems and documentation structure is described in an internal document. Changes in the information systems during recent years may be a challenge for the preservation of historical and technical information on nuclear installations.

The KFD has undertaken the development of assessment guides but the completion date is undefined since this has not been identified by KFD as a high priority task.

On rare occasions, for specific technical issues, KFD and NIV work together to define technical references. In particular, there have been discussions regarding instrumentation and control, however these discussions were suspended because the licensee postponed its requirement. The IRRS Team notes that according to expected ageing of such systems the need for such standards is clear, and they are known to have a long development period.

The identification by NIV and KFD of emerging needs for technical references could be part of a long term action plan.

Technical references for review and assessment

The NIV has developed NVRs for the Borssele NPP which are based on IAEA standards adapted to the local context.

The Dutch safety requirements document provides guidance for deterministic safety analysis to complement internal organisational and technical review plans. Guidance on probabilistic safety analysis is provided through IAEA guides for level 1 and level 2 PSA and through Dutch guidances for level 3 PSA.

Licensee calculations (mostly done by subcontractors) are checked for consistency but are not in all cases recalculated by KFD. NIV and KFD have a limited number of calculation codes for cross verification, and therefore rely on TSO to assess complex issues for NPP. Neither NIV nor KFD has the means to assess the validity of computer codes used by licensees in their safety cases. Second opinion calculation is not part of the standard approach and the regulatory body basically relies on its TSO (GRS) on a case by case basis.

The NIV, in cooperation with the German organization GRS, is developing a specific analytical tool consisting of a computer model of the reactor combined with thermal hydraulic and neutron codes for future reviews of the deterministic safety analyses of research reactors (i.e. PALLAS and OYSTER projects). Currently such a tool exists only for Borssele NPP, as developed by KFD, in cooperation with GRS.

The NIV & KFD have access to all the internal documentation of the licence holder that they consider necessary for review and assessment.

Uses of operating experience

The NIV does not formally collect foreign operating experience to assist in formulating regulatory requirements in licences. Operating experience is an input for the programme of inspections, and therefore KFD has a process in place under which it collects operating experience through official means (WGOE, IAEA IRS, Europeans clearing house, GRS operating experience system...), and produces an annual summary document about the national operating experience. However, KFD does not have a formalised process to guarantee exhaustive consideration of operating experience. This issue is addressed also in subsection 2.2.

Contracting TSO

The general practice for NIV and KFD is to define the extent and scope of TSO reviews through references to the licences. Both NIV and KFD are currently separately contracted with the same TSO.

The GRS is the main TSO for NPP on general nuclear safety issues and design, and it is also a historical stakeholder to the regulatory body. This relationship means that a significant technical knowledge and understanding of the history of technical issues at Borssele NPP is present in the TSO and available to the regulatory body. Though deliverables for each party are available to both, it would be more efficient if NIV and KFD would coordinate their demands.

The IRRS team noted that the Dutch company NRG provides technical services to NIV as well as in some instances regulated entities (such as Borssele NPP). The regulatory body therefore ensures that there are no conflicts of interest with regard to the TSO being used.

The IRRS Team has recognized that there is very limited nuclear safety related TSO capacity in the country. The concern that there would be a lack of necessary competence for the regulatory support in the future was one of the reasons for recommendation 5 in section 1.

The goal of NIV and KFD in the use of TSO is to be able to maintain internal competencies and to be able to specify demands, and assess the quality of deliverables (to act as an intelligent customer). Other knowledge entities may also be required as needed on a case-by-case basis (such as meteorological services). However, some of the technical issues are not supported by TSO which may render the in-depth analysis and decision-making difficult. NIV or KFD currently do not use advisory bodies but may occasionally require personal experts on a case by case basis.

The TSO deliverables generally comprise of a technical position, together with the justification of this technical position, and, as required, the supporting technical studies. These technical positions are archived in the technical project repository in the KFD information system. KFD demands to TSO may not be formalized on a systematic manner. The absence of an installation-based documentation system or a technical-issues-based documentation system in either NIV or KFD makes the constitution of a historical knowledge of installation or technical issues more difficult.

6.1.3 PERFORMANCE OF REVIEW AND ASSESSMENT

Format of demands and requirements by the regulatory body.

The NIV and KFD interact with licensees through the use of different types of documentation and the licensees have a right to appeal decisions of both NIV and KFD. In the case of NIV, this documentation could include:

- letter signed by the NIV management
- decision with a regulatory status
- licence
- regulations
- guides

The KFD interacts with licensees mainly through the use of letters and the main types of letters issued to licensees are:

- letter of confirmation of receipt of request
- letter indicating the intended time of review and assessment,
- requests for information,
- rejection of an application,
- declaration of no objection, no objection under conditions, or objection on the licensee request,
- evaluation report to the licensee, documenting the KFD position.

The General Administrative Act requires a response to a licensee submittal by KFD within 8 weeks. However, KFD can request additional time if the licensee submission involves complex matters.

6.2 REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

Review and assessment for nuclear power plants follows the general review and assessment practices described in a previous subsection.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

Review and assessment for research reactors does not differ significantly from general review and assessment practices described in a subsection 6.1, except that a graded approach is used in accordance with the graded approach principles set out in Appendix 6 of “Safety Requirements for Nuclear Reactors: Fundamental Safety Requirements” (draft version).

Depending on the unique characteristics of the research reactors, Appendix No. 6 provides guidance for the appropriate application of safety requirements by choosing which requirements can be waived, and which are fully or partially applicable. The safety analysis report (or other official document submitted to the regulatory body) for the research reactor will also include the licensee’s descriptions of the grading or waiving of certain requirements (in line with Annex No. 6 of DSR) which are always supported by a justification .

In line with their licence conditions both research reactors (HFR and HOR) are implementing ageing management programs which were approved by KFD. HFR has an additional program to monitor the ageing of the vessel material by irradiating samples at a larger flux than the hot-spot of the vessel.

Periodic safety reviews (PSR) are also conducted on research reactors. One of the results of the last PSR of the Delft research reactor is the requirement to develop an ageing management programme. This requirement will be included in a future revision of the licence.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The ILT applies a graded approach based on its multi-year plan when it comes to allocating resources for review and assessment of fuel cycle facilities. KFD has in place a generic process for review and assessment which is based on a so-called uniform process design, and which covers NPP, Research Reactors and is also applicable for fuel cycle facilities and waste management facilities.

The NIV has no administrative organisation in place to systematically organise and execute the review processes of fuel cycle facilities and does not rely on TSO support for this activity. Therefore, the regulatory body should complete implementation of processes for independent review and assessment of fuel cycle facilities in accordance with their stage in the regulatory process, including: initial review, subsequent reviews, reviews of changes to safety related aspects of the facility, reviews of operating experience, reviews of long term operation, life extension, decommissioning and release from regulatory control.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The review and assessment for radioactive waste management facilities is consistent with the general review and assessment practices described in a subsection 6.1. The regulations (BKse Decree) prescribe the minimum requirements to be included in the safety assessment. A safety assessment for the COVRA facility was initially developed in 1987 and updated in 1989 prior to granting the operational licence for the COVRA facilities. This has subsequently been updated in line with the requirement related to PSR of all licensed facilities.

The IRRS Team noted that, based on the extension of the current operational lifetime of the Borselle Nuclear Power Plant, an expansion of the current HABOG facility is envisaged. The regulations (BKSE Decree) require that an update of the safety report be submitted to the regulatory body for the planned expansion of this facility. In addition the licence for this facility would also require an amendment to address the envisaged expansion of the facility.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

The basis for review and assessment of radiation sources facilities is found in the Radiation Protection Decree and the Radiation Protection Regulations in combination with the system of licensing and inspections. RVO has a responsibility for review and assessment as part of its remit to issue authorisations. Activities of the licensee/applicant that require a licence or a modification to the licence are reviewed and assessed by RVO. This is done prior to issuance of the authorization. A graded approach is followed whereby the depth and scope of the review and assessment is based on the radiation risks associated with the radiation source or application. In all cases licence holders are required to carry out their activities in accordance with the ALARA principle.

As part of the licensing process, the applicant must forward a completed detailed application form together with a description of the practice, a justification of the practice, a risk assessment and a safety statement. RVO reviews and assesses the application based on internal procedures and formulates the licence conditions based on their existing model licences. Depending on the complexity of the application, the various Inspectorates may be consulted in relation to the enforceability of the licence conditions. The conditions will be more specific as the risks associated with the source/application are higher.

The RVO performs reviews with the use of a management system called MAVIM. As part of their internal procedures, the work of the person processing the licence is reviewed by a second person before moving to the drafting stage. The RVO reviewers are required to have attained a standard of expertise equivalent to RP Level 2-5.

The KFD has a responsibility for review and assessment as part of its supervision and inspection functions. A major point of the regulatory review and assessment by KFD is to verify whether the applicant for authorization or the authorized party complies with applicable safety requirements and the conditions of the authorization. This takes place over the lifetime of the facility and/or the duration of the activity.

The KFD use the HOLMES system for record keeping and follow-up of information exchange with licensees. Therefore, all the review findings are available for the inspectors, together with the deliverables from the licensee. It is possible for the reviewing inspector to send notifications in HOLMES to other inspectors, e.g. with information relevant for inspection activities. Additionally, the review findings are discussed at a general level in periodic meetings in KFD.

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The review and assessment for decommissioning activities is consistent with the general review and assessment practices described in subsections 6.1 and 6.6. The regulations (Bkse Decree and the Radiation Protection Decree and the Shutdown and Decommissioning Regulation) prescribe the requirements of the decommissioning plans that must be submitted in support of the decommissioning application.

The April 2011 legislative amendments prescribe that direct dismantling following shutdown of a facility is the preferred decommissioning strategy. It is however, recognised that decommissioning may not commence immediately or may take several years to complete. During this time it is important that the facility be maintained in a safe configuration, and that all items and systems important for safety of the decommissioning are clearly identified and properly maintained. The current regulations do not address the requirements of a deferred dismantling strategy.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of transport activities in the Netherlands is carried out using mode specific requirements found in the appropriate regulations. These regulations implement the applicable IAEA TS-R-1 modal (ADR, RID, ICAO and IMDG) requirements.

Currently, radioactive material packages in use in the Netherlands that require review are designed and manufactured in other countries, and accordingly are approved by the Competent Authority in that country. No application for a new-package design review, for a package of Dutch origin, has been received in the past ten years. In 2013, RVO validated 17 package designs for radioactive shipments that originated from non-ADR states. NIV performs the design review of foreign packages for use within the Netherlands, but there is limited experience in conducting new-package design reviews. In 2013, NIV validated five package designs for radioactive shipments that originated from non-ADR states.

The NIV is aware of the plans of a Dutch reactor operator to submit the design of a new nuclear package for design approval in the near future, and it is developing procedures for the submission and review of the new-package design. NIV is also working to identify a competent technical support organization (TSO) to assist with the detailed design and engineering review should a new-package design be submitted for approval.

Under the Nuclear Energy Act, NIV is responsible for maintaining national regulations for the safe transport of radioactive materials and ensuring they remain up-to-date. NIV consults with the appropriate mode-specific policy makers within the Ministry of Infrastructure and Environment in the development and review of proposed revisions. The final publication of new and revised rules is the responsibility of the Ministry of Infrastructure and Environment.

Applications for a transport licence can be created electronically using dynamic PDF or PDF forms. NIV provides guidance describing the information to be submitted with the application on line and as appropriate is incorporated into the application. Some guidance for completion of RVO transport licence applications is contained in the application form. An additional guidance brochure is under development by RVO and NIV and is scheduled for publication in 2015.

Safety documentation submitted by an applicant is compared with legal requirements for the design of type-approval and shipment. Licences for the shipment of radioactive materials are processed and issued in accordance with the Netherlands General Administrative Act.

6.9. SUMMARY

The NIV and KFD are both involved in review and assessment within their administrative field of competency. The inclusion of new requirements for existing installations is done through licence updates which entail a complete review of the requirements or through licence modifications that deal with updating requirements related to what might be encompassed by a given modification of licence conditions.

Some licence requirements are not fully consistent across the different installations due to the infrequent licence revisions and differences in the availability of regulatory reference documents for the different nuclear installations.

Proposed modifications in facilities are categorized according to their safety significance. The prioritization is made by the management of KFD, the general goal is to manage demands in predefined periods as far as practicable. Each significant activity is organized and managed on a project based approach.

Deliverables of the review and assessment are verified by the use of the “four eye principle” which requires that a document compiled by one person is validated by another. The quality will be further improved if the regulatory body finalizes and publishes the “Dutch Licensing Policy”, “Organisational Review Plan” and “Technical Review Plan”. It should also cover all types of facilities and all stages in the life time of facilities.

Review and assessment of research reactors, fuel cycle facilities, waste management facilities and radiation sources facilities follows the general review and assessment practices. The regulatory body should consider that the regulatory framework for decommissioning includes consideration of requirements related to safety aspects and financial resources if deferred dismantling has been selected.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

The KFD is responsible for the independent supervision (review and assessment, inspection and enforcement) of compliance by the licence holder(s) and other dutyholders with the requirements on the nuclear safety, waste, transport safety, radiation protection, security and non-proliferation (safeguards).

Common inspection methods mentioned in IAEA GS-G-1.3 are utilized including monitoring, direct observation, discussions, reviews, and examinations of procedures, records and documentation.

The KFD has inspection programs for the inspection of nuclear installations, transport of radioactive materials and radiation sources. The program for nuclear installations includes the Nuclear Power Plant Borssele, the two Research Reactors in operation (the High Flux Reactor in Petten and the HogerOnderwijs Reactor at Delft Technical University), fuel cycle facilities, and the waste storage facility COVRA.

The broad areas of inspection covered at nuclear installations (e.g. maintenance, operations, quality assurance and safety culture, etc.) are the same as those in the operating phase of the Appendix of GS-G-1.3. KFD planning goals are to inspect these areas at least once every two years.

The KFD prepares an annual inspection program for nuclear installations to plan the frequency and areas of inspection during the year. In preparing its annual inspection program, KFD applies a graded approach to plan inspections assigning frequent or more thorough inspections to more complex facilities or for those issues where it takes more effort to gain a sufficient understanding. This would, in general, mean that a complex facility such as Borssele Nuclear Power Plant would have more inspections planned than other less complex nuclear installations. KFD evaluates performance at the nuclear facilities via quarterly meetings and the facility inspection plan is reviewed and adjusted, if needed. The IRRS team noted that this process continues to evolve. Because of recent performance issues at Petten, the IRRS team noted that KFD adjusted its 2014 planned number of inspections at Petten to be higher than those planned for Borssele.

However, KFD does not have a prescribed minimum, or baseline level of inspection. In addition to using risk and licensee performance to set out its inspection strategy as discussed in the paragraph above, KFD makes inspection decisions based on the available resources. Also, not all inspection areas are covered. For example, KFD does not systematically conduct inspections on emergency preparedness to ensure arrangements are in place for nuclear and radiological emergencies such as emergency management structure, verification of effective implementation of emergency plans, follow up of lessons identified during exercises and other aspects because of the stress test follow up focus. (Refer to Module 10.1 for additional evidence).

The KFD has general inspection guidance which defines the basic inspection process and activities and is an essential foundation to the varying types and levels of inspection required for the major nuclear licensees. This guidance is neither plant nor inspection theme/scope specific and it does not provide sufficiently detailed guidance to enable a systematic and consistent approach to inspection. To improve consistency in each of the major inspection areas defined in GSR Part 1 and GS-G-1.3, e.g. structures, systems and components; operational activities and procedures; competence of staff, etc., more detailed inspection guidelines, or perhaps a strong knowledge management system, could ensure all inspectors work to a consistent and proportionate standard.

For the inspections on non-nuclear facilities and activities, guidance is clearly described in the questionnaires incorporated in Holmes. These questionnaires are based on the regulations and the common licence requirements for a specific branch or topic.

The KFD performs pro-active (planned) and reactive inspections. Inspection results are recorded in a written report, provided to the licensee, and stored in the electronic database system HOLMES. The KFD performs primarily announced inspections and has the authority to perform unannounced inspections. However, the team noted that inspectors rarely exercise their authority to conduct unannounced inspections. The KFD does not have formal guidance to plan and conduct unannounced inspections.

For nuclear installations, KFD is responsible for inspecting occupational radiation safety. In cooperation with KFD, inspection of conventional conditions is covered by the Dutch Inspectorate on occupational health (ISZW) which is

part of the ministry of Social Affairs and Employment (SZW). SZW is responsible for the regulations on occupational exposure control. In practice, there is limited interaction between KFD and ISZW except for coordination on conventional safety inspections at nuclear installations. There are few written agreements between KFD and SZW.

The KFD incorporates the subject of radiation safety for workers at nuclear installations into its general inspections. Although not implemented systematically, the general inspection practice includes areas related to: planned doses and evaluation, worker radiation protection policies, verification of worker monitoring, incidents, and periodic safety review.

The KFD identified, in its summary report and its action plan, two areas for improvement on this subject: specification of occupational exposure control in inspection programmes and clarifying the division of responsibilities between KFD and the ISZW. Based on review of information and discussions with KFD and ISZW representatives, the IRRS team believes that these initiatives would improve their program.

To oversee public exposure to radiation caused by the various licensees, KFD sometimes calls upon the services of a TSO (RIVM). RIVM performs the necessary measurements to arrive at a reliable estimate of discharge levels at the site boundary or environmental measurements. Furthermore, at nuclear installations with nuclear pressure equipment Lloyd’s Register performs inspections as the Notified Body for nuclear pressure equipment testing in the operating phase.

With respect to the inspections on radiation sources different branches of facilities using radiation sources are not inspected at all or very infrequently (for instance hospitals, dentists, luggage scanners, (local) waste disposals, low risk laboratories and industries etc).

For the inspections on transport of radioactive materials not all topics are covered sufficiently. For instance, KFD does not systematically conduct inspections on compliance assurance of transport packages. Further, for maritime transport the Netherlands Shipping Inspectorate component of the ILT, has not conducted any inspection of maritime Class 7 (Radioactive Materials) transport shipments since sometime in 2011 or 2012.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: KFD has developed and continues to develop an approach to the prioritisation of inspection activities across the nuclear licensees and other duty holders. The current approach appears to give the right outcomes, but the degree of rigour is unclear.

KFD rarely exercises its authority to plan and perform unannounced inspections.

KFD does not systematically conduct inspections of emergency preparedness and does not conduct inspections or infrequently on different kinds of facilities and activities with a somewhat lower risk (hospitals, dentists, luggage control, waste storage sites, laboratories, industries etc).

The Netherlands Shipping Inspectorate component of the Human Environment and Transport Inspectorate (ILT) has not conducted any inspection of maritime Class 7 (Radioactive Materials) transport shipments since sometime in 2011 or 2012.

| | |
|-----|--|
| (1) | GSR Part 1 Requirement 28 states that: <i>“Types of inspection of facilities and activities Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.”</i> |
| (2) | GSR Part 1 Paragraph 4.50 states that <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. <u>In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.</u>”</i> |
| R14 | Recommendation: The regulatory body should implement an inspection planning process that defines a baseline plan which includes adequate sampling of all regulated activities and facilities, types of inspections (scheduled and reactive, both announced and unannounced), frequency of inspections and areas and programmes to be inspected. This baseline should then |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

allow prioritization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: KFD has general inspection guidance which defines the basic inspection process and activities and is an essential foundation to the varying types and levels of inspection required for the major nuclear licensees and for other regulated duty holders. Detailed guidance is available for some inspections on non-nuclear facilities and activities. For the major licensees this guidance is neither facility nor inspection theme/scope specific.

| | |
|-----|---|
| (1) | BASIS: GS-G-1.3 Paragraph 4.1c states that <i>“For Internal Guidance ... appropriate subjects for guidance and instructions for inspectors could include the use of regulatory requirements, regulations and guides and industrial standards.”</i> |
| (2) | GS-G-1.3 Paragraph 4.1 also states that <i>“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.”</i> |
| S9 | Suggestion: The regulatory body should consider developing detailed guidance to address specific types of inspections. |

7.1.2. INSPECTION PROCESSES AND PRACTICES

Inspection results are reported at exit meetings held at the termination of the inspection followed by inspection reports sent to the licensee. Inspection reports are not automatically made public but will be provided to a member of the public if a request is made. Additionally, KFD does not routinely send inspection reports to NIV. Inspections letters about inspections on non-nuclear facilities or activities are sent to ISZW, IGZ, RVO and SodM and the local government.

If appropriate, actions are discussed with the licensee at the exit meeting and documented in the inspection report. All actions include an ultimate date for fulfilling the action. If necessary, enforcement actions are formulated. The action points and enforcement actions are monitored by follow-up inspections. KFD has a registration system HOLMES which can be used to account for the total number and due dates for actions. However, the ARM and the IRRS team found that use of this system is inconsistent. The IRRS team noted that this issue is partially addressed by the KFD action plan. The IRRS team also observed that the primary responsibility for managing and ensuring follow up on the completion of action items for inspections rested with the inspector who performed the inspection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: KFD uses a registration system HOLMES which can be used to account for the total number and due dates for actions. The ARM and the mission found that use of this system is inconsistent.

| | |
|-----|--|
| (1) | BASIS: GS-G-1.3 Paragraph 3.1 states that <i>“The management within the regulatory body of inspection activities is an important element of the authorization process. Consideration should be given to assigning managerial responsibility to a single individual or organizational unit. These responsibilities should include: ensuring that follow-up actions from inspections, including dissemination of findings, are taken</i> |
| S10 | Suggestion: The regulatory body should consider implementing measures to ensure that the action tracking system is consolidated and consistently used so that it provides a high level of confidence that all of the inspection findings are tracked and closed in pre-determined timescales, delays are escalated for resolution as necessary, and actions can be collated and reviewed to help inform regulatory feedback and learning processes. |

7.1.3. INSPECTORS

Dutch law provides the inspectors with the necessary powers to perform inspections and enforce requirements. This includes the authority to enter any place whenever this is necessary to perform their duty, access to information/documents, and that persons and licence holders are obliged to cooperate with an inspector.

The KFD has in total a staff of about 40 people. KFD uses a lead inspector concept at nuclear facilities and does not maintain resident inspectors. KFD has an inspector rotation policy but they are not rigorously implementing it. In addition, KFD uses inspectors with specific expertise at all installations depending on the need.

Inspectors are trained on inspection methods, radiation protection, facility design (including simulator training for the nuclear power plant Borssele), emergency response, etc. KFD inspectors involved in inspections at the HFR facility have had dedicated training on HFR systems. However, there are no standard training requirements specified in any of the internal procedures. For the non-nuclear inspectors there are basic training requirements related to radiation protection level 3, BOA, ADR, etc. If one of these trainings is not passed, the inspector can not fulfil his/her job. Further assurance measures for training and knowledge of inspectors are foreseen.

The KFD has identified the need for further development of competence management and qualification of staff as part of the KFD action plan and this is further discussed in Module 3.3 of this report.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The IRRS team visited the Borssele Nuclear Power Plant, accompanied the KFD lead inspector on a plant safety inspection, accompanied a KFD inspector on emergency preparedness response and met with the plant management.

The IRRS team observed the lead inspector review the periodic test program and follow up on deviations submitted as part of a required report from the licensee. These observations included the inspector's detailed interview with responsible licensee staff, verification of records and checks of procedures. The IRRS team noted that the inspector was knowledgeable of the subject matter and interacted professionally with the licensee staff.

The IRRS team met with managers at NPP Borssele to discuss any feedback related on inspections. NPP Borssele managers indicated that they hold a safety culture meeting with KFD annually and that there are two KFD inspectors that review safety culture and human factors. The managers also indicated that they felt that the extent of safety culture oversight by KFD could be increased.

7.3. INSPECTION OF RESEARCH REACTORS

The IRRS team visited the High Flux Reactor at Petten, accompanied the KFD lead inspector on an inspection, and met with the plant management.

The IRRS team observed the lead inspector investigating licensee actions connected with events that occurred in the past. Event reports and root cause analysis were reviewed and several HFR staff members were interviewed. It was noted that interviews were conducted in a well structured manner and initial conclusions and inspection results were clearly communicated both to interviewed individuals and to HFR management.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

The KFD has an annual inspection programme for nuclear installations which includes fuel cycle facilities. KFD also covers non-nuclear environmental topics during these inspections. However, there are no specific guidelines for inspections of Fuel Cycle Facilities. This issue is addressed by suggestion 9 in subsection 7.1.

The KFD employs a graded approach, meaning that installations with a higher safety risk are inspected more frequently. In that sense, there is a general perception among inspectors that URENCO in Almelo is a low risk facility, especially when compared to the nuclear power plant. Moreover, there is a general increase in compliance of this facility as measured by the track record of the inspections, and a high competence of the staff associated with an indication of a strong safety culture. However, these positive factors could possibly be reflecting on the actual conduct of the inspections scheduling and planning, which has appeared to prioritize less compliant areas of the facility, in detriment of areas with a good track record of compliance, but that could still present nuclear or radiological hazards. In order to avoid reducing the level of safety of the facility KFD should ensure that all topics

and areas relevant for this facility are systematically inspected. This issue is addressed by recommendation 14 in subsection 7.1.

The inspection conducted in URENCO in Almelo has provided the IRRS team with a positive feedback on the preparation and undertaking of inspections. It has also indicated that KFD and URENCO have open channels of communication with respect to inspection results. Despite the acknowledgement of some delay in issuing inspection reports, it is worth noting that KFD not only provides inspection reports of fuel cycle facilities to licensees, but has also an established procedure for acknowledging the receipt of the inspection report by the licensee, for receiving written comments and feedback on the report, and for scheduling regular high-level meetings with the licensee to discuss the outcomes of the inspection program, which may lead to the continuous improvement of the safety of the facility.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

The IRRS team accompanied an inspector during his inspection of the predisposal radioactive waste management facility COVRA. The IRRS team members observed that the inspector demonstrated good knowledge of the facility and current issues and the interactions with the licensee were professional.

In the frame of this inspection, the IRRS team members conducted an interview with the facility management on how inspections and controls are implemented. The facility management identified that while they were satisfied with the controls performed and the knowledge and expertise of the inspectors, there was sometimes confusion regarding the roles of the different parts of the regulatory body. Recommendations related to this are included in module 1.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES

The KFD inspection responsibility in the field of radiation sources is outlined in the document “Inspection Strategy for Nuclear Installations, the Transport of Radioactive Material and Radiation”. Target groups have been defined as Radioactive Discharges and Waste Management; Holders of Sealed Sources; Organisations which use Sealed-Source Radiation Emitting Equipment and naturally occurring radioactive material (NORM) Industries. In addition “Holders of Complex licences” form a particularly important target group.

Inspection Planning is conducted by an Inspection Plan Development Team (IPOT) which is a multi-disciplined Team drawn from the Department of Analysis and Investigation in ILT. KFD compiles specific annual inspection plans consistent with the ILT long-term strategy plan and such plans are based on past experience; current developments; operational experience feedback; risk-led supervision and the graded approach. Once the Inspection Plans have been finalised, KFD subdivides inspections into the following phases: Preparing; Implementing; Reporting and Intervening. The issue of inspection planning is addressed by the recommendation 14 in subsection 7.1.

It was observed during the inspections of radiation source facilities that the inspectors followed their standard protocol of preparing, implementing and reporting, and the inspectors were deemed to be competent and professional.

Inspectors prepare for the inspection by reviewing the licence and the detailed annual report from the licensee. A check list is drafted based on information from HOLMES and on specific questions that the Inspector will prepare from his review. Inspections follow a standard format of introductory meeting, inspection and then close out meeting with licensee representatives where the findings are discussed. Following the inspection the inspector inputs the information into HOLMES. All relevant written paperwork from the inspection such as Inspector Notes are put into HOLMES as well. A standard letter (Inspection Report) is drafted and filled in by the inspector. All letters are reviewed by a peer inspector prior to issuing to the licensee or duty holder. Inspectors are responsible for the follow-up and close out of inspections. They use HOLMES (Inspection Report/Findings; Cover Letters; Warning Letters; Enforcement Tools and Recording Findings) to assist them in this.

To establish public exposure to radiation caused by some licensees, KFD may call upon the services of TSO (RIVM). RIVM performs the necessary measurements to arrive at a reliable estimate of discharge levels at the site boundary or environmental measurements.

Two scrap metal facilities in the Netherlands have been granted an authorisation but a very good interaction also exists between KFD and the other scrap metal facilities in the Netherlands. Recently the KFD has conducted digital inspections to ascertain compliance with the provisions of the decree for detection of radioactive contaminated metal and scrap and the response to the digital inspections is very encouraging.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

The inspection for decommissioning facilities follows the same principles as the inspection for other regulated facilities.

On completion of decommissioning the operator is required to demonstrate that the end state criteria as defined in the decommissioning plan and any additional regulatory requirements have been met. The nuclear and non-nuclear facilities and activities cannot be released from regulatory control until this is approved by the regulatory body.

It was noted by the IRRS team that guidance regarding the procedure for decommissioning the termination of decommissioning and release from regulatory control is currently being developed. Recommendations in this regard are detailed in subsection 9.5.

7.8. INSPECTION OF TRANSPORT

Radioactive material transport inspections are planned, performed and assessed to determine transport licensee compliance with the Nuclear Energy Act and the appropriate topical decrees.

The ILT exercises regulatory oversight over for Class 7 (Radioactive Materials) transport. These ILT inspection departments have the following roles in the oversight effort:

| Inspection Departments | Role |
|--|------------------------------------|
| Nuclear Safety, Security, and Safeguards (KFD) | Public & Environmental Protection |
| The Rail and Road Transport Inspectorate | Road (ADR) |
| The Rail and Road Transport Inspectorate | Rail (RID) |
| The Netherlands Civil Aviation Authority | Air (ICAO) |
| The Netherlands Shipping Inspectorate | Maritime & Inland Water (IMDG/ADN) |

In addition, ISZW has the authority for inspecting the occupational radiation protection component of radioactive materials transport licensee programs. However, radioactive material transport is viewed as a low risk activity and consistent with a graded approach, ISZW does not routinely inspect radioactive material transport occupational exposure programs.

In general, the scope of the regulatory inspections corresponds to the potential risks posed by the shipment. All planned inspections are focused on the compliance of the shipment with the relevant provisions of the transport licence and with the appropriate mode-specific regulations. Reactive inspections are performed when, in the judgment of the cognizant inspection component, an abnormal occurrence requires immediate investigation or if there are concerns about the licensee’s capability to implement the appropriate corrective actions in response to an event.

In 2013 and 2014, the KFD met or surpassed its goal for the number of completed Class 7 inspections. The mode-specific transport inspection departments surpassed their goal in 2013, however in 2014, the mode-specific transport inspection departments only accomplished 20% of the number of planned Class7 inspections.

However, the Netherlands Shipping Inspectorate component of ILT has not conducted any inspections of maritime Class 7 (Radioactive Materials) transport shipments since sometime in 2011 or 2012. Several factors contributed to the decision to not perform any maritime Class 7 and to perform less mode-specific transport inspections than planned inspections including a shortage of operational transportation inspectors qualified and available to perform Class 7 inspections and exigent circumstances that diverted the qualified Class 7 maritime inspection staff to perform other inspections.

The IRRS team observed that the ILT inspection program evaluates the licensee’s compliance with the conditions of their licence, including emergency preparedness specific to transportation, physical protection arrangements, driver fitness for duty, stowage during carriage, and the possession of required transport documents. The extent of

the ILT inspection program is not based on a systematic analysis of the target group of authorised parties and number and type of transport operations. These issues are addressed in recommendation 14 in subsection 7.1.1.

Upon the completion of a transportation inspection, ILT inspectors provide the licensee's management with a summary of the results of the inspection, including any violations noted. KFD inspection records are maintained in the HOLMES registration system whereas other ILT inspection records are maintained on other various data systems.

The KFD began to use detailed inspection procedures in July 2014. These procedures have to be completed (see suggestion 9 in subsection 7.1.1). Inspector feedback on the new inspection guidance is gathered during periodic inspection staff meetings. RID and ADR inspectors that conduct transportation inspections on rail and road modes are provided a ruggedized computer loaded with inspection guidance and documentation software and equipped with remote wireless access to various databases.

Some delays in the production of inspection reports were reported by KFD.

If an inspection should identify one or more violations, ILT inspectors document the findings and notify the licensee of the violation in writing. Licensees are required to notify the ILT of the actions taken to correct the violations and to prevent their future recurrence. Inspectors (only so-called BOA's) are authorized to issue citations including fines. All inspectors have the authority to suspend a shipment and prevent its movement until violations have been corrected.

7.9. SUMMARY

The regulatory body has a large scope of inspection responsibilities given the diversity of nuclear and radiation facilities and activities. As a result of its review, the IRRS Team identified items that led to recommendations and suggestions as summarized below:

- The regulatory body should implement an inspection planning process that will include prioritization of planned inspections, cover adequate sample of regulated activities and facilities, type of inspections (scheduled and reactive, and announced and unannounced), frequency of inspections and areas and programmes to be inspected.
- KFD has general inspection guidance which defines the basic inspection process. However, this guidance is not plant or inspection theme/scope specific and it did not provide sufficient detail guidance to enable a systematic and consistent approach to inspection.
- KFD has the HOLMES system to capture and track inspection data. However, the ARM and the IRRS team found that use of this system is inconsistent. The IRRS team noted that this issue is partially addressed by the KFD action plan.

Overall, there are potential improvements identified by the IRRS team and by the regulatory body via its self-assessment. The regulatory body has proactively developed an action plan that addresses many of the issues.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

General

Enforcement policy

The enforcement strategy of KFD is based upon a policy document on enforcement. Various procedures are used for enforcement.

Graded approach

The General Administrative Law Act (Awb) contains general principles of proper governance. One of these principles is the principle of proportionality. This means that actions by the government must be proportional with the severity of non-compliance. The enforcement actions of KFD must be in line with this principle. Furthermore, if the regulator believes the licensee or dutyholder is unlikely to self-correct a non-compliance, then the severity of the enforcement action increases. This is included in the ILT approach as the principle 'soft if possible, hard if necessary' which is applied by KFD as well.

Enforcement tools and powers mentioned in the regulation

In the event of deviation from, or non-compliance with, the regulatory conditions and requirements, KFD takes enforcement actions. These actions could lead to shutting down the nuclear installation and/or revoking the licence. Enforcement procedures have been established describing how the KFD reacts in cases of non-compliance.

The enforcement instruments available enable a graded approach to non-compliances or deviations. They range from a financial coercion order, through an administrative coercion order which gives the inspector the potential to stop activities or shut down a facility, to revocation of the licence.

In the enforcement strategy the responsibility for compliance and therewith for safety is primarily on the licensee or duty holder. The strategy does not explicitly include safety culture aspects. However with the graded approach employed (explained above), an adequate safety culture or a generally good performance can be taken into account.

The Dutch system of administrative law (governed by the Awb) provides the possibility for the licensee or duty holder to appeal decisions and ultimately challenge enforcement actions in court. During the appeal process, the initial enforcement action stands until the appeal has been decided.

8.2. ENFORCEMENT IMPLEMENTATION

Enforcement and mandates

The KFD inspectors have been mandated by the minister of EZ via the Inspector General ILT, to use the enforcement instruments described in Section 8.1 of this report. Enforcement is used to correct non-compliances. All enforcement decisions and actions are peer reviewed by another inspector, the "4 eyes" approach, and discussed in expertgroup meetings. In specific cases, such as actions that can have political implications, the inspector has to discuss the action to be taken with KFD management. There is a document giving inspectors guidance on this decision making process. This document also shows where the inspector needs to hand over the case to a more qualified investigator a 'boa' - an inspector with the formal additional authority to start a penal process. A range of tools is available to the inspectors which include the ability to act directly and independently from management when there is a need for urgent enforcement action.

The current process is highly dependent upon the experience of the inspector, the opportunity for benchmarking in the weekly expert meetings, and the peer review by a colleague. This approach may be appropriate for large scale regulatory inspection of multiple duty holders in the sources, transport and similar industry groups. For the licensed nuclear facilities a more structured management approval process should be considered to improve consistency and to ensure the enforcement is in line with other regulatory goals and strategies, particularly reinforcing the licensees' responsibility for safety and the impact on nuclear safety culture. This should not be onerous as the number of enforcement decisions needed for the major licensed sites should be low, due to the high standards expected of high hazard facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: KFD has developed a process for enforcement which gives significant responsibility to individual inspectors and uses their peer review “4 eyes” process and the expertgroup meetings to generate a level of consistency. The clarity of the level of management approval in this process is currently open for interpretation.

(1)

BASIS: GS-G-1.3 Paragraph 5.6 states that “In normal situations, decisions concerning enforcement actions, particularly those involving fines, curtailment of activity or suspension of authorization, should be approved by the regulatory body in accordance with the procedures established in the State concerned.”

S11

Suggestion: The regulatory body should consider a change to the enforcement procedures to define criteria when the issue is sensitive and requires management participation in all significant enforcement actions, excepting those which require urgent regulatory intervention.

When enforcement activity has the potential to lead to criminal proceedings, a “boa” inspector is used. Currently KFD has 5 boa-type inspectors.

In cases that may lead to criminal proceedings, the boa does not act under the authority of his managers at KFD but under that of the public prosecutor. The ultimate decision to prosecute lies with the public prosecutor and is separate from the Regulatory Body.

Transparency and openness related to the enforcement process and decision making

The KFD does not automatically make enforcement decisions public. If asked to, the request will be granted because of the regulation set out in the Act Government Information (Public Access) Act (Wob). The Wob (in its Article 10) specifies some cases in which such information will not be provided, like disproportionate disadvantage for the licensee or other stakeholders.

Implementation of enforcement measures – experience

Until about three years ago for KFD’s department of Nuclear Safety (KFD-NS), the dominant enforcement instrument was the discussion with the licensee in combination with sending the inspection report. KFD-NS made very limited use of sanction instruments, like the financial coercion order. This has changed and as a result the frequency of applying sanctions has increased. In contrast, KFD’s Radiation Protection department has always used all possible enforcement instruments.

Training of enforcement

Basic training for all inspectors of KFD addresses enforcement. A number of inspectors have also been trained to act as “boa”, this position also requires an ongoing training programme.

To support enforcement decision making process, weekly internal meetings between inspectors (Expert Group Meeting) are used to exchange examples and to discuss experiences, relevant developments and new issues concerning the use of these tools. The purpose of this is to increase the professionalism of the inspectors and to improve consistency.

Measuring effectiveness of enforcement

As the change in enforcement policy for KFD-NS has only been in place for around three years, no review of the effectiveness of the enforcement approach has been undertaken. For other licensees and duty holders, significantly more enforcement history is available and could be reviewed for effectiveness. Currently KFD does not have a system by which the effectiveness of its enforcement actions can be monitored.

Sufficient time has now elapsed since the change in enforcement strategy such that a review of the effectiveness should be undertaken.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: No system exists in which the effectiveness of regulatory enforcement actions is monitored.

| | |
|-----|---|
| (1) | BASIS: GS-G-1.3 Paragraph 6.1 states that <i>“The regulatory body should have a system to audit, review and monitor all aspects of its inspection and enforcement activities to ensure that they are being carried out in a suitable and effective manner..”</i> |
| S12 | Suggestion: The regulatory body should consider developing and implementing a system to monitor the effectiveness of its enforcement actions. |

8.3. SUMMARY

The KFD has a policy document on enforcement, supported by various procedures. Two findings were identified leading to suggestions. Firstly, the effectiveness of enforcement actions taken by KFD has not been reviewed systematically, and no process exists for such a review of effectiveness. As the aim of enforcement is to ensure non-compliance with authorizations or licence conditions are rectified in a timely manner, a review to ensure the revised strategy adopted by KFD-NS should be considered. This review of effectiveness should also consider the wider pool of transport, radiation sources and other nuclear regulatory enforcement within KFD and ILT.

Secondly, the level of management approval of enforcement action is not aligned with the expectations of the relevant IAEA safety guide. Overall, the approaches to enforcement within the sections of KFD regulating different parts of the nuclear industry currently vary. Changes in the last three years have generally made the enforcement regime for nuclear safety of the major licensees more robust and consistent. The IRRS observations support the regulatory body’s view that the enforcement regime is effective and helps ensure ongoing compliance. A systematic review to confirm this observation would help improve the confidence of stakeholders.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The regulatory framework of Netherlands is structured at different levels. The basic legislation governing nuclear activities is contained in the Nuclear Energy Act (NEA), which provides the basis for a system of more detailed safety regulations on the application of nuclear technology and materials. The requirements of NEA are implemented through different decrees and supporting regulations which are generally binding. Various industrial codes and standards, proposed by applicant can also be included as a part of licensing conditions. Apart from this system, the Netherlands also develops so-called Nuclear Safety Rules (NVRs). NVRs are based on the Safety Standards issued by the IAEA. Necessary amendments are made to the IAEA safety standards as per their applicability in Netherlands which then become the NVRs. The NVRs are binding for an installation or nuclear facility, as far as they are attached to the licences. Graded approach is reflected in legislation through the requirements of the Nuclear Energy Act and the underlying safety regulations being more extensive for activities involving fissionable materials and nuclear facilities than those for activities involving radioactive materials.

Since nuclear facilities in Netherlands are few in number and diverse in nature the regulatory body has adopted this approach of specifying specific requirements in the licence, tailored to the characteristics of the installations rather than developing its own detailed guidance documents/guides. The regulatory body arranges meetings with the licence holder to make an agreement on the safety evaluations required to be performed and submissions to be made with the application. After the review carried out within the regulatory body / through TSO, appropriate licensing conditions are attached to the licence which include among others a specific selection of available Nuclear Safety Rules (NVRs) and other nuclear codes and standards. The licence is made available to public for comments and after considering the public comments, if any, the licence is issued.

Regulations or 'ministerial orders' are issued by the Minister of Economic Affairs (EZ) and are mandatory for all facilities and activities under its regulatory control. These regulations set high level requirements. Formal responsibility for the preparation, review and revision of regulations rests with NIV. Acts, Decrees, Ordinances and Regulations & Guides are issued by the Government and prepared by the Regulatory Body.

Proposals to prepare or modify a regulation are prepared by NIV. The draft regulation is approved by the Minister of EZ. During the drafting phase, decision to obtain comments of external experts and stake holders including public is taken on a case to case basis.

There is no systematic review and revision of regulations. Regulations are modified when necessary to fulfil mandatory international obligations such as IAEA Treaties or Euratom Directives. Otherwise regulations can be reviewed and revised when deemed necessary or they can also be initiated by signals of an Inspectorate. This procedure is being practiced to prepare/modify the regulations, however there is no documented procedure/guidance in place for the preparation/modification of regulations, except the standard procedure for revision of legal documents. The regulatory body should consider developing a tailored guidance on the process of document development/revision which includes obtaining comments from the stakeholders and feedback from other processes such as licensing and inspection.

The regulatory body in the Netherlands intends to review and update regulations and guides every 5 years. This policy, however, is not being realized in practice presently.

All legislations pertaining to radiation protection are published in the Official Journal (Laws and Decrees) or the Official (Government) Gazette (Ministerial Regulations) and are also made available on the internet. In addition, authorisations including licence conditions are published on the website of the Ministry of Economic Affairs and are accessible to everyone.

The KFD carries out inspections and periodic safety reviews. Checklists are available for NPPs in which areas to be inspected are identified. Detailed guidance for carrying out regulatory inspections and PSR is not available. Emphasis is laid on periodic meetings between experts within the NIV/KFD to take decisions on the plan of activities and revising the checklists. Operating experience feedback within the KFD and RVO is also considered during these discussions, but there is no formal mechanism to consider OEF for different facilities and activities and reviewing their inhouse procedures for further improvements.

The NIV has not issued detailed regulatory requirements in the form of guides for the benefit of applicant to know in advance the content and format of application and the licensing process to be followed by NIV. NIV relies on licensing requirements in the form of NVRs while issuing a licence. To maintain the consistency in licencing process of NIV, the licencing conditions of earlier licences in similar facilities are referred to. Due to non-availability of these standard guidance documents, the stakehoders including the applicant/licence holder are not aware of the regulatory bodies' requirements and expectations for nuclear facilities.

Recently, the regulatory body has been preparing the new and detailed 'Dutch Safety Requirements' (DSR) and various guidelines, also including lessons learnt post-Fukushima. On the basis of the DSR a new regulation is currently being drafted which contains the latest developments in science and technology with regard to nuclear safety. The scope of the new Regulation is the design and operation of new water cooled and water moderated reactors. For new Research Reactors the regulatory body intends to apply a justified graded approach of the specific requirements for Nuclear Power Plants. The regulatory body should prepare such detailed updated regulations for other facilities as well.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body considers IAEA requirements as appropriate and attaches them as licence conditions. Heavy reliance on licence conditions for individual facilities could lead to inconsistent regulation of similar safety issues within the different licences.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 Requirement 32 states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i> |
| S13 | Suggestion: The regulatory body should consider further development of its regulations and guides to ensure the consistent regulation of all facilities. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body does not have in place a mechanism to periodically revise the existing regulations.

| | |
|-----|--|
| (1) | BASIS: GSR Part 1 Requirement 33 states that <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.”</i> |
| R15 | Recommendation: The regulatory body should develop and implement a procedure on the development and periodic revision of regulations and guides. |

A policy issue was discussed regarding the Dutch approach to regulation which applies fewer regulatory requirements on authorized parties and relies more heavily on the use of licence conditions to prescribe the safe operation for nuclear and radiological activities. Most of the IRRS team members participated in the discussion and provided insights on the control of regulated activities in their counties.

The main conclusions included were:

- All countries use a combination of regulatory requirements and licence conditions to prescribe safety of nuclear and radiological facilities;
- It is better to inspect for safety against the more prescriptive licence conditions and associated technical specifications than the higher level regulatory requirements; therefore, having more extensive licence conditions could benefit the regulatory body's oversight of facility safety;
- The use of more licence conditions and less regulatory requirements provides the regulatory body greater flexibility to quickly respond to safety issues without the rigor of pursuing rulemaking for new regulations;
- Heavy reliance on licence conditions for individual facilities could lead to inconsistent regulation of similar facilities with different licence conditions; and

- In the event that new applications for research and power reactors are anticipated the Netherlands should consider further development of its regulations to ensure the consistent regulation of facilities.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES

The Nuclear Installations, Fissionable Materials and Ores Decree (Bkse) regulates all practices involving fissionable materials and nuclear facilities (including licensing). The Bkse sets out additional regulations in relation to a number of areas, including the licence application procedure for the construction, commissioning and operation of a nuclear reactor, and associated requirements.

The NVRs are attached as licence conditions to cover the different requirements of NPPs including design basis, design extension, operational limits and conditions, operator qualification and training, accident management, surveillance, inspection, periodic safety review, etc. and become a legal binding on the Licence Holder.

In the licences of Research Reactors and Fuel Cycle Facilities s, NVRs are not attached, rather IAEA Safety standards are directly referred to. There are no regulations and guides for fuel cycle facilities. In absence of standard procedures and methodology for review and assessment, personal opinions may play an important role and it may be difficult to maintain consistency in the licensing process.

Also, the regulatory body does require that the site evaluation of a fuel cycle facility includes pre-operational environmental and radiological characterization, as well as an assessment of the foreseeable natural and human-made changes in the area over a period that encompasses the projected lifetime of the facility (see also Module 5, par. 5.2).

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Provisions for discharge of radioactive waste are made in the Radiation Protection Decree article 35. Clearance of materials from regulatory control is regulated in the Radiation Protection Decree, article 37.

The COVRA sets specific waste acceptance criteria for those waste generators who decide to process and condition their waste themselves. COVRA has developed criteria for the acceptance of the common waste streams, which are laid down in the procedures of the management system, and require approval of the director KFD. The waste generators who decide to process and condition their waste themselves will contact COVRA. In these cases COVRA sets specific waste acceptance criteria.

Articles 22 and 33 of Nuclear Energy Act deals with the requirements of legacy waste and unauthorised radioactive material. The individual who possesses or takes possession, without authorisation to do so, of fissile materials or ores or of radioactive materials, suspects anything to be fissile materials or ores or radioactive materials, is obliged to communicate this to the Mayor of the municipality in which the goods are located.

The RAW packages designs are approved in line with the IAEA requirements and their use is regulated through the licensing system. The COVRA licence condition requires COVRA to develop and maintain procedures for the stacking of the waste for easy retrievability.

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES

General regulations for storage, control of radiation sources, notification of incidents and removal of radiation sources are stipulated in the Radiation Protection Decree and the regulations implementing the Radiation Protection Decree. Additional requirements for handling all types of radiation sources are laid down in licence conditions.

Although RVO is regulating radiation sources, facilities and activities, the formal responsibility for the preparation, review and revision of regulations rests with NIV. Acts, Decrees, Ordinances and Regulations & Guides are issued by the Government and prepared by the Regulatory Body. The graded approach is reflected in legislation through the requirements of the Nuclear Energy Act and the underlying safety regulations being more extensive for activities involving fissionable materials and nuclear facilities than those for activities involving radioactive materials.

During the drafting phase, NIV seeks the involvement of stakeholders like Licence Holders, NGOs and the public. Traditional approaches in addition to more novel approaches such as seminars, workshops, citizen panels and internet consultation are utilised.

The RVO and the Inspection Authorities KFD, I-SZW, IGZ, and SodM are involved in revising and updating regulations and as part of the procedure for developing regulations the Inspectorates have to conduct a HUF-check (H= Enforcement, U= Applicability, F= Fraud-Proof). The results of the HUF check and the way the comments have been incorporated have to be published in the explanatory memorandum of the regulations.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The decommissioning strategy in the Netherlands for nuclear facilities is through the ‘Nuclear Installations, Fissionable Materials and Ores Decree’ and is based on the polluter pays principle. The decommissioning plan of nuclear facilities is required to be periodically updated every 5 years during the lifetime of the facility and a licence is required to be obtained by the facility owner for decommissioning. However it was observed that the submitted initial and periodic decommissioning plans (other than the final decommission plan) do not include a safety assessment demonstrating the feasibility and safety of the proposed decommissioning actions. The current regulations need to be updated to address this aspect.

The BKSE Decree stipulates that the licensee for a nuclear facility shall submit an end-report to the regulatory body together with an application for withdrawal of the licence. The decommissioning ordinance stipulates that the licensees shall demonstrate the end-state of decommissioning, which is described in the decommissioning plan. The endstate of decommissioning shall be green field (unrestricted release), unless the licensee was given a special permission to do otherwise. In any case, for withdrawal of the licence, the site has to comply with the release limits. As per the Nuclear Energy Act licence cannot be withdrawn if a facility cannot be released for unrestricted use. The regulatory body currently has no formal requirements and procedural measures related to the end state of decommissioning, termination of the decommissioning licence and the release of sites from regulatory control. It was also observed that while the official national policy is return of site to green field status and unconditional clearance of site, the regulatory body has identified that in some special cases conditional release of sites or release of site with residual levels of radioactivity may be required. It was informed that a procedure is being drafted with assistance from the TSO (TÜV Nord).

The licensee is required to have a financial provision to cover the costs of decommissioning for nuclear installations, which will have to be updated and approved every time the decommissioning plan is updated. The April 2011 legislative amendments prescribe that direct dismantling following shutdown of a facility is the preferred decommissioning strategy, It is however recognised that decommissioning may not commence immediately and may take several years to complete. During this time it is important that the facility is maintained in a safe configuration and all items and systems important for safety of the decommissioning are clearly identified and properly maintained. The current regulations need to be updated to address this matter.

For non-nuclear facilities, no regulations/formal guidance has been established, other than the specific requirements put down in the licences. These requirements demand that the disposal of the sources and the decommissioning must be done as soon as practicable and according to a plan approved by the authorities, and in some cases, according to a specific decommissioning licence. Responsibilities with respect to financial provisions for decommissioning of radiation facilities are not existing. It was informed a general guidance is being developed for the entire clearance process, in conjunction with clearance of nuclear facilities.

During decommissioning the licensee is responsible for record keeping. After withdrawal of the licence, the records are transferred to COVRA. However it was noted that the requirements related to records that are to be retained during the lifetime of the facility are very generic and do not contain details on the specific records to be retained with respect to decommissioning. Lack of these details can result in important records not being retained and considered in the decommissioning planning.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The current regulations do not require the development and submission of a safety assessment in support of initial decommissioning plans.

| | |
|-----|---|
| (1) | BASIS: GSR PART 6 in para 7.4. states that <i>“The licensee shall prepare and submit to the regulatory body an initial decommissioning plan together with the application for authorization to operate the facility. This initial decommissioning plan shall be required in order to identify decommissioning options, to demonstrate the feasibility of decommissioning, to ensure that sufficient financial resources will be available for decommissioning, and to identify categories and estimate quantities of waste that will be generated during decommissioning.”</i> |
| (2) | BASIS: GSR PART 6, Requirement 3 states that <i>“Assessment of safety for decommissioning Safety shall be assessed for all facilities for which decommissioning is planned and for all facilities undergoing decommissioning”.</i> |
| R16 | Recommendation: The regulatory body should update the current regulation related to decommissioning to include, taking into account the graded approach, a requirement that safety of decommissioning is assessed for all facilities for which decommissioning is planned. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The current regulations do not include the requirements related to the end state of decommissioning and removal of regulatory control

| | |
|-----|---|
| (1) | BASIS: GSR Part 6 Requirement 5 Responsibilities of the regulatory body for decommissioning states <i>The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility’s lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met”.</i> |
| R17 | Recommendation: The regulatory body should develop requirements on the end state of decommissioning, termination of the authorization for decommissioning and on the release of the facility and/or the site from regulatory control. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body has the legal power to require financial provisions for decommissioning from licence holders of nuclear power plants, research reactors, HASS (high-activity sealed sources) and scrap metal facilities. However, there is no legal provision to require such provisions for others nuclear facilities, including fuel cycle facilities.

| | |
|-----|--|
| (1) | BASIS: GSR Part 6 requirement 9 states that <i>“Responsibilities in respect of financial provisions for decommissioning shall be set out in national legislation. These provisions shall include establishing a mechanism to provide adequate financial resources and to ensure that they are available when necessary, for ensuring safe decommissioning.”</i> |
| (2) | GSR Part 6 para 3.3 states that <i>The responsibilities of the regulatory body shall include: ... Establishing requirements for the licensee’s financial assurance for</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|---|
| | <i>decommissioning and requirements for a mechanism to ensure that adequate resources will be available when necessary for safe decommissioning ...</i> |
| (3) | GSR Part 6 para 6.3 states that . <i>If financial assurance for the decommissioning of an existing facility has not yet been obtained, adequate financial resources shall be put in place as soon as possible. Approval of a renewal or extension of the authorization for operation of the facility shall include provisions for financial assurance.</i> |
| R18 | Recommendation: The regulatory body should establish regulations related to the assurance of financial resources needed for timely and safe decommissioning of all regulated facilities, both nuclear and non-nuclear facilities. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The requirements of “Shutdown and Decommissioning Regulation” do not address necessity to take into account safety related aspects if deferred dismantling strategy has been selected

| | |
|-----|---|
| (1) | BASIS: GSR Part 6, para.7.14 states that <i>“If deferred dismantling has been selected as a decommissioning strategy, the licensee shall demonstrate in the final decommissioning plan and supporting documents that such an option will be implemented safely. The availability of adequate financial resources to ensure that the facility is maintained in a safe condition during the deferral period and for subsequent decontamination and/or dismantling shall be demonstrated”</i> |
| (2) | BASIS: GSR PART 6 Para 8.2 states that In the case of deferred dismantling, the licensee shall ensure that the facility is maintained in a safe configuration so that subsequent decontamination and/or dismantling can be performed. An adequate programme for maintenance, monitoring and surveillance, which shall be subject to approval by the regulatory body, shall be developed to ensure safety throughout the period of deferral. |
| R19 | Recommendation: The regulatory body should ensure that the regulatory framework for decommissioning includes consideration of requirements related to safety aspects and financial resources if deferred dismantling has been selected. |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The existing regulations do not specify the records, relevant for decommissioning, that are required to be kept during the lifetime of facility.

| | |
|-----|---|
| (1) | BASIS: GSR PART 6 paragraph 7.7 states that <i>“Appropriate records and reports that are relevant to decommissioning (e.g. records and reports of events) shall be retained by the licensee throughout the lifetime of the facility. The design of the facility, modifications to the facility and the facility’s operating history shall be identified and shall be considered in preparing the decommissioning plans. If permanent shutdown takes place before a final decommissioning plan has been prepared, such a plan shall be prepared as soon as possible and adequate arrangements shall be made to ensure the safety of the facility until the approval of the final decommissioning plan.”</i> |
| R20 | Recommendation: The regulatory body should develop guidance and update regulation taking into account requirement related to keeping records of information that will be relevant for decommissioning. |

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Requirements of IAEA Transport Regulations (TS-R-1 / SSR-6) are implemented in the Dutch legislation. The Netherlands is represented in the IAEA Transport Safety Committee (TRANSSC), the UN committees responsible for the UN Model Regulations (Orange book) and the committees for the Modal Transport Regulations. IAEA

advisory material for the IAEA Transport Regulations and guidance material are used for emergency response for incidents/accidents occurring during the transport. The use of the Package Design Safety Report Guide, established by the European Association of Competent Authorities is promoted. In the Netherlands, like other European countries, the international transport regulations are applied to the transport of all radioactive sources covering all modes of transport.

9.7. SUMMARY

The regulatory framework of Netherlands is in general structured at the higher level to provide a legal basis to its processes. However, absence of detailed regulatory guides make the regulatory body rely heavily on the licensing requirements. The regulatory body does not have detailed guides for its other processes also like inspection, etc. The regulatory body does not have a policy in place for the periodic revision of its existing regulations, which it intends to do in future every 5 years.

The regulatory framework for decommissioning needs to be strengthened specifically related to making financial provisions decommissioning of radiation facilities, requirements on the end state of decommissioning, termination of the authorization for decommissioning and on the release of the facility and/or site from regulatory control etc.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

The Nuclear Energy Act, the Radiation Protection Decree, and the National Nuclear and Radiological Response Plan (NCS) provide for the responsibilities and tasks of the authorities that are responsible for nuclear and radiological emergency management (preparation and response).

The Nuclear Energy Act defines two categories for preparations for and intervention in accident or long term exposure, namely category A and category B objects.

The National Government is responsible for managing emergencies involving category A objects, and the coordinating Mayor of the Safety Region (which is a region organizing the fire services, police, medical assistance and crisis management under one regional administrative authority) is responsible for managing accidents involving category B objects under the Disasters and Major Accidents Act. For the case of a radiological incident in a neighbouring country, three safety regions have made crisis arrangements with neighbouring States. ILT/Emergency Management (ILT/TAN) is the National Competent Authority under the IAEA Emergency Conventions, develops and manages the National Nuclear Emergency Plan, and it coordinates the National Nuclear Assessment Team (EPAN). TAN also advises the Safety regions in establishing regional emergency response plans.

The NIV and RVO/TSB are responsible for legislation, policy, standards and licencing aspects of emergency preparedness and response related to category A and B objects.

During preparedness, KFD is required to inspect compliance with legislation and licence conditions related to nuclear and radiological emergencies. During the response to an emergency, KFD employees assess the status of the emergency situation, determine the potential source term and participate in EPAN activities (Front-Office and Back-Office for Radiological Information, BORI). The role of KFD during the response is defined in the National Nuclear and Radiological Response Plan and included in a draft procedure (in case of Category A object) where four persons are able to make source term determination and four persons are able to establish plant emergency status.

The Radiation Protection Decree includes general requirements on emergency preparedness and response. In the case of non-nuclear facilities the licence only contains a general requirement to mitigate the consequences of the incident and two conditions for notification by operators to local authorities regarding the location of radioactive sources and to national authorities if a radiological emergency has occurred. There are no additional conditions for general, functional or infrastructural elements of emergency preparedness and response or NVRs. As a consequence emergency preparedness and response arrangements are not considered in the issuing of a licence by RVO.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Although there are some requirements for emergency preparedness and response for non-nuclear facilities, RVO does not require the establishment of emergency preparedness and response arrangements as part of its licencing process.

- | | |
|------------|--|
| (1) | BASIS: GS-R-2 para 5.19 states that <i>“The operating organization [of a facility or practice in threat category I, II, III or IV] shall prepare an emergency plan that covers all activities under its responsibility, to be adhered to in the event of an emergency. This emergency plan shall be coordinated with those of all other bodies having responsibilities in an emergency, including public authorities, and shall be submitted to the regulatory body.”</i> |
| (2) | BASIS: GS-G-2.1 in para 3.8 states that <i>“The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention...The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. The regulatory body shall require that the emergency arrangements “shall be tested in an exercise before the commencement of</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|---|
| | <i>operation [of a new practice]. There shall thereafter at suitable intervals be exercises of the emergency [arrangements], some of which shall be witnessed by the regulatory body.”</i> |
| (3) | BASIS: GS-G-2.1 in para 3.9 states that “ <i>In fulfilling its statutory obligations, the regulatory body... shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;... shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):... the requirements for incident reporting;... and emergency preparedness arrangements.”</i> |
| R21 | Recommendation: The regulatory body should make provisions for non-nuclear licensees to have in place clearly defined arrangements on emergency preparedness and response before issuing the licence. |

The responsibilities of the licence holders of facilities and activities in Category A and B objects are described in the Nuclear Energy Act and in the licences. In the case of Category A, the operator and the Safety Region shall make arrangements to ensure compatibility between on-site and off-site aspects. In the case of Category B object, the licence holder is obliged to report to the responsible Competent Authorities and the Mayor and hand over all information required for crisis management to the regional or national authorities.

During preparedness, KFD is required to inspect compliance with legislation and licence conditions related to nuclear and radiological emergencies.

Emergency preparedness and response inspections conducted at the Borssele NPP and other nuclear facilities do not cover the full scope of arrangements in the licence and NVRs are not inspected regularly. The inspectors acknowledged during the interviews that a more frequent and systematic approach for inspections on emergency preparedness and response would provide for more effective regulatory control while enhancing their familiarity with the licensee facilities, tools and processes. The turnaround time for regulatory reports to the licensee is not always in line with the in-house KFD arrangement. For other category B objects no specific inspections on emergency preparedness and response are performed.

Assessment of threats

Requirements for operators to conduct a threat assessment are included in the authorisations and the Radiation Protection Decree, requiring the assessment of all potential accident scenarios associated with the facility or activity. For nuclear installations, a threat assessment is required and must be renewed every ten years. For Nuclear Power Plant and Research Reactors, a PSA Level 3 is also required. For non-nuclear facilities there are no requirements to periodically review and update the threat assessment or guidance on how to conduct the threat assessment.

The potential threats in the Netherlands classified as Category A and B objects are documented in the NCS subplan, the National Response Plan NPK (NPK response Plan) and are not consistent with the categorisation in GS-R-2. Accidents with Category A objects have an impact that reaches beyond local environment, and accidents with category B objects only have local and regional impact..

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The threat assessment established in the country considers Categories A and B objects based on the significance of the event (regional or national impact). This threat categorization is not consistent with GS-R-2 and does not provide an optimal basis for a graded approach to the development of emergency preparedness and response regulations

| | |
|-----|---|
| (1) | BASIS: GS-R-2 para. 3.15 states that “... <i>The threat assessment shall be so conducted as to provide a basis for establishing detailed requirements for arrangements for preparedness and response by categorizing facilities and practices consistent with the five categories shown in table 1.”</i> |
|-----|---|

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|---|
| S14 | Suggestion: The regulatory body should consider improving the requirements and criteria for the establishment of the threat categorization of facilities and activities in accordance with GS-R-2. |
|-----|---|

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

The operator is responsible for the management of an emergency occurring on-site while the local, regional or national authorities are responsible for its management outside the facility. The Borssele NPP has dedicated staff for emergency preparedness as well as standby shifts. The transition from normal to emergency situation is addressed in the emergency plans, which are assessed by KFD. Apart from the generic requirements in the NVRs in the case of the Borssele NPP, there are no other explicit requirements on the licensee emergency management structure for other facilities and activities.

The adequacy of the emergency management structure is tested by KFD mainly during several emergency exercises conducted annually at the Borssele NPP.

For other nuclear facilities the response organization may be a combination of industrial safety and nuclear management departments.

In the case of non-nuclear facilities and activities, KFD does not perform specific inspections on emergency preparedness and response and does not witness nor evaluate emergency exercises.

Identifying, notifying and activating

The Nuclear Energy Act makes provision for identification and notification in the case of an accident with a Category A or B object. The incident/accident classification system used by the Borssele NPP is in line with the classification system used in the NCS and Response (NPK Response Plan) and is based on a previous IAEA classification system consisting of four emergency classes. The current IAEA classification system is included in the NCS and steps to harmonise classification systems with neighbouring countries have been initiated. For other nuclear installations, classification systems are in place, following regional nuclear emergency preparedness plans.

The KFD staff are on standby and are notified of nuclear and radiological emergencies through redundant communication systems and are expected to report to its Emergency Control Room within two hours. Identification and notification requirements and arrangements are in place at relevant scrap metal facilities for the discovery/detection of potential “orphan” sources.

Some of the response time objectives for the Borssele NPP as defined in the licensing procedures are not consistent with GS-G-2.1 and are not evaluated by KFD during emergency exercises. For other facilities the response time objectives have not been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Some of the response time objectives for identification, notification and activation at facility, local and national level are established for the Borssele NPP but are not consistent with GS-G-2.1, and such objectives are not explicitly required and not implemented by other facilities and activities.

| | |
|-----|--|
| (1) | BASIS: GS-G-2.1 in paragraph 6.5 states that “ <i>The arrangements for facilities in threat categories I, II and III should be established with the goal of meeting the time objectives given in Appendix VI.</i> ” |
| (2) | BASIS: GS-G-2.1 Appendix VI states that “ <i>Response time objectives are suggested time objectives for selected critical response functions or tasks for facilities in threat categories I, II and III. They should, once established, be part of the performance objectives for a response capability and should be used as part of the evaluation criteria for exercises</i> ” |
| S15 | Suggestion: The Regulatory Body should consider clearly defining criteria for response time objectives for all relevant threat categories and evaluating compliance with response time |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

criteria during emergency exercises.

Taking mitigatory actions

Arrangements have been made to initiate a prompt search and to issue a warning to the public in the event of a dangerous source possibly being in the public domain. So-called first aid companies with expertise in radiation protection are available to provide services to both KFD or to licensees in the case of radiological emergencies.

Taking urgent protective action

Generic Intervention Levels for urgent and longer term protective actions have been established in the National Response Plan NPK (NPK Response Plan), however the levels are not consistent with the values in GS-R-2. Criteria for termination of urgent protective actions are not available except for return after evacuation.

Arrangements have been made with neighbouring countries to introduce matching emergency measures and Generic Intervention Levels. The policy for emergency planning zones is being evaluated, in order to establish a range of intervention levels for the different zones and also to cater for events involving foreign plants. Criteria and the use of measurable quantities i.e. operational intervention levels (OILs) for decision making in the case of taking urgent and early protective actions and other response actions have not been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The current values established in the national system as action levels, intervention levels and guidance values for emergency workers are not in line with the values established in IAEA safety standards.

| | |
|-----|--|
| (1) | BASIS: GS-R-2 para 4.45 states that “ <i>Optimized [national] intervention levels [for taking urgent protective actions] shall be [established that are in accordance with international standards], modified to take account of local and national conditions ...</i> ” |
| (2) | BASIS: GS-R-2 para 4.71 states that “ <i>... arrangements shall be made for promptly assessing the results of environmental monitoring and monitoring for contamination on people in order to decide on or to adapt urgent protective actions to protect workers and the public, including the application of operational intervention levels (OILs) with arrangements to revise the OILs as appropriate to take into account the conditions prevailing during the emergency.</i> ” |
| (4) | BASIS: GS-R-2 para 4.60 states that “ <i>National guidance that is in accordance with international standards shall be adopted for managing, controlling and recording the doses received by emergency workers...</i> ” |
| S16 | Suggestion: The Regulatory Body should consider aligning action levels, intervention levels, and guidance values for emergency workers with IAEA standards. |

Providing information and issuing instructions

It is a regulatory requirement (Nuclear Energy Act) that operators provide the Mayor immediately with all information needed to be able to instruct and inform the public.

Protecting emergency workers

The Nuclear Energy Act states that persons employed by services or organisations who can be deployed to manage an accident involving a Category A object or an accident involving a Category B object regularly receive information on the risks involved in the performance of their tasks and on the precautions they should take. Guidance levels for emergency workers are included in the Radiation Protection Decree. The level for life saving actions, important and valuable material interests and for supporting and performing of radiological measurements, and other protective actions are higher than IAEA recommended levels (see Recommendation above). The protection of emergency workers and the recording of doses during nuclear and radiological emergencies are the responsibility of each response organisation. However, these aspects are not systematically verified by KFD.

Assessing the initial phase

If an emergency occurs, the licensees and any person with knowledge about the emergency is required by the Nuclear Energy Act to inform the relevant local and regional authorities immediately. In this regard, the operator of the Borssele NPP has established emergency action levels and provides the necessary information to KFD in order for them to estimate the source term. KFD is able to receive real-time plant data and process information for this purpose.

Managing the medical response

Provision is made in the Nuclear Energy Act for the decontamination, medical investigation and treatment of persons and animals affected by a nuclear or radiological emergency. There is coordination between the operator and the local medical services of the Safety Regions.

Other activities in emergency preparedness

There are requirements in the Nuclear Energy Act for Category A and B objects where the authority responsible for surface water shall introduce measures, with police assistance if necessary, to minimise the effects on surface water. Defined criteria for agricultural countermeasures and countermeasures against ingestion and longer-term protective actions are in place in the National Response Plan NPK (NPK Response Plan) for foodstuffs, milk, cheese etc. but these are not consistent with IAEA standards.

Requirements and arrangements in line with international standards and guidance have not been established for the transition from emergency phase operations to routine long term recovery operations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Requirements and arrangements for recovery operations are not defined in the national regulatory system.

(1)

BASIS: GS-R-2 para. 4.99 states that “*Arrangements shall be established for the transition from emergency phase operations to routine long term recovery operations. This process shall include: the definition of the roles and functions of organizations; methods of transferring information; methods of assessing radiological and non-radiological consequences; and methods of modifying the actions taken to mitigate the radiological and non- radiological consequences of the nuclear or radiological emergency.*”

R22

Recommendation: The Regulatory Body should ensure that requirements and arrangements are established for recovery operations in line with international standards.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority

The Nuclear Energy Act makes provision for responsibilities, preparations for, and intervention in, accidents or long-term exposure, for accidents involving a Category A or Category B object. Below the Nuclear Energy Act, Decrees, and NVRs provide for additional requirements from IAEA standards on emergency preparedness and response. For non-nuclear activities the requirements are not elaborated in NVRs, but the general requirements of the Radiation Protection Decree apply. KFD monitors compliance with legislation and licences through compliance assurance and safety assessments. For nuclear installations the verification of emergency preparedness and response arrangements is primarily done through witnessing exercises.

Organization

Apart from the NVRs there are no specific requirements relating to organisation and staffing of the licensees with respect to emergency preparedness and response. The Borssele NPP has three persons responsible for emergency preparedness, and all six emergency standby shifts participate in the annual exercises. The staffing for nuclear installations is primarily verified through witnessing exercises, and not during inspections.

Coordination of emergency response

Requirements and the coordination between the various organizations with responsibilities regarding the response to an incident involving a nuclear facility or radioactive source is described in the Nuclear Energy Act, the NCS, and the National Response Plan NPK (NPK Response Plan). In the case of nuclear installations there is coordination between KFD, TAN and other national stakeholders. For other radiological emergencies the inspectors of KFD advise the regional government on risks and measures.

Plans and procedures

Regulatory requirements on plans and procedures are included in the licence for nuclear installations and approved by KFD. The Borssele NPP has an on-site emergency plan, which is periodically exercised by the operator, and involves KFD, TAN and off-site organisations. For other radiological emergencies there are only general requirements for emergency preparedness and response in the Radiation Protection Decree and Licences. KFD does not verify if emergency plans are in place at all relevant facilities. This is covered in Section 7.1, recommendation 14.

Logistical support and facilities

The requirements for logistical support and facilities are included in the NVR for the Borssele NPP. There is an Emergency Control Center at the plant, and there are plans to establish a new Emergency Control Center away from the reactor as part of the improvements after Fukushima. Communications equipment has also been procured for redundancy purposes. Borssele NPP reactor and systems data is available at the request of KFD in two locations. For the research reactors facilities to respond to emergencies are also in place. Logistics are not taken into account in the inspection strategy. This is covered in Section 7.1, recommendation 14.

Training, drills and exercises

The Nuclear Energy Act states that the relevant portfolio Minister and the Authority responsible for the Safety Region shall be responsible for preparing the emergency organisation to manage accidents involving Category A and B objects effectively in the Netherlands. In particular, they shall also ensure that practice drills are held and that the necessary agreements are in place for the effective management of such accidents.

The KFD participates in a full scale national exercise conducted by TAN every five years and in all annual Borssele NPP emergency exercises. One or two KFD-inspectors are deployed to the Plant Emergency Operations Center for training oversight and liaison roles. Some emergency exercises at non-nuclear facilities are conducted but KFD does not participate or observe, and there is no report provided to KFD for evaluation purposes. KFD does not follow up on corrective actions resulting from any emergency exercises conducted.

The provision of GS-R-2, NVR 2.2.6, and “Preparedness of the operating organization (licensee) for emergencies at nuclear power plants” (adaptation of IAEA Safety Guide Safety Series No. 50-SG-06) are included in the Borssele NPP licence. The operator is required to have training sessions for maintenance of emergency preparedness focused on updating the expertise of staff and instructions in emergency situations. The operator is also required to provide specialised training and retraining to off-site personnel having emergency response responsibilities. There are no similar requirements stipulated for non-nuclear facilities. This is covered in Section 7.1, recommendation 14.

Quality assurance programme

There are requirements for the licensees to have in place management systems, and inspections are carried out by KFD. There are however no specific obligations on the licensee to include emergency preparedness and response in the management system.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

Regulatory bodies roles during response to a nuclear or radiological emergency are stipulated in the relevant legislation, decrees and emergency plans. NIV, KFD and TAN participate in the Working Groups on Education, Training and Exercises, Plans & Procedures, Category A region consultation, and the Working Group for the National Coordination of Measurements during Radiation Incidents and the National Radioactivity Monitoring Network.

For nuclear and radiological emergencies KFD receives notification and information on the emergency classification, and determines the source term to be used by relevant authorities as a basis for the calculation of the doses to the public. For radiological emergencies KFD provides advice to the Safety Regions directly. KFD is developing its management system, and it is recognised that in-house emergency response procedures should be reviewed, finalised and included in this management system.

The KFD has its own emergency organisation arrangements which includes communication and coordinating with the operator and the EPAn during the response. KFD DENKTANK has a system to have on-line access to Borssele NPP data on request. KFD has its own emergency control room equipped with the necessary telecommunications to discuss with the emergency staff of the nuclear installations and to exchange information with all other response parties involved through web based systems.

The KFD emergency organisation activation is tested about ten times per year. For nuclear emergencies, the inspectors of KFD have a training program, and NIV, KFD and TAN representatives in EPAn undergo training organized by TAN.

Verification of the effectiveness of the in-house arrangements is not systematically performed, and lessons learnt from external and in-house exercises are not systematically addressed.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|--|--|
| Observation: The actions to be performed by KFD during the response to a nuclear and radiological emergency for all Threat Categories, namely to monitor the situation, to independently determine the source term and to provide advice to the Government via the National Nuclear Assessment Team are not proceduralized. | |
| (1) | BASIS: GS-R-2 para. 5.21 states that <i>“The operating and response organizations shall develop the necessary procedures, analytical tools and computer programs in order to be able to perform the functions specified to meet the requirements for emergency response established in Section 4.</i> |
| S17 | Suggestion: The Regulatory Body should consider finalizing its procedures for responding to a nuclear and radiological emergency. |

10.5. SUMMARY

The roles and responsibilities of the regulatory bodies in preparedness and response to nuclear and radiological emergencies are defined and coordination arrangements are in place. Requirements and arrangements are established for the Borssele NPP, and emergency exercises are conducted periodically. The regulatory bodies have the infrastructure to support its advisory role during the response to an emergency.

Threat categorization, requirements and arrangements for all licensees to have clearly defined arrangements on emergency preparedness and response, systematic verification of compliance to requirements are not fully in line with GS-R-2. The regulatory body should also consider allignment of criteria for response time objectives, action levels, intervention levels, and guidance values for emergency workers with IAEA standards. Recovery requirements and arrangements should also be defined. In addition the regulatory body should consider formalising its internal emergency procedures.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Regulatory framework and responsibilities

The regulatory framework for medical exposure control in the Netherlands is based on General Health Care legislation, as well as on specific regulatory requirements in the field of radiation protection in medical radiation applications. The Individual Healthcare Professions Act defines the policy for the use of radiation in medicine, whereas the Care Institutions (Quality) Act obliges health care institutions to deliver responsible, quality-system-based care to patients. The Radiation Protection Decree (RPD), transposes the EC Directives 96/26 and 97/43 into the national legislation. The Ministerial Regulation concerning expertise requirements for radiological procedures, include the expertise requirements for the various categories of practitioners. Joint Ministerial Regulation on Radiation Protection includes administrative and organisational measures for radiation protection.

The distribution of radiological equipment in the Netherlands is limited, since the medical applications of ionising radiation are performed mainly in hospitals and a limited amount of private clinics.

The organisations involved in the regulatory framework of radiation protection and safety related to medical exposure of patients are the Ministry of Health, Welfare and Sport (VWS), the regulatory body, the Health Care Inspectorate (IGZ), performs the inspections, and the RVO, issues the licence and provides advice on radiation protection. There are arrangements in place for collaboration and information exchange between the authorities (e.g. regular meetings and exchange of the inspections results).

A graded approach is included in the policy for the medical exposure and is applicable to all aspects of the regulatory framework.

Health care framework in the Netherlands is characterised by generally and openly formulated standards, which are not legally binding, but when issued by the Scientific, Professional or other relevant societies, their implementation becomes mandatory for the registered members. The IGZ relies on health care providers to implement these standards. Typical examples include quality control protocols, referral criteria, minimum staffing and training requirements, specialties recognition criteria, requirements and performance methodology for peer reviews. The standards serve as guidelines for the protection of the patient and there is evidence that they are widely accepted and used in practice by the authorities and the professionals as the state of the art documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Guidelines used for the protection of the patient are prepared by the Scientific and Professional Societies and are widely used by authorised parties as well as for inspections, but they are not formally endorsed by the regulatory body.

(1)

BASIS: GSR PART 3 Requirement 3 states *“The regulatory body shall establish or adopt regulations and guides for protection and safety and shall establish a system to ensure their implementation.”*

R23

Recommendation: The regulatory body should establish or adopt regulatory guides for the protection and safety of patients.

Medical practices are authorised through licensing or notification (for example dental e.g.). Requirements are included in the Ministerial Regulation on Radiation Protection or in the licensing conditions. The VWS has officially mandated the RVO for the licensing of medical facilities.

There is no established system for the regular inspections. Inspections are based on risk assessments of institutions, mainly in terms of risk to the patient. Radiation is not a priority for the Dutch IGZ as it is categorised as lower-risk than other risk factors. The risk assessments are based on internal inspections carried out on a representative sample base. Inspections are also performed by the KFD within hospitals in the context of the control of radiation sources and by ISZW for the occupational exposure. It is recognised that this system can result in duplication of work for the licensees for general and organizational aspects concerning radiation protection. One inspection programme co-

ordinating the working plan could ameliorate significantly the efficiency and effectiveness of the inspections and would reduce the workload. The issue of inspection planning is also addressed in section 7 of this report.

A robust system for the recognition of specialties and for the education and training is implemented in the Netherlands.

Justification of medical exposure

Article 55 of RPD provides for the justification of the medical exposures. Physicians and dentists are qualified to justify exposures for their individual patients. New practices are justified by the Scientific Societies, whereas within the hospitals the decision is taken by a committee where the responsible physicians, the medical physicist and the RPE participate. Referral guidelines are issued by the Scientific Societies in the form of "Field Standards".

Health screening programmes are regulated by the Health Screening Act (Wet op bevolkingsonderzoek) of 1992. Exposing symptom-free individuals, in the context of the early detection of disease, out of the scope of the Health Screening Act, is prohibited in the Netherlands. The medical exposure of volunteers is subject to the approval by the Medical Ethics Review Committee.

Optimization of medical exposure

The regulations explicitly establish the principle of optimisation and include provisions for the establishment of Dose Reference Levels (DRL), Dose Constraints (DC) and Quality Assurance Programmes.

The RPD states: "VWS shall promote the establishment and use of DRLs for radiodiagnostic procedures and the drawing up of protocols on this subject". The VWS has requested the National Committee for Radiation Dosimetry to establish the DRL's and publish them as Field Standards. There are no specific requirements in the licence conditions to register and review the local DRLs. As there is no established standard for this moment, the IGZ has not yet established a more systematic approach to the use of DRLs

The RPD provides for the establishment of DC for volunteers participating in biomedical research; the ethics committee specify appropriate values on a case by case basis.

The RPD states "VWS may lay down dose constraints for exposures ... and rules may be laid down by regulation of Our VWS ...". It is not a binding requirement and the VWS has not specified the rules. In practice, instructions and advice is given to the caregivers and comforters (and to the patients) in order to minimise their doses and the value of 1 mSv is used as the dose constraint for caregivers and comforters.

The RPD gives the general provisions for design and operational considerations. Further requirements are implicitly deduced from the field standards and quality control protocols. Hospitals are obliged to have a quality system in place and to be accredited or certified. Compliance with the conditions is checked during the licensing procedure. The relevant professional bodies themselves carry out mutual quality control checks. The IGZ verifies whether hospitals participate in this quality control process.

In the Netherlands, the use of any radiological equipment that does not bear a CE mark is prohibited.

The RPD requires that radiological equipment must be calibrated, however there is no specific requirement regarding the calibration of sources giving rise to medical exposure, apart from what is implicitly deduced from the quality system. Some requirements regarding calibration of equipment and sources are expressed as licence conditions. According to field standards and quality system provisions, the calibration of all sources is performed during acceptance, prior to clinical use, and after maintenance under the responsibility of the medical physicist.

Pregnant women and breast feeding women

The IAEA GSR Part 3 requirements regarding the pregnant and breast feeding women are included in regulatory requirements and the IGZ verifies their implementation during the inspections. The IRRS team noted that there are signs, requesting female patients to notify the staff in the event of a pregnancy or breast-feeding posted in radiological centres or nuclear medicine departments, even if there is no such requirement.

Release of patients after radionuclide therapy

Before and after radionuclide therapy, patients and carers are provided with written instructions. The amount of administered radioactivity is determined on the basis of field standards. For patients who have undergone

radionuclide therapy, discharge from hospital is subject to strict rules, which are included in the licence conditions. The RPD does not establish release criteria of the patients who have undergone radionuclide therapy. Methodology and release criteria are given in the Aanbevelingen “Het werken met therapeutische doses radionucliden”, Min VROM, Min SZW, NVNG 2004.

Unintended and accidental medical exposures

The Netherlands has legal requirements aimed at preventing accidents and unintended exposure to ionizing radiation. During the licensing procedure, it must be demonstrated that quality systems and safety systems are in place to prevent accidents. Within hospitals safety and management systems, both prospective and retrospective risk analyses are included. The IGZ ensures that the safety management system is functional. Based on the same legislation, accidents must be reported to the IGZ, whereas all incidents and accidents must be reported to the hospitals internal incident reporting system (that includes all kind of incidents) and to the RPE. RPD Article 13 also includes provisions for accidents and incidents dealing with ionising radiation. Additionally, licencess include a condition that, in the event of incidents involving ionizing radiation, the IGZ must be informed since it is actively involved in investigations carried out by hospitals. The IRRS team acknowledges this approach.

Reviews and records

There are no mandatory legal provisions regarding radiological reviews. The requirement for reviews and audits is implicitly implemented through the requirement of the quality systems in hospitals. Audits are performed by the Scientific and Professional Societies (one peer review every 5 years) and internal audits are performed more frequently, according to the requirements of the Care Institutions (Quality) Act and the Individual Healthcare Professions Act.

In nuclear medicine and radiotherapy departments, audits are carried out by multidisciplinary teams consisting of members of the various societies. In radiology departments, audits are carried out by the Radiological Society of the Netherlands and the Society of Radiographers. Audits include compliance with justification and optimisation requirements and since recently, clinical audits are also included. The IGZ verifies that peer reviews are performed. The IGZ may request copies of the reports of the peer reviews and might conduct an in-depth review and verify that procedures, protocols and equipment are in place.

According to licence conditions a radiological report has to be submitted to RVO/TSB (IGZ has access to RVO database) on annual basis.

The Care Institutions (Quality) Act requires recording any delegation of responsibilities. The same applies to any radiation protection training given to members of staff. The Care Institutions (Quality) Act requires that records are always available, as part of the quality system. During inspections records are reviewed.

Patient dose information (for nuclear medicine and radiotherapy) has to be recorded for each individual patient. Information relevant to diagnostic radiological procedures is recorded in the PACS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Provisions for establishing DRLs, for placing signs in waiting areas for pregnant or breastfeeding female patients, for the establishment of dose constraints for carers and comforters (and the issue of guidance) and for calibration of sources giving rise to medical exposure, exist but not as clear regulatory requirements.

| | |
|-----|--|
| (1) | BASIS: GSR Part 3 Req. 34 states <i>“The government shall ensure that ... diagnostic reference levels, ..., are established”</i> |
| (2) | BASIS: GSR Part 3 paragraph 3.148 states <i>“The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established: ... (a) dose constraints, for exposures of carers and comforters..... ”</i> |
| (3) | BASIS: GSR PART 3 paragraph 3.172 states that <i>“Registrants and licensees shall ensure that relevant dose constraints are used in the optimisation of protection and safety in any procedure in which an individual acts as a carer or comforter”</i> |
| (4) | BASIS: GSR PART 3 paragraph 3.174 states <i>“Registrants and licensees shall ensure that signs in appropriate languages are in place in public places, waiting rooms for patients, cubicles and other</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|---|
| | <i>appropriate places and that”</i> |
| (5) | <p>BASIS: GSR PART 3 paragraph 3.166 states “<i>In accordance with para. 3.153(d) and (e), the medical physicist shall ensure that:</i></p> <p><i>(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;</i></p> <p><i>(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;</i></p> <p><i>(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;</i></p> <p><i>(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.</i></p> |
| S18 | <p>Suggestion: The regulatory body should consider strengthening the requirements for:</p> <ul style="list-style-type: none"> • the establishment, the use and the systematic revision of the dose reference levels, at national and local level, • the establishment of dose constraints for carers and comforters and the issue of the respective guidelines for their use, • the registrants and licensees that signs in appropriate languages are placed to request female patients undergoing a radiological procedure to notify, in case of pregnancy or breast feeding (for nuclear medicine), • ensuring the calibration of sources giving rise to medical exposure. |

The established regulatory framework for the protection of patients provides a robust basis to assure that medical exposure is justified and optimised. Some discrepancies should be resolved during the transposition of the EC Directive 59/2013.

11.2. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

The IRRS team noted that regulation of radioactivity and protection of the public is governed by the Nuclear Energy Act and subsidiary regulations. There is however currently no national policy and strategy for the management of existing exposure situations and the remediation thereof.

Control of Indoor Radon

The Netherlands has previously undertaken three studies on indoor radon (1985, 1995 and 2005). A fourth study is current being conducted and the results are expected in 2015. The earlier studies indicated that indoor radon levels are relatively low (average value in the order of 20 Bq/m³). The IRRS team noted that at present the Netherlands has not established a reference level related to protection from indoor radon.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There is currently no national policy related to management of existing exposure situations and remediation thereof. Additionally there is currently no defined reference level related to protection of the public from radon indoors. However, studies have suggested that indoor radon is not a major health concern in the Netherlands

(1)

BASIS: GSR PART 3 Para 5.20 states “*Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered ..., the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes:*

(a) Establishing an appropriate reference level for 222Rn for dwellings and other buildings with high occupancy factors for members of the public, with account taken of the prevailing social and

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|--|
| | <i>economic circumstances, that in general will not exceed an annual average activity concentration due to 222Rn of 300 Bq/m³</i> ”. |
| (2) | <p>BASIS: GSR PART 3 Para 5.3 states “<i>The government shall include in the legal and regulatory framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The government, in the legal and regulatory framework, as appropriate:</i></p> <p><i>(a) Shall specify the exposure situations that are included in the scope of existing exposure situations;</i></p> <p><i>(b) Shall specify the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified;</i></p> <p><i>(c) Shall assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to other relevant authorities and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions;</i></p> <p><i>(d) Shall provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate.</i></p> |
| R24 | <p>Recommendation: The Government should establish provisions for the management of existing exposure situations and the remediation thereof. These provisions should include a national reference level for protection against indoor radon.</p> |

Control of Discharges

The IRRS team noted that the development review and approval of discharges from authorised facilities is consistent with the approach detailed in GSR Part 3 and other IAEA safety standards.

The maximum annual exposure to members of the public is prescribed in the Radiation Protection Decree as being less than 1 mSv. To ensure compliance with this limit, the regulatory body has established facility or practice specific limits of less than 0.1mSv/a; and requires optimisation of releases below this value. Lower limits for constraint of the optimisation have also been specified and are:

- 0.001 mSv per year in the case of gaseous or liquid discharges
- 0.01 mSv in the case of external radiation

The IRRS team noted that the regulatory body plans to review and update the current requirements related to environmental monitoring required of licensees. The planned revision of requirements is aimed at ensuring: consistent and systematic evaluation of environmental monitoring programmes at all regulated entities; prompt identification and reporting of unplanned releases to the environment and detection of build-up or increases in concentrations of radioactivity in the environment; and Systematic evaluation of total exposure of members of the public from all sources.

Further, the IRRS team was informed that while the regulatory body does confirmatory monitoring of the actual discharges from the regulated facilities there is no confirmation or verification of the results of environmental monitoring reported by the Licensees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulatory body in the Netherlands does not undertake an independent verification of environmental radioactivity reported by the regulated entities.

| | |
|-----|--|
| (1) | <p>BASIS: GSR PART 3 Requirement 32 states “<i>The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available</i>”.</p> |
| (2) | <p>BASIS: GSR PART 3 paragraph 3.135. states “<i>The regulatory body shall be responsible, as appropriate, for:</i></p> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| | |
|-----|---|
| | <p>(c) Making provision for an independent monitoring programme.</p> <p>(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments.”</p> |
| R25 | <p>Recommendation: The Regulatory body should undertake independent verification of the environmental monitoring reported by regulated facilities.</p> |

Evaluation of National levels of Radiation

The National Institute for Public Health and the Environment (RIVM) conducts monitoring of external gamma radiation on a national basis using a network of fixed monitoring stations. Additionally, there are a number of mobile measuring stations which can be deployed in specific circumstances. The RIVM also conducts monitoring of rainwater and dust in air.

A number of other Ministries in the Netherlands collect data related to radioactivity in soil, drinking water, grass, milk, food substances, river and sea water, sediments etc. These results are all submitted to RIVM for consolidation.

Clearance

The regulatory body in the Netherlands has prescribed clearance levels in the Radiation Protection Decree and implementing regulations. The values prescribed relate to the release of moderate quantities of material and unconditional release. The regulatory body has identified the need for additional clearance values applicable to:

- release of bulk quantities of material,
- conditional clearance of materials,
- materials representing mixtures of artificial and natural nuclides

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The established clearance levels require updating to address identified deficiencies.

| | |
|-----|--|
| (1) | <p>BASIS: GSR Part 3 Requirement 8: Exemption and clearance states: “The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control”.</p> |
| R26 | <p>Recommendation: The regulatory body should update the established clearance levels to include the release of bulk quantities of material, the conditional clearance of materials and materials representing mixtures of artificial and natural nuclides.</p> |

Consumer products

The IRRS team noted that the regulatory body plans to introduce new requirements related to the regulation of consumer products containing radioactivity. This will include requirements on manufacturers of consumer products to provide a justification to the regulatory body and prohibition on consumer products deemed as being not justified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are presently limited, very generic, requirements related to the control of consumer products.

| | |
|-----|--|
| (1) | <p>BASIS: GSR Part 3 Para 3.139 states: “Upon receipt of a request for authorization to provide</p> |
|-----|--|

| | |
|-----|--|
| | <p><i>consumer products to the public, the regulatory body:</i></p> <p>(a) <i>Shall require the provider of the consumer product to provide documents to demonstrate compliance with the requirements in paras 3.138-3.144;</i></p> <p>(b) <i>Shall verify the assessments and the selection of parameters presented in the request for authorization;</i></p> <p>(c) <i>Shall determine whether the end use of the consumer product can be exempted;</i></p> <p>(d) <i>Shall authorize the provision to the public of the consumer product, where appropriate, subject to specific conditions of authorization ”.</i></p> |
| S19 | <p>Suggestion: The regulatory body should consider establishing more specific requirements related to consumer products, consistent with the recommendation in IAEA documents GSR Part 3.</p> |

11.3. SUMMARY

The regulatory framework for the control of medical exposure and its level of implementation is well advanced and in line with IAEA GSR Part 3 requirements. Some discrepancies should be resolved during the transposition in the national legislation of the EC Directive 59/2013.

The arrangements for control of public and environmental exposure and in particular the control of discharges are well established and have been demonstrated to be effective. There is currently no policy for the management of existing exposures and remediation thereof. It is further noted that the regulatory body does not undertake independent verification of the environmental monitoring reported by regulated facilities.

Despite the low national indoor radon levels the regulatory body or the government is encouraged to establish a national reference level for protection against indoor radon. Furthermore, the existing clearance levels established by the regulatory body have been identified as requiring update and enhancement.

The regulatory body should consider establishing more specific requirements related to consumer products.

12. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

12.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

Emergency response by the regulatory body

On the day of the TEPCO Fukushima Daiichi accident organizations of the regulatory body (RIVM and KFD) took steps to obtain reliable information on the status of the NPP affected by the natural catastrophe. The Duty Officer for nuclear emergency management (from TAN, Ministry of Infrastructure and Environment) informed the chair of the National Nuclear Assessment Team for radiological analysis and information (EPAn) which, in reply to the events activated its Back-Office for Radiological Information (BORI). EPAn is an interdepartmental advisory organization of the Ministerial Commission for Crisis Response for nuclear and radiological emergencies. BORI, coordinated by RIVM, consists of expert from national experts and research institutes, with complementary expertise needed for an integrated radiological assessment during nuclear and radiological emergencies. BORI coordinates modelling and monitoring activities of these institutes.

A rough estimate of the source term from the TEPCO Fukushima Daiichi units was prepared by KFD and its radiological consequences was prepared by BORI. On the next day the EPAn was activated (a Front-Office for delivering expert advices to the minister/government on countermeasures which should reduce the effects of radiation for the population and the environment and Back Offices for gathering and elaborating technical information on the accident and its consequences). The EPAn Front-Office was manned with communication experts, KFD experts, radiation protection experts, occupational exposure experts, health care experts, transport experts and it remained active until mid June (with lowering frequency of meetings). During this period the Back-Office for Radiological Information prepared about 50 reports to the EPAn Front-Office. This latter met 33 times and produced 12 reports analysing the situation in Japan and advising the Dutch government and governmental organizations. Many suggestions were addressed to Dutch citizens in Japan; some of them are quoted at the end of this subsection. Others emphasized that the effect of the accident on the Netherlands was negligible. The results of the analyses were also communicated to the Dutch Embassy in Tokyo.

The supervising minister was regularly informed on the situation in Japan and on its implications on the Netherlands. Based on briefing by the minister, developments in Fukushima were weekly discussed by the Council of Ministers.

A daily or sometimes more frequent information exchange was kept with GRS (Germany) and information arrived also from international and foreign organizations and networks like IAEA (USIE), EU (Ecurie, EU Clearinghouse), OECD/NEA, ASN (France).

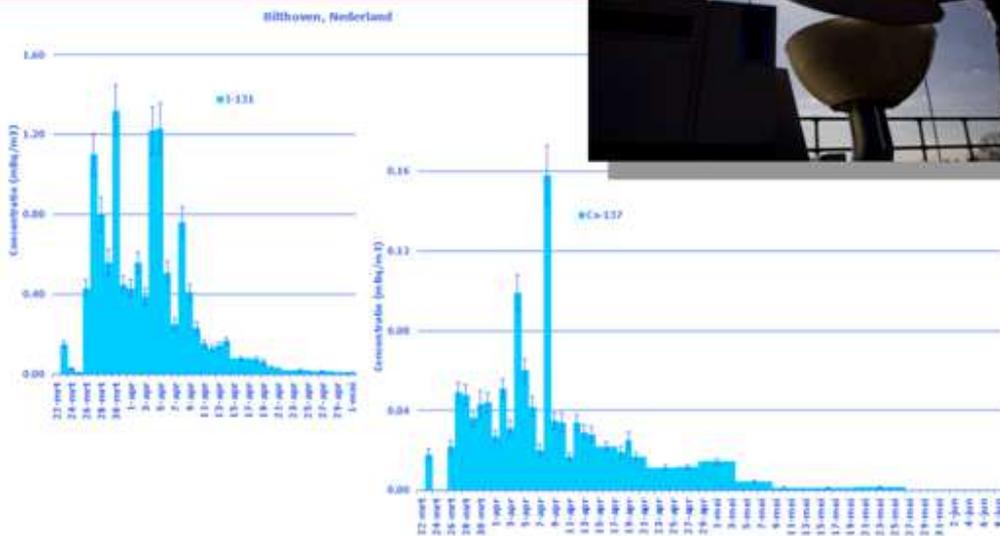
Goods arriving from Japan to the Netherlands were subject to radiological examinations also prior to the accident. In normal circumstances 75% of the incoming containers are examined. After the accident a procedure was compiled by the regulatory body in order to advise border guards on the methodology of the examinations, screening levels were revised and discussed. Ships arriving to Dutch harbours were surveyed on open sea in order to prevent unwanted radiation exposure of workers. Radiation levels of containers in the shipments were measured in the harbours and surface contamination and the contents of the containers were examined further whenever needed. A monitoring programme for foods arriving to the Netherlands from Japan was performed. In the period of April-2011 to beginning of 2012, as much as 49 containers exceeded the threshold radiation level of 10 nSv/hours at 1 m, 19 out of them needed cleaning. Contamination examinations were extended to the engines of the KLM flights arriving from Japan. Dutch passengers arriving from Japan were offered the possibility of whole body counting, and in the early days 21 persons requested measurements.

In neither of these examinations was it necessary to take special measures for excessive radiation level.

Dutch citizens in Japan were advised via the Tokyo embassy on relying upon the communication by the Japanese authorities. They were suggested to follow instructions of the Japanese authorities, to stay in Japan when being far away from the accident site, to avoid traveling north from Tokyo and to stay away from the area affected by the accident. As a precautionary measure, KIO₃ tablets were shipped to Tokyo for a possible iodine prophylaxis if needed, yet there was no need to administer the tablets to Dutch citizens.

Monitoring of airborne contamination was intensified in Netherlands on March 20 until June 2011. No radiation level needing specific measures was observed. The results are illustrated by the figure below (courtesy of RIVM).

Air borne activity



Air borne radioactivity in the Netherlands due to Fukushima accident, measured and reported by RIVM (from Friday March 25 onward)

Immediate actions related to licensees

Based on the results of past safety increasing measures and of the latest periodic safety assessment of the Borssele NPP, KFD decided on not initiating specific inspections related to the accident on the sites. Unlike in case of many other countries, there was little specific pressure from the general public, neither from the politics to demonstrate the ability for conducting prompt and targeted actions by the regulatory body or by the licensees.

Technical reasons behind the decision were that flooding and earthquake hazard analyses were performed in the framework of the PSR completed in 2003, and the measures stemming from these analyses were completed in 2007. Furthermore, the results of the inspections by the NPP in reply to the WANO requirements right after the accident were shared with the regulatory body.

Assessment of the safety of the nuclear installations in light of the lessons learned from the accident was started in the framework of the ENSREG initiated targeted safety reassessment project, called Stress Test (ST). Unlike in most European countries, in the Netherlands all important nuclear installations were included into the exercise, i.e. Borssele NPP, facilities at the Petten site (including the High Flux Reactor) the research reactor in Delft, the waste storage facility COVRA in Vlissingen and the uranium enrichment plant URENCO in Almelo. The ST of the NPP was performed according to the schedule by ENSREG, i.e. the final report by the licensee was submitted to the regulatory body in October 2011, was assessed by KFD and NIV and a national report was submitted to ENSREG by the end of 2011. Important findings in and actions offered by the ST national report are quoted in the next section.

Other nuclear installations conducted and finished their ST in the following months. The latest ST was for the high active waste building in COVRA and was finished by June 2013. It is worth mentioning that for the evaluation of the stress test reports of the licensees experts from various non-nuclear areas were invited, that resulted in appearance of fresh and unexpected insights and ideas in the nuclear way of thinking.

Public communication

Following the activation of the National Nuclear Assessment Team (EPAN) questions and answers were published on a dedicated webpage of the Ministry of Economic Affairs, first related mainly to the situation in Japan, later

mainly to the consequences on the Netherlands and to the consequences of visiting Japan. In early April the typical daily number of visitors of the Fukushima-related page was about 350.

To receive and answer questions from the public a so called ‘call center’ was established in the Ministry of Foreign Affairs. Some tens of questions were received and answered. Note that another call center was operated for journalists and a green number for the general public also existed.

Compared with other European countries, in the Netherlands the public was not very much worried about neither the possible domestic consequences of the accident nor the safety of Dutch nuclear installation in extreme circumstances. Public communication on the TEPCO Fukushima Daiichi accident had limited extensions. No press releases were issued by the regulatory body organizations or their supervising ministries, and representatives of the regulatory body had very few media appearance. Typically representatives of the research and university areas were interviewed by the media.

Public hearings were organized on the ST results with moderate participation in Borssele and in Petten; no such hearings were needed in the neighbourhood of the other nuclear installations.

Results of polls on nuclear acceptance in the Netherlands before the accident were quite stable. After the accident the Dutch regulatory body did not perform specific surveys of the impact of the accident on public opinion. Some surveys were carried out by private institutions. Generally speaking a decrease of the acceptance was measured, largely varying between different surveys (from 6,5% to 45%).

Follow up actions

As a direct response in the first months after the accident, a dedicated project was started at RIVM (commissioned by NIV) to model the expected exposure due to surface contamination of non-food commodities, with the goal to develop a method for the determination of limits for surface contamination of goods. This work led to an internal RIVM-report and was also presented at several international meetings (e.g. IRPA June 2014). At the time of the IRRS missions results of the project are to be presented and discussed in a consultancy meeting at IAEA.

Lessons learned from immediate actions

The accident had no direct impact on the working method of the Dutch regulatory body. It was, however, concluded that in case of a nuclear emergency extending over a longer period of time this would face the involved organizations with serious problems with respect to simultaneous staffing of the emergency preparedness and response organizations and performing the normal regulatory duties.

Further lessons were learned from the ST exercises and shall be discussed in the next section. One of them is worth mentioning here: it has been decided that the KFD inspection programme should be revised for extending it in order to detect precursor events, and specific inspection areas shall be included into the inspection plan based on the experience gained from the ST exercise. The areas foreseen are earthquake resistance of SSC’s; flood resistance of buildings and SSC’s; emergency preparedness and response; organization issues; SAMGs; accident management measures; emergency power supply; fuel storage facility and fuel handling; containment venting; PARs; systems for dosimetry and systems for monitoring during accidents.

12.2 TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT

In line with the initiatives by the European Commission and the European Nuclear Safety Regulators Group (ENSREG), the Netherlands participated in the targeted safety re-evaluation (Stress Test) of its nuclear power plant. By definition the ST addressed earthquake, flooding and other extreme natural events (also in combinations) as well as potential loss of safety functions (electrical power and/or ultimate heat sink), severe accident management and emergency preparedness and response. Beyond the scope defined by ENSREG, the Dutch regulatory body required the completion of stress test exercises for the two research reactors, waste storage facility and uranium enrichment plant as detailed in the previous section. Furthermore, the Dutch regulatory body required to analyze man-made extreme events. The results of the assessments related to the Dutch NPP shall be briefly discussed below.

Stress Test results and regulatory position

In the area of earthquakes, the ST report states that the Netherlands in general, and the site of the Borssele NPP in specific are regions with low seismic activity. The design basis of the NPP was selected with sufficient conservatism, whereas the frequency of an event exceeding the design basis is in the range of $3 \cdot 10^{-5}$ per year. Certain measures were suggested by the licensee to further increase the seismic resistance of the plant, e.g. establishing seismic resistant Emergency Control Center; establishing storage facilities for portable equipment needed by emergency response units; increasing the autarky time above 10 hours; performing Seismic Margin Assessment or seismic PSA to reduce uncertainties in seismic margins; strengthening off-site power supply; developing Extensive Damage Management Guidelines (EDMGs); etc. The regulatory body in general agreed with the steps suggested by the licensee.

Flooding is an external hazard to consider in all types of activities in the Netherlands. The actual design basis for the Borssele NPP is 7.3 meters above NAP, which has been reviewed and accepted again in the latest PSR in 2013. The actual margins allow a flood height of 8.55 m above NAP. In the ST report, the licensee proposes further measures to increase resistance against floods. Some of these measures are largely similar to those listed above for earthquakes (EDMG, Emergency Control Center, storage for equipment); others address establishment of independent voice and data communication means and improvement of plant autonomy. The regulatory body called the attention of the licensee to the importance of considering the effectiveness of any measure before its implementation. It was also stressed that little is known about the impact of floods with very large return periods and it needs further investigations.

A large number of external weather condition types were considered in the ST report related to temperatures, wind, rain, ice, snow, lightning and any credible combinations of theirs. In general terms, the ST report concludes that although the NPP is able to withstand those extreme weather conditions, plant walk-down checklists need to be prepared and reviewed for the foreseeable hazard types. The regulatory body called again the attention to the necessity of investigating the effectiveness of the proposed measures and also raised the issue of minimum depth of underground piping for protection against freezing as a possible direction of further investigations.

To decrease the impact of loss of off-site electrical power, the ST report envisages a number of measures: strengthening the off-site power supply; possibility of transferring diesel fuel from one diesel generator to another; reducing connection time of mobile diesel generators; EDMGs; etc. Besides requiring the assessment of the effectiveness of the foreseen measures, the regulatory body also raised the possibility of a cliff edge effect by running short of lubricating oil and the importance of re-evaluating of the various alternative power sources envisaged by the licensee. In addition the capabilities to cope with station black-out situations during mid-loop operation should be developed and corresponding procedures should be prepared and validated.

In case of loss of ultimate heat sink, the licensee proposes a number of additional measures to increase robustness. These relate on one hand to development of EDMGs and on the other hand additional ways of increasing robustness of spent fuel pool cooling. The regulatory body requires the assessment of the effectiveness of the measures as well as of the availability of fire extinguishing system for the roles foreseen by the licensee in cooling the pool.

Combination of LOOP and LOUHS is also considered in the ST report with some measures additional to those mentioned in the two paragraphs above. The regulatory body, among others, calls the attention of the licensee to the fact that certain SSCs considered to be available in the measures foreseen are not designed, classified or tested for such roles, which, although is acceptable for severe accident management, calls for further assessments.

In enhancing severe accident management capabilities of the NPP, the ST report refers to the measures proposed also against extreme natural hazards, i.e. various EDMGs; Emergency Control Center; storage for EPR equipment; independent voice and data communication. The regulatory body, besides the suggestions given before also proposes to study the international post-Fukushima SAMG developments (attention should be given to SAMGs specific for spent fuel pool accidents) and to re-assess the staffing of the licensee's emergency response organization including assessment of the potential dose to workers.

Finally the ST report deals separately with measures meant to maintain containment integrity after fuel damage. Two such measures are considered: external pressure vessel cooling and hydrogen treatment. The regulatory body

requests further assessments on one hand and consideration of accident management measures after containment failure on the other hand.

The ST report deals also with the potential cliff edge effects. Four types of cliff edge effects are identified: availability of staff; failure of SSCs; availability of diesel fuel; availability of cooling water. Further studies are required on these issues.

Stress Test of installations other than NPP

The ST required by the regulatory body from the two research reactors, waste storage facility and uranium enrichment plant identified no issues requiring intervention. Possible steps resulting in further increase of safety have been identified (mostly aiming at further studies and elaboration of specific procedures). Realization of these steps is foreseen in the framework of the next licence renewal or revision of these facilities.

Activities related to the IAEA Nuclear Safety Action Plan

The Advance Reference Material of the IRRS mission reports on the status of the tasks foreseen by the IAEA Nuclear Safety Action Plan. According to this report, out of the 25 Action Plan items the Netherlands completed 13, 8 are ongoing, 3 are partly ongoing partly open and one is open. The open action is related to the invitation of an EPREV mission, the partly open actions are: nuclear education and training; use of information on radwaste and related issues; nuclear research and development.

CONCLUSION [1]

The IRRS team concluded that the nuclear and radiation safety regulatory body in the Netherlands took appropriate actions in reply to the implications of the TEPCO Fukushima Dai-ichi accident. It also concluded that further effective steps are needed in order to make sure that the regulatory body is capable to deliver its emergency response responsibilities in a long lasting nuclear emergency within or in the vicinity of the Netherlands.

12.3 PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT

The National Action Plan (NAcP) presented to the IRRS team is an updated form of the plan originally submitted for discussion to ENSREG in December 2012, reviewed by ENSREG in April 2013 and submitted to the Sixth Review Meeting of the Convention on Nuclear Safety in April 2014. It contains the actions of the licensee and of the national organizations resulted from the stress test exercise of the Dutch nuclear power plant.

The major actions in the NAcP relate to the issues mentioned in the previous section in connection with the various hazard topics i.e. better protected Emergency Control Center; storage facilities for portable equipment; spent fuel pool cooling; transfer and connection of mobile DGs; independent voice and data communication system; fire protection issues; increasing the autarky time; development of various Extensive Damage Management Guidelines; assessment of the need of SAM equipment upgrade; further studies on various hazards.

The deadlines in the NAcP are between 2012 and 2016. The implementation of most measures is on schedule. Recently the licensee requested revision of deadlines and scope of some measures, in view of new insights and difficulties in realising some hardware solutions. Discussion with the regulatory body on these issues is ongoing. The licensee submits reports on its progress four times a year. The regulatory body conducts targeted inspections following the report submittals. Topical inspections/reviews are planned on specific issues like seismic margin reassessment, flooding protection, airplane crash impact mitigation. The inspections are part of the yearly inspection planning. The reviews are mainly done in the framework of the review and assessment of the periodical safety review of 2013.

The NAcP also addresses the national regulatory body in several actions. The most notable ones are as below:

- drafting requirements for the design and construction of new research reactors and nuclear power plants

- drafting requirements and guidance related to internal and external hazards
- studying new financing mechanisms for licence application management
- studying the implications of the German phase-out decision on the operation of the Dutch NPP
- making the management aware of the importance of regulatory body safety culture

Besides these activities, actions are foreseen related to the duties of the Dutch nuclear and radiation safety regulators in the emergency preparedness and response activities. Accordingly harmonized efforts are planned with the neighbouring countries in defining the protective zones and in conducting joint exercises. Most of the actions are due to be completed in 2013 - 2014; some of them are of continuous nature. Implementation of most actions is on schedule. Some delay is related to the creation of a new organization of the regulatory body by 2015 and some actions will be taken up in the new organization (e.g. the management of Safety Culture within the Regulatory Body).

CONCLUSION [2]

The IRRS team concluded that the possible implications of the TEPCO Fukushima Daiichi accident on nuclear and radiation safety in the Netherlands were thoroughly assessed and the actions that may further enhance the nuclear and radiation safety in the country in general and the safety of the operating nuclear power plant in specific were determined and scheduled for realization in an Action Plan. No short or medium term change in the nuclear and radiation safety regulatory practice was deemed necessary as a consequence of the lessons learned from the accident, yet the inspection programme of the regulatory body shall be enhanced to cover areas of importance in preventing a large scale nuclear accident.

12.4 CONCLUSIONS BY REVIEWED AREAS

Note: The significance of Fukushima implications was considered as part of the review of each IRRS module. The review conclusions below and the plans presented by the Netherlands to further address issues associated with the TEPCO Fukushima Daiichi accident in the coming years should be included in the scope of the follow-up IRRS mission to be invited by the Netherlands.

Module 1: Responsibilities and Functions of the Government

The Nuclear Energy Act (Article 40) regulates the preparation of the emergency response organization; this is laid down in the National Nuclear and Radiological Response Plan (NCS), and the National Nuclear Emergency Plan which is based on the previous one. The Nuclear Energy Act and the Radiation Protection Decree set rules for intervention in case of accidents or prolonged exposure and the preparation thereof. The minister of Economic Affairs coordinates efforts on management of nuclear accidents and is also responsible for the radiation protection measures. Within the framework for safety, provisions are made to ensure that the regulatory body is also effectively independent in emergency situations.

CONCLUSION [3]

The IRRS team concluded the existing status of the legal framework to be appropriate. Upon review of the advance reference material and thorough discussions with the counterparts, the IRRS team found that the regulatory body is committed to act as necessary.

Module 2: Global Nuclear Safety Regime

The Netherlands is a contracting party to, and has ratified and fully implemented the obligations of the:

- Convention on Nuclear Safety (CNS)
- Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (JC)
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency

- Convention on Early Notification of a Nuclear Accident

International (IAEA) review-missions are an integral part of the supervision-strategy of the Nuclear Inspectorate (KFD) of the RB. Recent examples are SALTO-missions (2009, 2012 and 2014), IPSART-missions (2009 and 2013), Waste safety appraisal (2009).

CONCLUSION [4]

The IRRS team considered the status of international cooperation achieved by the Netherlands as appropriate.

Module 3: Responsibilities and Functions of the Regulatory Body

The team found that during the TEPCO Fukushima Daiichi accident the NIV, RVO/TSB and KFD were independent nuclear and safety regulators reporting to the ministry of Economic Affairs. The mandate of the NIV and KFD allows the necessary actions to be taken in a timely manner to intervene during normal operation and in case of an accident to ensure safety. In case of emergency a National Nuclear Assessment Team (EPAn) is formed. The EPAn provides timely information and advices for Policy Teams to take proper actions and decisions. According to the Nuclear Energy Act the Minister can order the authorized party to take any of these actions and decisions. NIV, RVO/TSB and KFD have appropriate structure and responsibilities to set the requirements and to conduct oversight to minimize the possibility of an accident, in an event of an accident to mitigate the consequences. These actions are pre-planned and described in the procedures. A good contact to all government parts exists. While an update of the National Crisis Management Policy Plan was published in October 2014, pre-planning tasks, responsibilities and roles should nonetheless be structured and described. Emergency exercises are held several times in a year. NIV, RVO/TSB and KFD have taken seriously their functions of that the public is duly informed and there are arrangement made to ensure the information even in case of severe damage of infrastructure.

The NIV and KFD did not request immediately after the accident any assessment or inspection to be made by the licence holder of the nuclear power plant. However NIV and KFD have the mandate and means to require enhancement of safety as needed.

CONCLUSION [5]

The IRRS team concluded that further actions are needed and are suggested concerning the formalizing and structuring the preparedness phase of emergency arrangements with the TAN and other governmental organizations.

Module 4: Management System of the Regulatory Body

After the TEPCO Fukushima Daiichi accident, actions were carried out, e.g. stress test including peer review and follow up and actions from the IAEA action plan. The management system is assessed and improved by using PDCA cycle (Plan, Do, Check, Act) methodology.

Regarding the fact, that the regulatory body has not completely established and implemented an Integrated Management System yet, self-assessments and independent assessments are not conducted regularly.

Based on the conclusion of an analysis of the capacity and financial resources needed for the activities to be carried out by the new regulatory body, the capacity and the financial resources of the merging organizations may not be sufficient to meet all IAEA standards. Nevertheless, increases are not foreseen.

The KFD has defined fields of expertise necessary to conduct the regulatory activities; with a staff member assigned to each field in order to assure competence.

All the three main entities in the Regulatory Body actively encourage safety culture. The regulatory body has started elaborating and executing a Safety Culture development process but it is not completed yet. It should be noted that, training of the skills of learning and questioning attitude is part of the personnel policy within NIV.

The KFD has a policy document on communication with subtitle “transparency and openness first”. The public website of the KFD summarizes the policy of the different sections of the KFD and incidents are reported on it.

The Netherlands has MOU's with various countries (a formal Agreement between Netherlands and Germany (NDKK) – and a the memorandum of understanding with Belgium) dealing with exchange of information with neighbouring countries, and steps to harmonise classification systems with neighbouring countries have been initiated. A program on Regulatory Experience Feedback (REF) is under development.

CONCLUSION [6]

The IRRS team concluded that the necessary actions in order to complete the program for establishing and implementing an Integrated Management System to enhance safety have been recognised by the regulatory body.

Module 5: Authorization

The Dutch system for authorization for all nuclear facilities (see section 5) has not been modified as a consequence of the TEPCO Fukushima Daiichi accident. No changes to the licensing procedure have been made.

The licensing procedure for new nuclear installation involves an Environmental Impact Assessment (EIA) in which the site-related external hazards are evaluated. If not acceptable, the new installation at the proposed site can be rejected.

As a result of the stress test that was performed on all Dutch nuclear facilities, a series of specific modifications to improve safety have been identified by the licensees. In a letter of the Minister of Economic Affairs, the licensees were ordered to implement these measures in accordance with an approved planning. The authorization of such modifications will be followed-up by the regulatory body within the established authorization system. If these modifications require a licence modification, the licensee is asked to file a licence application to NIV. The progress and timely implementation of all stress test modifications will be followed up by KFD.

In the future revision licences of the Borssele NPP (2015), HFR (2015) and Delft research reactor (2016), these stress test modifications will be taken into account where needed in the licence conditions.

CONCLUSION [7]

The IRRS team concluded that, with respect to the TEPCO Fukushima Daiichi accident no particular concern related to the authorization process was raised. The regulatory body has an adequate authorization process to enforce necessary safety improvements as well as to authorize their implementation.

Module 6: Review and Assessment

The main activity in the area of review and assessment, which was performed after the TEPCO Fukushima Daiichi accident, has been conducted by the regulatory body in the frame of the European Stress Tests. All nuclear installations in the Netherlands were asked by the Minister of Economic Affairs to perform this exercise. The ENSREG requirements/methodology was used as the assessment framework. In addition to the ENSREG format, the licensees in the Netherlands were asked not to limit the scope of initiating events to earthquakes, and flooding, but also to include human-induced external hazards (aircraft crash, external explosions,...).

A specific project team within KFD and NIV conducted the review and assessment of the licensee stress test reports. For the nuclear power plant the TSO GRS was asked to provide a second opinion on the work of KFD. During the review and assessment of the licensee stress test reports, the regulatory body also used expert advice from other Dutch authorities (for example Dutch Royal Meteorological Institute, Water State Authority, Department of Mines...) for specific topics within their scope of competence.

The regulatory body is currently drafting new Dutch Safety Requirements, which will contain additional detailed requirements on design extension conditions. Present methods for and assessment of external hazards, in specific of off-shore seismic activity and combination of events are being reviewed. It will include international good practice on the assessment of earthquake hazards for a region with low seismicity. Based on the lessons learned from the TEPCO Fukushima Daiichi accident, these Dutch Safety Requirements will also contain specific design

requirements such as diverse ultimate heat sinks, containment structure for a spent fuel pool, emergency response centre, etc.

The Dutch regulatory body took active part in the work that WENRA has taken up on behalf of ENSREG in order to further improve regulations for review and assessment following the main conclusions of the European Stress Tests. The new WENRA SRLs will be integrated in the Dutch regulatory framework through the Dutch Safety Requirements regulation. The revisions to the IAEA safety standards as described in IAEA DS 462 have also been taken into account in drafting the DSR.

CONCLUSION [8]

The IRRS team acknowledged that the regulatory body participated in the European stress tests, which were applied to all Dutch nuclear facilities with a slightly enlarged scope with respect to the ENSREG specifications. Related to topics such as flooding, earthquake and extreme weather conditions, the Dutch regulatory body used available expertise from other Dutch authorities.

Module 7: Inspection

For potential pre-cursor events, KFD and the licensees have a form of analysis in place to review the events, but a more systematic approach has been identified by KFD as a future programme of work.

For inspection of the NPP, a programme of post Stress Test inspection and assessment has been developed by KFD and will be implemented in 2014 and after. These focus on the quarterly reports provided by the licensee. The KFD activities include assessment of submitted information and studies, such as new flooding or seismic margin studies, and inspection of new equipment such as satellite communications. These assessments and inspections also review progress with the overall improvement programme agreed by the licensee with NIV and KFD.

The agreed improvement programme appears to have delivered both on and off site additional power and cooling systems, together with improved communications. Although no systematic follow-up on inspection programme is in place for the additional protection systems, this is consistent with the findings from other parts of the inspection programme, including EPR. Nevertheless, as this additional equipment has been included as part of the emergency programme, it will be covered by the sampling programme, and is covered by the licensee which requires that all installed systems, safety classified or not, be fit for purpose.

The full improvement programme following the stress tests has not yet been agreed between KFD and the licensees. This is because the studies currently being undertaken and yet to be delivered could result in further improvements being identified. Once these studies have been submitted and assessed and agreement has been reached on additional improvements – if any -, KFD is committed to inspecting progress with the agreed improvement plan to the completion of the Fukushima upgrade programme.

CONCLUSION [9]

The IRRS team concluded that the stress test process has identified improvement activities which were agreed between the licensee and regulator and the assessment and inspection programme covers these in a satisfactory manner, the existing status is appropriate at this stage of the upgrade programme. Further improvement activities may also be identified from studies yet to be completed, and the regulatory body is committed to act as necessary.

Module 8: Enforcement

The lessons learned from the TEPCO Fukushima Daiichi accident included a review of the existing enforcement regime to ensure it would be sufficient to address a situation similar to the accident. This led to the conclusion that an accident of that magnitude could be covered by the current enforcement regime and that no changes to the enforcement regime are needed.

Delays in the implementation of the agreed improvement plan at Borssele led to an enforcement letter being issued to the licensee stating the timescale the regulator expects for completion of the agreed improvement programme.

CONCLUSION [10]

The IRRS team concluded that with respect to enforcement, no concerns are raised in the light of learning from the TEPCO Fukushima Daiichi accident.

Module 9: Regulations and Guides

Prior to the TEPCO Fukushima Daiichi accident, the regulatory body was in the process of developing new regulations on safety requirements for new reactors, specifically on the design and operation of new water cooled and water moderated reactors. Post Fukushima, the regulatory body incorporated in the DSRs a number of the lessons learned from the accident using IAEA DS 462 as a reference basis. The requirements related to external hazards, emergency preparedness and response, etc have been included in these DSRs. Furthermore, the fulfilment of three fundamental safety functions in the design of the reactor viz. reactivity control, core cooling and containment of radioactivity have also been addressed in the DSRs.

A stress test was carried out for all nuclear facilities which brought out that provisions already existed to take care of most of the safety functions. The outcomes of these stress tests are being followed up by KFD. Aspects related to cooling of spent fuel stored inside the containment, enhancing the instrumentation for monitoring the reactor state, provisions for large amounts of contaminated water at site in case of an accident, etc. are also being followed up by KFD. The DSRs have been reviewed by the IAEA and most of the recommendations are being implemented in the new Dutch Regulation.

An important aspect to be considered in case of the Dutch approach is that they accord great importance to the IAEA regulatory documents which they adapt according to their system and attach as safety rules in the form of NVRs to the licence. Following this approach the regulatory requirements of Netherlands are upgraded in accordance with the revised IAEA requirements.

CONCLUSION [11]

The IRRS team concluded that post Fukushima aspects will be addressed in the Dutch Safety Requirements for the new build nuclear power plants. Those requirements will be generally applicable for new build research reactors with application of a graded approach.

Module 10: Emergency Preparedness and Response – regulatory aspects

No recovery plans or procedures have been established for the late phase after a radiation emergency has occurred. TAN has recognized the need to develop a national strategy and procedures for the recovery phase, specifically for handling large volumes of all radioactive wastes after a nuclear emergency.

The need to align the threat categorization in the Netherlands with the international standards has been recognized and will be explored by the regulatory body. The IRRS team considers that NIV should initiate steps to make this categorization consistent with the referred standards. Similarly, the need to update the emergency classification scheme in the national nuclear and radiological emergency plan in line with international standards has been acknowledged.

In the current Dutch regional nuclear emergency plan in Zeeland (Rampbestrijdingsplan Nucleaire Installaties), multi-facility or multi-unit accidents are not considered. Discussions regarding the impact of multi-unit nuclear emergencies with neighbouring countries have been initiated. However coordinated actions in this regard have not yet been implemented.

The TAN and EPAn have specified roles during response which are coordinated with other response organizations, including KFD. During exercises KFD has a dual role in evaluating the licensee response and determining the source term for the use by other authorities. The IRRS team considers that the KFD responsibilities should be clearly and formally established.

Borssele NPP plans to establish a new emergency response centre away from the reactor as part of the improvements after the accident. Communications equipment has also been procured for redundancy purposes and is stored in current emergency locations and facilities. Borssele NPP has also updated a procedure for extreme

weather conditions. It was noted by the team that some of these improvements are not systematically reviewed by KFD.

CONCLUSION [12]

The IRRS team concluded that regulatory body has recognized the necessary actions in response to the TEPCO Fukushima Daiichi accident. Necessary further actions have been planned including the establishment of a new emergency response centre for the Borssele NPP and bilateral discussion with neighbouring countries regarding the impact of multi-unit nuclear emergencies. Further actions are needed to develop a recovery strategy and procedures, formalization of regulatory body responsibilities.

APPENDIX I – LIST OF PARTICIPANTS



INTERNATIONAL EXPERTS:

| | | |
|---------------------------|--|--|
| STRITAR Andrej | Slovenian Nuclear Safety Administration | andrej.stritar@gov.si |
| REGIMBALD André | Canadian Nuclear Safety Commission (CNSC) | andre.regimbald@cnsccsn.gc.ca |
| ALTORFER Felix | Swiss Federal Nuclear Safety Inspectorate (ENSI) | felix.altorfer@ensi.ch |
| BODIS Zoltanne | Hungarian Atomic Energy Authority (HAEA) | bodis@haea.gov.hu |
| DONALD John | Office for Nuclear Regulation (ONR) | john.donald@onr.gsi.gov.uk |
| FIGUEIRA DA SILVA Eduardo | National Nuclear Energy Commission – Brazil | efsilva@cnen.gov.br |
| FISCHER Bernhard | Federal Office for Radiation Protection | bfischer@bfs.de |
| FOUCHER Laurent | Autorite de Surete Nucleaire (ASN) | laurent.foucher@asn.fr |
| HOWE Allen | U.S. Nuclear Regulatory Commission (NRC) | allen.howe@nrc.gov |
| JAERVINEN Marja-Leena | Radiation and Nuclear Safety Authority (STUK) | marja-leena.jarvinen@stuk.fi |
| KAMENOPOULOU Vasiliki | Greek Atomic Energy Commission | vkamenop@ecae.gr |

| | | |
|-------------------------|--|--|
| KILOCHYTSKA Tetiana | State Nuclear Regulatory Inspectorate of Ukraine | kilochytska@hq.snrc.gov.ua |
| MADDEN Jack | Environmental Protection Agency (EPA) | jmadden@rpii.ie |
| MALHOTRA Reeta Rani | Atomic Energy Regulatory Board (AERB) | reetamalhotra@aerb.gov.in |
| MULLER Alan | National Nuclear Regulator | amuller@nnr.co.za |
| PATHER Thiagan | National Nuclear Regulator | tpather@nnr.co.za |
| PELCHAT John | U.S. Nuclear Regulatory Commission (NRC) | john.pelchat@nrc.gov |
| SERENAITE Dovile | Radiation Protection Centre | dovile.serenaite@rsc.lt |
| VAN WONTERGHEM Frederik | Federal Agency for Nuclear Control | frederik.vanwongerghem@fanc.fgov.be |
| ZAGRAJEK Marcin | National Atomic Energy Agency (PAA) | marcin.zagrajek@paa.gov.pl |
| HULSMANS Mark | Observer - European Commission (EC) | mark.hulsmans@ec.europa.eu |
| PAGAR Sunil | Observer - Atomic Energy Regulatory Board (AERB) | sunil@aerb.gov.in |
| LIAISON OFFICERS | | |
| KOBETZ Tim | Division of Nuclear Installation Safety | t.kobetz@iaea.org |
| MANSOUX Hilaire | Division of Nuclear Safety and Radiation Waste | h.mansoux@iaea.org |
| BRUNO Gerard | Division of Nuclear Safety and Radiation Waste | g.bruno@iaea.org |
| LUX Ivan | Division of Nuclear Installation Safety | i.lux@iaea.org |
| SALINAS MARIACA Rodrigo | Incident and Emergency Centre | r.salinas@iaea.org |
| REBIKOVA Olga | Division of Nuclear Installation Safety | o.rebikova@iaea.org |
| LIAISON OFFICERS | | |
| SEDEE Aad | Ministry of Economic Affairs (EZ) | a.g.j.sedee@minez.nl |
| JANSEN Robert | Nuclear Inspectorate (KFD) | rob.jansen@ILenT.nl |

APPENDIX II – MISSION PROGRAMME

First Week

| Time | SAT | SUN | MON | TUE | WED | THU | FRI | SAT | SUN | | | | | | |
|----------------------------|-------------------------|--|------------------|-----------------------|-----------------------|---|-----------------------|--------------------|------------------------------|-------------------------------|---|---|------------------------------|--------------------------------------|--|
| 9:00-10:00 | Arrival of Team Members | Team building meeting: • 5 minutes/TM self-intro • Refresher training | Entrance Meeting | Interviews | Visits | Interviews | Visits | Interviews | Visits/EPR exerc. | DTC writes introductory parts | TM write Report TL and DTL review introductory part Draft text to TL | <ul style="list-style-type: none"> • Discussing and improving Draft Report • Cross-Reading • TL, DTL, TC and DTC read everything | Free day, Social Tour | Reading, Cross-reading of the Report | |
| 10:00-11:00 | | | | | | | | | | | | | | | |
| 11:00-12:00 | | | | | | | | | | | | | | | |
| 12:00-13:00 | | Lunch | Lunch with Host | Standing lunch | | Standing lunch | Standing lunch | Standing lunch | Policy Discussions | Standing lunch | | | | | |
| 13:00-15:00 | | | | Interviews | | Interviews | Visits | Interviews | Visits | DTC writes introductory parts | Policy Discussions | Policy Discussions | | | |
| 14:00-15:00 15:00-16:00 | | Initial Team Meeting: • IRRS process • Main objectives • Report writing • Schedule • First observations • In-Group discussions | Interviews | Interviews | Visits | Interviews | Visits | Interviews | Visits | DTC writes introductory parts | Secretariat edits the report Preliminary Draft Report Ready | Cross-reading by TM | | | Discussion of the results of Cross-Reading |
| 16:00-17:00 | | | | | | | | | | | | | | | Finalization of the report parts by team members |
| 17:00-18:00 | | | | Daily Team Meeting | Daily Team Meeting | Daily Team Meeting: Discussion of findings | Daily Team Meeting | Daily Team Meeting | Daily Team Meeting | Daily Team Meeting | Daily Team Meeting | | | | |
| 18:00-20:00 | | Informal dinner | Team Dinner | Dinner | Dinner | Dinner | Dinner | Dinner | Dinner | Dinner | Dinner | | | | |
| 20:00-24:00 | | | | Writing of the report | Writing of the report | Secretariat edits Report TM write Report | Writing of the report | TM Read Draft | Secretariat edits the report | | | | | | |

Second Week

| | MON | TUE | WED | THU | FRI | |
|-------------|---|--|--|--|--------------------------------------|-------------------------------|
| 9:00-10:00 | Individual discussions of Rs, Ss and GPs with counterparts / TC, DTC prepares Executive Summary | Common read through and finalisation of the report by the Team | | Host reads Executive Summary And Draft | Submission of the Final Draft | 9:00-10:00 |
| 10:00-12:00 | | Submission of the Draft to the Host | | | | Exit Meeting Press Conference |
| 12:00-13:00 | Standing lunch | Standing lunch | Lunch | Standing Lunch | | 12:00-13:00 |
| 13:00-14:00 | Team discussion of the changes in observations due to discussions with counterparts | Host reads Draft | Discussion of Executive Summary and TC, DTC prepares exit presentation / TC drafts the Press Release | Written comments by the Host | Departure Home | 13:00-15:00 |
| 14:00-15:00 | | | | | | |
| 15:00-17:00 | Team included agreed changes into report | Deliver Executive Summary to Host | Discussion with Host | Briefing of the Director Finalisation of the press release | | 15:00-17:00 |
| 17:00-18:00 | Cross-Reading, TL, DTL, TC and DTC read everything | | | | | |
| 18:00-20:00 | Dinner | Dinner | Farewell Dinner | | | 18:00-20:00 |
| 20:00-21:00 | Secretariat includes changes | | Team meeting for finalisation of the Report | | | 20:00-21:00 |
| 21:00-24:00 | | | | | | 21:00-24:00 |

APPENDIX III – SITE VISITS

1. Anthony van Leeuwenhoek Hospital, Amsterdam
2. Applus RTD HASS applications, Rotterdam
3. COVRA Interim Waste Storage Facility, Borssele
4. EPZ/KCB Nuclear Power Plant, Borssele
5. NRG/HFR Research Reactor, Petten
6. URENCO Fuel Cycle Facility, Almelo

APPENDIX IV – LIST OF COUNTERPARTS

| | IRRS Experts | Lead Counterpart | Support Staff |
|-----------|--|---|---|
| 1. | LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES | | |
| | ALTORFER Felix FISCHER Bernhard | LEIJENDEKKER Rita DELFINI Genevra | JANSEN Rob PIERSMA, Barto, SEDEE Aad |
| 2. | GLOBAL NUCLEAR SAFETY REGIME | | |
| | ALTORFER Felix FISCHER Bernhard | DELFINI Genevra LEIJENDEKKER Rita BOXMAN Hubert | JANSEN Rob PIERSMA, Barto, SEDEE Aad |
| 3. | RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | | |
| | BODIS Zoltanne JAERVINEN Marja-Leena MALHOTRA Reeta | VAN LIMBORGH, Anneke VOGELS Marli VERZANDVOORT, Marcel | VAN LEEUWEN Damie |
| 4. | MANAGEMENT SYSTEM OF THE REGULATORY BODY | | |
| | BODIS Zoltanne JAERVINEN Marja-Leena MALHOTRA Reeta | VAN LIMBORGH, Anneke NIEDERLÄNDER Andrea VERZANDVOORT, Marcel SORMANI Patricia | VAN LEEUWEN Damie GULIK, John van MULLER, Ramon |
| 5. | AUTHORIZATION | | |
| | BRUNO Gerard FIGUEIRA DA SILVA Eduardo FOUCHER Laurent KILOCHYTSKA Tetiana MADDEN Jack PATHER Thiagan PELCHAT John SERENAITE Dovile VAN WONTERGHEM Frederik ZAGRAJEK Marcin | KLOMBERG Theo VAN DER WIEL Louis LINDHORST Lutz AERNSBERGEN Lodewijk DE KOFF Sigrid VERMEULEN Ton KUIPERS Gerritjan TER MORSHUIZEN Mathieu FRANKEN Yuri | AUWERDA Gert Jan GOPAL – KALI Mithra TJIN-ASJOE Dennis VAN DER HEIJDEN Trude VAN GELDER Iris VAN LEEUWEN Damie HEIJNINK Wessel VAN DER HEIJDT Bertie |
| 6. | REVIEW AND ASSESSMENT | | |

| | IRRS Experts | Lead Counterpart | Support Staff |
|-----------|--|---|---|
| | BRUNO Gerard FIGUEIRA DA SILVA Eduardo FOUCHER Laurent KILOCHYTSKA Tetiana MADDEN Jack PATHER Thiagan PELCHAT John SERENAITE Dovile VAN WONTERGHEM Frederik ZAGRAJEK Marcin | KLOMBERG Theo VAN DER WIEL Louis LINDHORST Lutz AERNSBERGEN Lodewijk DE KOFF Sigrid VERMEULEN Ton KUIPERS Gerritjan TER MORSHUIZEN Mathieu FRANKEN Yuri | AUWERDA Gert Jan VAN DER HEIJDT Bertie GOPAL – KALI Mithra TJIN-ASJOE Dennis VAN DER HEIJDEN Trude VAN GELDER Iris VAN LEEUWEN Damie HEIJNINK Wessel STEENHUIZEN, Margreet DUBBERS, Yvonne |
| 7. | INSPECTION | | |
| | BRUNO Gerard DONALD John FIGUEIRA DA SILVA Eduardo HOWE Allen KILOCHYTSKA Tetiana MADDEN Jack PATHER Thiagan PELCHAT John SERENAITE Dovile ZAGRAJEK Marcin | VERWEIJ Bert VAN LONKHUIJZEN Wouter VAN MEGGELEN Jan BREAS Gerard MEULMEESTER, Martijn de ARENDS, Patrick | TOLUD, Wilma LEEUWEN, Yvonne KOCH, Werner JANSEN, Kees KOSSEN, Rob ROZEMA, Harold VLIET, Martijn van BERLO, Marcel van LAMMERS, Eric |
| 8. | ENFORCEMENT | | |
| | BRUNO Gerard DONALD John FIGUEIRA DA SILVA Eduardo HOWE Allen KILOCHYTSKA Tetiana MADDEN Jack PATHER Thiagan PELCHAT John SERENAITE Dovile ZAGRAJEK Marcin | VERWEIJ Bert VAN LONKHUIJZEN Wouter VAN MEGGELEN Jan | |
| 9. | REGULATIONS AND GUIDES | | |

| | IRRS Experts | Lead Counterpart | Support Staff |
|------------|---|---|--|
| | BODIS Zoltanne BRUNO Gerard FIGUEIRA DA SILVA Eduardo JAERVINEN Marja-Leena KILOCHYTSKA Tetiana MADDEN Jack MALHOTRA Reeta PATHER Thiagan PELCHAT John SERENAITE Dovile ZAGRAJEK Marcin | KLOMBERG Theo VAN DER WIEL Louis AERNSBERGEN Lodewijk DE KOFF Sigrid VERMEULEN Ton KUIPERS Gerritjan TER MORSHUIZEN Mathieu FRANKEN Yuri | AUWERDA Gert Jan GOPAL – KALI Mithra TJIN-ASJOE Dennis VAN DER HEIJDEN Trude VAN GELDER Iris VAN LEEUWEN Damie HEIJNINK Wessel |
| 10. | EMERGENCY PREPAREDNESS AND RESPONSE | | |
| | MULLER Alan SALINAS Rodrigo | GÖRTS Peter MOLHOEK Wim VAN DER VEEN Henk BOXMAN Hubert | HEIJNINCK Wessel BIJHOLT Jette ARENDS, Patrick KELLER, Bernd |
| 11. | ADDITIONAL AREAS | | |
| | BRUNO Gerard KAMENOPOULOU Vasiliki KILOCHYTSKA Tetiana PATHER Thiagan | VAN DER WIEL Arno MEINDERS Lammert SLEIDERINK Hedwig LOUIS Thierry ROOBOL Lars GODTHELP Barbara TIJSMANS Miriam BREAS Gerard ARENDS Patrick TER MORSHUIZEN Mathieu KELLER Bernd FRANKEN Yuri | HENSBERGEN Saskia GOPAL – KALI Mithra TJIN-ASJOE Dennis SLAPER Harry WALSWEER, Arjan OOSTERHOF, Sikko |
| 12. | REGULATORY IMPLICATIONS OF THE TEPKO FUKUSHIMA DAI-ICI ACCIDENT | | |
| | LUX Ivan | DELFINI Ginevra ARENDS Patrick | |

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|---|--|---|
| 1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES | R1 | Recommendation: The government should provide a consolidated, overarching national policy and strategy for safety, including radioactive waste management and disposal, and including human and financial resources, as well as a framework for research and development. |
| | R2 | Recommendation: The government should make legal provisions to require financial provisions for nuclear and non-nuclear facilities, for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities. |
| | R3 | Recommendation: The government should separate the regulatory body from the ministry that has responsibility in respect of the facilities regulated by the regulatory body or responsibility for energy policy. |
| | S1 | Suggestion: The government should consider explicitly stating in the legal framework that the fundamental principle of prime responsibility for safety rests with the person or organisation responsible for facilities and activities, that give rise to radiation risks. |
| | R4 | Recommendation: The government should make provisions to foster the effective coordination of and collaboration between and within the regulatory authorities. |
| | GP1 | Good Practice: The specific and comprehensive regulatory provisions in place allows for effective control of contaminated scrap metal and safe management of the contaminated material. |
| | R5 | Recommendation: The government should, as an essential element of the national policy and strategy for safety, make provisions for the necessary professional education and training, research and development to build and maintain the competence of a sufficient number of suitably qualified and |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|--|--|---|
| | | experienced experts in nuclear and radiation safety and increase its resilience. |
| 2. GLOBAL NUCLEAR SAFETY REGIME | GP2 | Good Practice: The Dutch regulator has taken the initiative to start a KWUREG. KWUREG is expected to harmonize experience from all countries with Siemens/KWU reactors i.e. for long term operation and to promote closer cooperation of those countries to cope with the effect of the phase-out in Germany. |
| | R6 | Recommendation: The regulatory body should organize activities related to operating and regulatory experience feedback (e.g. exchange of information including experience from other countries, analysis and reporting) in a structured and systematic way. This should also include feedback on measures taken in response to information received. |
| 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | R7 | Recommendation: The regulatory body should ensure that its structure and organisation enable effective fulfilment of its statutory obligations and there are no restrictions to the exchange of information between policy making, developing regulations and guides, licensing, review and assessment, inspection and enforcement functions at all levels. |
| | R8 | Recommendation: The regulatory body should develop and implement policies and practices to promote common safety culture. |
| | R9 | Recommendation: The regulatory body should assess its resources and competency needs, against the strategies and regulatory functions and take the measures to ensure it has sufficient resources to fulfil its statutory obligations. |
| | R10 | Recommendation: The regulatory body should develop a systematic, structured and formalised training programme for current and new staff involved in the management and implementation of the regulatory activities. In particular the verification of adequate competence of certified inspectors should be included. The efficiency of the programme should be verified periodically. |
| | S2 | Suggestion: The regulatory body should consider establishing an advisory body or bodies to give technical or other expert professional advice as necessary in |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|---|--|---|
| | | support of regulatory functions. The regulatory body should consider inviting participation of international experts to such Advisory body/bodies. |
| | S3 | Suggestion: The regulatory body should consider making arrangements to ensure and verify that there is no conflict of interest in its technical support organisations. |
| | R11 | Recommendation: The regulatory body should consolidate and improve its systems for keeping all records relating to the safety of facilities and activities, including registers and documents related to administrative support. |
| | S4 | Suggestion: The regulatory body should consider including all authorized radiation sources in the national source register. |
| 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY | R12 | Recommendation: The regulatory body should complete its program for establishing and implementing an Integrated Management System. This should include development of all processes, description of interactions between processes, internal procedures to perform different tasks and promotion and support of strong safety culture in the organisation. |
| | S5 | Suggestion: The regulatory body should consider allocating sufficient resources to establish, implement, assess, maintain and continually improve the management system. |
| 5. AUTHORIZATION | R13 | Recommendation: The regulatory body should enhance the consistency of different licences by using similar reference documents in the licences of all nuclear facilities (NVR and/or IAEA Safety standards and guides). |
| | S6 | Suggestion: The regulatory body should consider extending the scope of authorisation to include the Import/Export of high activity sealed radioactive sources. |
| 6. REVIEW AND ASSESSMENT | S7 | Suggestion: The regulatory body should consider finalizing and publishing the “Dutch Licensing Policy”, “Organisational Review Plan” and “Technical Review Plan” in order to provide clarity and transparency in the licensing process. |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|----------------|--|--|
| | S8 | <p>Suggestion: The regulatory body should consider extending the scope of the “Dutch Review Plan” to give guidance on the licensing and review and assessment for</p> <ul style="list-style-type: none"> • other types of nuclear facilities (including fuel cycle facilities and waste management facilities) • all stages of the life cycle of the nuclear facility (siting, design, construction, commissioning, operation and decommissioning). |
| 7. INSPECTION | R14 | <p>Recommendation: The regulatory body should implement an inspection planning process that defines a baseline plan which includes adequate sampling of all regulated activities and facilities, types of inspections (scheduled and reactive, both announced and unannounced), frequency of inspections and areas and programmes to be inspected. This baseline should then allow prioritization.</p> |
| | S9 | <p>Suggestion: The regulatory body should consider developing detailed guidance to address specific types of inspections.</p> |
| | S10 | <p>Suggestion: The regulatory body should consider implementing measures to ensure that the action tracking system is consolidated and consistently used so that it provides a high level of confidence that all of the inspection findings are tracked and closed in pre-determined timescales, delays are escalated for resolution as necessary, and actions can be collated and reviewed to help inform regulatory feedback and learning processes.</p> |
| 8. ENFORCEMENT | S11 | <p>Suggestion: The regulatory body should consider a change to the enforcement procedures to define criteria when the issue is sensitive and requires management participation in all significant enforcement actions, excepting those which require urgent regulatory intervention.</p> |
| | S12 | <p>Suggestion: The regulatory body should consider developing and implementing a system to monitor the effectiveness of its enforcement actions.</p> |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|---------------------------|--|---|
| 9. REGULATIONS AND GUIDES | S13 | Suggestion: The regulatory body should consider further development of its regulations and guides to ensure the consistent regulation of all facilities. |
| | R15 | Recommendation: The regulatory body should develop and implement a procedure on the development and periodic revision of regulations and guides. |
| | R16 | Recommendation: The regulatory body should update the current regulation related to decommissioning to include, taking into account the graded approach, a requirement that safety of decommissioning is assessed for all facilities for which decommissioning is planned. |
| | R17 | Recommendation: The regulatory body should develop requirements on the end state of decommissioning, termination of the authorization for decommissioning and on the release of the facility and/or the site from regulatory control. |
| | R18 | Recommendation: The regulatory body should establish regulations related to the assurance of financial resources needed for timely and safe decommissioning of all regulated facilities, both nuclear and non-nuclear facilities. |
| | R19 | Recommendation: The regulatory body should ensure that the regulatory framework for decommissioning includes consideration of requirements related to safety aspects and financial resources if deferred dismantling has been selected. |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|---|--|--|
| | R20 | Recommendation: The regulatory body should develop guidance and update regulation taking into account requirement related to keeping records of information that will be relevant for decommissioning. |
| 10. EMERGENCY PREPAREDNESS AND RESPONSE | R21 | Recommendation: The regulatory body should make provisions for non-nuclear licensees to have in place clearly defined arrangements on emergency preparedness and response before issuing the licence. |
| | S14 | Suggestion: The regulatory body should consider improving the requirements and criteria for the establishment of the threat categorization of facilities and activities in accordance with GS-R-2. |
| | S15 | Suggestion: The Regulatory Body should consider clearly defining criteria for response time objectives for all relevant threat categories and evaluating compliance with response time criteria during emergency exercises. |
| | S16 | Suggestion: The Regulatory Body should consider aligning action levels, intervention levels, and guidance values for emergency workers with IAEA standards. |
| | R22 | Recommendation: The Regulatory Body should ensure that requirements and arrangements are established for recovery operations in line with international standards. |
| | S17 | Suggestion: The Regulatory Body should consider finalizing its procedures for responding to a nuclear and radiological emergency. |
| 11. ADDITIONAL AREAS | R23 | Recommendation: The regulatory body should establish or adopt regulatory guides for the protection and safety of patients. |
| | S18 | Suggestion: The regulatory body should consider strengthening the requirements for: |

| AREA | R: Recommendations S: Suggestions GP: Good Practices | Recommendations, Suggestions or Good Practices |
|------|--|---|
| | | <ul style="list-style-type: none"> • the establishment, the use and the systematic revision of the dose reference levels, at national and local level, • the establishment of dose constraints for carers and comforters and the issue of the respective guidelines for their use, • the registrants and licensees that signs in appropriate languages are placed to request female patients undergoing a radiological procedure to notify, in case of pregnancy or breast feeding (for nuclear medicine), • ensuring the calibration of sources giving rise to medical exposure. |
| | R24 | <p>Recommendation: The Government should establish provisions for the management of existing exposure situations and the remediation thereof. These provisions should include a national reference level for protection against indoor radon.</p> |
| | R25 | <p>Recommendation: The Regulatory body should undertake independent verification of the environmental monitoring reported by regulated facilities.</p> |
| | R26 | <p>Recommendation: The regulatory body should update the established clearance levels to include the release of bulk quantities of material, the conditional clearance of materials and materials representing mixtures of artificial and natural nuclides.</p> |
| | S19 | <p>Suggestion: The regulatory body should consider establishing more specific requirements related to consumer products, consistent with the recommendation in IAEA documents GSR Part 3.</p> |

APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

| AREA | NO. | CONCLUSION |
|--|------------|---|
| TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT | 1 | The IRRS team concluded that the nuclear and radiation safety regulatory body in the Netherlands took appropriate actions in reply to the implications of the TEPCO Fukushima Dai-ichi accident. It also concluded that further effective steps are needed in order to make sure that the regulatory body is capable to deliver its emergency response responsibilities in a long lasting nuclear emergency within or in the vicinity of the Netherlands. |
| PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT | 2 | The IRRS team concluded that the possible implications of the TEPCO Fukushima Daiichi accident on nuclear and radiation safety in the Netherlands were thoroughly assessed and the actions that may further enhance the nuclear and radiation safety in the country in general and the safety of the operating nuclear power plant in specific were determined and scheduled for realization in an Action Plan. No short or medium term change in the nuclear and radiation safety regulatory practice was deemed necessary as a consequence of the lessons learned from the accident, yet the inspection programme of the regulatory body shall be enhanced to cover areas of importance in preventing a large scale nuclear accident. |
| 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | 3 | The IRRS team concluded the existing status of the legal framework to be appropriate. Upon review of the advance reference material and thorough discussions with the counterparts, the IRRS team found that the regulatory body is committed to act as necessary. |
| 2. | 4 | The IRRS team considered the status of international cooperation achieved by the Netherlands as appropriate. |
| 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | 5 | The IRRS team concluded that further actions are needed and are suggested concerning the formalizing and structuring the preparedness phase of emergency arrangements with the TAN and other governmental organizations. |

| AREA | NO. | CONCLUSION |
|---|-----|---|
| 4. MANAGMENT SYSTEM OF THE REGULATRY BODY | 6 | The IRRS team concluded that the necessary actions in order to complete the program for establishing and implementing an Integrated Management System to enhance safety have been recognised by the regulatory body. |
| 5. AUTHORIZATION | 7 | The IRRS team concluded that, with respect to the TEPCO Fukushima Daiichi accident no particular concern related to the authorization process was raised. The regulatory body has an adequate authorization process to enforce necessary safety improvements as well as to authorize their implementation. |
| 6. REVIEW AND ASSESSMENT | 8 | The IRRS Team acknowledged that the regulatory body participated in the European stress tests, which were applied to all Dutch nuclear facilities with a slightly enlarged scope with respect to the ENSREG specifications. Related to topics such as flooding, earthquake and extreme weather conditions, the Dutch regulatory body used available expertise from other Dutch authorities. |
| 7. INSPECTION | 9 | The IRRS team concluded that the stress test process has identified improvement activities which were agreed between the licensee and regulator and the assessment and inspection programme covers these in a satisfactory manner, the existing status is appropriate at this stage of the upgrade programme. Further improvement activities may also be identified from studies yet to be completed, and the regulatory body is committed to act as necessary. |
| 8. ENFORCEMENT | 10 | The IRRS team concluded that with respect to enforcement, no concerns are raised in the light of learning from the TEPCO Fukushima Daiichi accident. |
| 9. REGULATONS AND GUIDES | 11 | The IRRS team concluded that post Fukushima aspects will be addressed in the Dutch Safety Requirements for the new build nuclear power plants. Those requirements will be generally applicable for new build research reactors with application of a graded approach. |

| AREA | NO. | CONCLUSION |
|----------------------------|-----|--|
| 10. REGULATIONS AND GUIDES | 12 | The IRRS team concluded that regulatory body has recognized the necessary actions in response to the TEPCO Fukushima Daiichi accident. Necessary further actions have been planned including the establishment of a new emergency response centre for the Borssele NPP and bilateral discussion with neighbouring countries regarding the impact of multi-unit nuclear emergencies. Further actions are needed to develop a recovery strategy and procedures, formalization of regulatory body responsibilities. |

APPENDIX VII – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

| | Title English (Bold = translated documents; <i>italic</i> = not translated) |
|--------------|--|
| 00.0 | |
| 00.01 | Nuclear Energy Act |
| 00.02 | Radiation Protection Decree |
| 00.03 | Fissionable Materials and Ores (Recording) Decree |
| 00.04 | Fissionable Materials, Ores and Radioactive Materials Transport Decree |
| 00.05 | Nuclear Facilities, Fissionable Materials and Ores Decree; |
| 00.06 | <i>Import, Export and Transit Decree</i> |
| 00.06 sub | Amendment to Import and Transit Decree Implementation of Waste Directive |
| 00.07 | <i>Exemptions Decree ministry of defence Nuclear Energy Act</i> |
| 00.08 | Nuclear Energy Act - Fees Decree |
| 00.09 | Nuclear Energy Act – Confidentiality Decree |
| 00.10 | Radioactivity Contaminated Scrap Detection Decree |
| 00.11 | <i>Decree Implementing articles 22 and 33 of the Nuclear Energy Act</i> |
| 00.12 | <i>Establish decree of Nuclear Planning and Advice Unit</i> |
| 00.13 | <i>General Provisions Act Environmental Law</i> |
| 00.14 | Regulation Implementing Radiation Protection Decree EZ |
| 00.15 | Ministerial Ordinance on quality assurance Nuclear Power Plants |
| 00.16 | General Administrative Law Act |
| 00.17 | Decree designating supervisors and responsibility to perform under the Nuclear Energy Act |
| 00.18 | <i>Decree designating Lloyds as notified body for nuclear equipment under pressure</i> |
| 00.19 | Designation of Institutions (Section 22) Regulation |

| | |
|-------|---|
| 00.20 | Constitution |
| 00.21 | <i>Regulation on the Radiation Protection of Workers 2014”</i> |
| 00.22 | <i>Regulation Warning signaling Ionizing Radiation</i> |
| 00.23 | <i>Regulation Analysis Effects of Ionizing Radiation on the Environment</i> |
| 00.24 | Justification of Uses of Ionizing Radiation (Publication) Regulation |
| 00.25 | <i>Regulation Consumable Goods for Radiation Protection</i> |
| 00.26 | <i>Regulation Indicator Instruments containing Radionuclides</i> |
| 00.27 | Number not used |
| 00.28 | Application of the Nuclear Energy Act (Confidentiality) Decree |
| 00.29 | Number not used |
| 00.30 | <i>Regulation ionizing smoke detectors 2004</i> |
| 00.31 | <i>Temporary Regulation Expertise Radiation Protection</i> |
| 00.32 | <i>Regulation Facilities Very Low Radioactive Waste</i> |
| 00.33 | Number not used |
| 00.34 | Nuclear Facilities and Fissionable Materials (Security) Regulation |
| 00.35 | Nuclear Safety Regulation |
| 00.36 | Shutdown and Decommissioning Regulation |
| 00.37 | Fissionable Materials and Ores (Reporting) Order |
| 00.38 | Regulation implementing Directive nr. 2009/71/Euratom on nuclear safety |
| 00.39 | Nuclear Pressure Equipment Regulation |
| 00.40 | Nuclear liability act |
| 00.41 | Public Access to Government Information Act |
| 00.42 | <i>Decree submandate, responsibility and powers ILT related to supervision of the KEW</i> |

| | |
|--------------|---|
| 00.43 | Amendment of the Nuclear Energy Act i.c.w. the setting-up of the NSRPA: Explanatory Memorandum |
| 00.44 | Modification of Licence KCB (2011) |
| 00.45 | <i>Licence GKN</i> |
| 00.46 | <i>Licence NRG</i> |
| 00.46 sub | Licence NRG - conditions attached to the licence |
| 00.47 | <i>Licence NRG</i> |
| 00.48 | <i>Licence Interfacultair Reactor Institute (IRI), 18-11-1996</i> |
| 00.49 | <i>Licence COVRA</i> |
| 00.50 | Amendment of the Nuclear Energy Act i.c.w. the setting-up of the NSRPA: Notes on individual sections |
| 00.51 | <i>Establish decree of ILT</i> |
| 00.52 | Environmental Act chapter 1, 2, 7 |
| 00.53 | Amendment of the Nuclear Energy Act in connection with the setting-up of the Nuclear Safety and Radiation Protection Authority: Bill |
| 00.54 | Establishing Decision Review General Government Terms and Conditions for the award of contracts for the provision of services (ARVODI-2011) |
| 00.55 | Shutdown and Decommissioning Regulation |
| 00.56 | <i>High-Activity Sealed Sources Decree</i> |
| 00.57 | <i>Working conditions Act</i> |
| 00.58 | Relevant parts of the Autonomous Administrative Bodies Enabling Act |
| 00.59 | Radioactively Contaminated Scrap Metal (Detection) Regulation |
| 00.60 | Licence for Borssele Nuclear Power Plant 1999 |
| 00.61 | Licence Urenco |
| 00.62 | <i>Decree mandate, proxy and authorization inspector-general ILT (the Nuclear Energy Act)</i> |
| 00.63 | <i>Organization-, mandate- and Proxydecision Directorate Safe and Sound Work 2009</i> |
| 00.64 | <i>Organization-, mandate- and Proxydecision Inspector-General SZW</i> |

| | |
|-------------|---|
| 00.65 | <i>Environmental Impact assesment Decree</i> |
| 00.66 | Licence provisons of the Nuclear Energy Act for Borssele Nuclear Power Plant |
| 00.67 | Decisions on Mandates |
| 00.68 | The safety of Borssele NPP - Report of the Benchmark Committee |
| 00.69 | Agreement establishing the Nuclear Safety Benschmarking Committee Borssele |
| 00.70 | Rules of Procedure of the Benschmarking Committee |
| 00.71 | <i>Economic Offences Act</i> |
| 00.72 | KCB fuel diversification; Assessment Report of the technical safety rationale |
| 01.0 | |
| 01.01 | Outlines Dutch policy for radiation protection and nuclear safety |
| 01.02 | <i>Organizational Model new RB (ANVS)</i> |
| 01.03 | Department of Nuclear Safety, Security and Safeguards: organization KFD as part of the Regulatory Body' |
| 01.04 | Organizational Chart ILT |
| 01.05 | <i>Civil service data security regulations</i> |
| 01.06 | National report of the Kingdom of the Netherlands for the Sixth Review Meeting CNS in April 2014 - Letter to the Dutch House of Representatives on the 6th Joint Convention report |
| 01.07 | Letter tot Parliament Conditions for new Build |
| 01.08 | Radioactive waste policy in the Netherlands; an outline of the government's position |
| 02.0 | |
| 02.01 | Strategy and policy regarding international Nuclear Energy Act (KEW) activities |
| 02.02 | The International Activities Process at the Department of Nuclear Safety, Security and Safeguards |
| 02.03 | <i>Working instruction to execute international activities</i> |
| 02.04 | Operational Experience Feedback (OEF) Strategy |
| 02.05 | <i>Process description Operational Experience Feedback – Selection & Analysis</i> |

| | |
|-------------|--|
| 02.06 | <i>Working Instruction Reporting Events</i> |
| 02.07 | Memorandum of Understanding (MoU) with the USNRC for the exchange of technical information and cooperation - date 18-9-2013 |
| 02.08 | <i>Formal Agreement Netherlands and Germany (NDKK)</i> |
| 02.09 | Summary report of the 1st KWU REGULATORS CLUB MEETING d.d. 19th of June 2013 |
| 02.10 | Report on events in Dutch Nuclear facilities during 2012 |
| 02.11 | Report on events in Dutch Nuclear facilities during 2013 |
| 02.12 | <i>Letter to EPZ requesting a study about the effect of super storms on KCB</i> |
| 02.13 | <i>Letter to EPZ about Hydrogenflakes in the reactorvessels of Belgian reactors</i> |
| 02.14 | <i>Nuclear Installations Doel 3 and Tihange 2 (Belgium) and the effect on KFD-inspections in the NPP Borssele</i> |
| 02.15 | Number not used |
| 02.16 | <i>two examples of reports to IRS</i> |
| 02.17 | Netherlands' National Report. For the 2nd Convention on Nuclear Safety (CNS) Extraordinary Meeting to be held in August 2011 |
| 02.18 | Summary Record of the 15th Meeting of the Committee of Nuclear Regulatory Activities (CNRA) - Working Group on Operating Experience (WGOE) – 24/27-3-2014 |
| 02.19 | Report International Nuclear and Radiological Event Scale (INES) Technical meeting , Vienna 2012 July, 16-20 |
| 02.20 | <i>Memorandum of Understanding with Belgium</i> |
| 02.21 | National Report of the Netherlands (4th Joint Convention on Waste and Spent Fuel) |
| 03.0 | |
| 03.01 | Regulatory framework and Task definition |
| 03.02 | KFD Mission & Strategy |
| 03.03 | Strategy and policy for Knowledge Management |
| 03.04 | Internal Communication Strategy of the Department of Nuclear Safety, Security and Safeguards. Focus on Openness and Transparency |
| 03.05 | Information management and document management |
| 03.06 | Expert groups |

| | |
|-------|--|
| 03.07 | Decisionmaking and independency |
| 03.08 | Safety Culture - part of MS |
| 03.09 | Development of Safety Performance Indicators for KFD - cover with 4 annexes |
| 03.10 | <i>Year plan 2014</i> |
| 03.11 | External Communications Strategy of the KFD - Openness and transparency are paramount |
| 03.12 | <i>Working instruction Annual Trainingplan</i> |
| 03.13 | Working instruction competence survey |
| 03.14 | Work plan 2014 Nuclear Facilities and Safety Program Directorate |
| 03.15 | <i>Annual Plan TSB/division of labor</i> |
| 03.16 | <i>business function model for ILT</i> |
| 03.17 | <i>Inspection plan development team 2015</i> |
| 03.18 | <i>business function model for ANVS</i> |
| 03.19 | <i>Overview disciplines (part of RM 03.03)</i> |
| 03.20 | Knowledge Area of the Nuclear Facilities and Safety Program |
| 03.21 | <i>Reinforcement of KFD from 2014</i> |
| 03.22 | <i>Strategic competences map</i> |
| 03.23 | <i>Balanse Score Card KFD (BSC), production data</i> |
| 03.24 | <i>Working instruction purchasing KFD</i> |
| 03.25 | <i>Working instruction Purchasing external providers of services/goods</i> |
| 03.26 | Policy Advising |
| 03.27 | <i>Resources</i> |
| 03.28 | Actionplan KFD for IRRS-mission 2014 |
| 03.29 | <i>Summary of achievements 2013</i> |

| | |
|-------------|---|
| 03.30 | Framework Agreement' Technical Knowledge and capacity Support for the KFD |
| 03.31 | <i>Agreement with NRG regarding policy advice on Nuclear Safety and Radiation Protection</i> |
| 03.32 | Enhanced Technical Support to the Nuclear Regulatory Authority of the Netherlands in the Field of Nuclear Safety of New Nuclear Facilities (GRS-NIV) |
| 03.33 | IAEA's letter about regulatory authority |
| 03.34 | <i>Internal memo on Lloyds'</i> |
| 03.35 | <i>Basic training program KFD</i> |
| 03.36 | <i>Multiyear financial budget KFD</i> |
| 03.37 | Action plan NIV |
| 04.0 | |
| 04.01 | Description of the Management System of the Department of Nuclear Safety, Security and Safeguards (KFD) |
| 04.02 | Number not used |
| 04.03 | Process description of Plan-Do-Check-Act Cycle in the MS |
| 04.04 | <i>Project plan 'quality impulse licencing Nuclear Energy Act'</i> |
| 04.05 | <i>Report quality enhancement project team radiation protection 2014</i> |
| 04.06 | <i>Action plan MS NIV/TSB</i> |
| 04.07 | <i>Stakeholders about their relationship with the Nuclear Installations and Safety Directorate (NIV) and the Department of Nuclear Safety, Security and Safeguards (KFD) – May 2014</i> |
| 04.08 | <i>Stakeholder analysis regarding to the activities of TSB</i> |
| 04.09 | <i>Procedure and index preventive and corrective measures</i> |
| 04.10 | <i>Process description Managerial assessment MS</i> |
| 04.11 | <i>Process description internal audits</i> |
| 04.12 | <i>KFD-agreements to use Holmes</i> |
| 04.13 | <i>Managerial assessment management system KFD</i> |
| 04.14 | <i>Brochure Demanded Information for applying a licence for Activities according to articles 15a, 29+34 Nuclear Energy Act</i> |

| | |
|-------------|--|
| 04.15 | Table of contents of Management system KFD |
| 04.16 | <i>Requirement for Information security</i> |
| 04.17 | <i>Future scenarios for Team Radiation</i> |
| 04.18 | Number not used |
| 04.19 | <i>Communicationpan TSB contains mission statement</i> |
| 04.20 | <i>Risk Inventory and assessment Domain Hazardous Industries of ILT</i> |
| 04.21 | Sufficient Authority? Quick scan of the capacity needed for the regulatory body |
| 05.0 | |
| 05.01 | Final Decision on the Expansion of Urenco Almelo |
| 06.0 | |
| 06.01 | Review and Assessment Strategy |
| 06.02 | Process description Review and Assessment |
| 06.03 | <i>Working instruction periodic safety review document</i> |
| 06.04 | <i>Working instruction single case assessment document</i> |
| 06.05 | <i>Working instruction continuous assessment document</i> |
| 06.06 | <i>Document on safety review and assessment approach</i> |
| 06.07 | <i>Simulation/calculation tools</i> |
| 06.08 | <i>Manual licencing procedure</i> |
| 06.09 | <i>Review and assessment programme</i> |
| 06.10 | <i>Document on safety review and assessment references</i> |
| 06.11 | <i>Process measures to standardize the process of review and assessment</i> |
| 06.12 | <i>10EVA13 KCB counterpart-list GRS-KFD</i> |
| 06.13 | <i>Template review and assessment report document</i> |

| | |
|-------------|--|
| 06.14 | <i>Review and assessment plan</i> |
| 06.15 | <i>Process design authorization document</i> |
| 06.16 | <i>Review and assessment framework for the 3rd Periodic Safety Review</i> |
| 06.17 | Complementary Safety margin Assessment COVRA N.V. (HABOG) |
| 06.18 | Netherlands' National Report on the Post-Fukushima Stresstest for the Borssele Nuclear Power Plant |
| 06.19 | National Action Plan (NacP) for the follow-up of post-Fukushima Dai ichi related activities |
| 06.20 | Final Report Complementary Safety margin Assessment |
| 06.21 | Complementary Safety margin Assessment - stress test of the HOR |
| 06.22 | Complementary Safety Margin Assessment "Onderzoekslocatie Petten" |
| 06.23 | Complementary Safety Margin Assessment Urenco Netherlands BV |
| 06.24 | <i>Netherlands National Report Fukushima Stresstest for "Onderzoekslocatie Petten"</i> |
| 06.25 | <i>Netherlands National Report Fukushima Stresstest for the HOR</i> |
| 06.26 | Letter to Parliament about the assessment of the stress test reports of the Higher Education Reactor (TU Delft) and the High Level Radioactive Waste Treatment and Storage building (COVRA) |
| 06.27 | Assessment of the stress test report entitled "Complementary Safety margin Assessment COVRA N.V. (HABOG) |
| 06.28 | <i>Letter to licensee on stress test measures which are formally requested by the regulatory body</i> |
| 06.29 | <i>Netherlands National Report Fukushima Stresstest for URENCO</i> |
| 06.30 | Country Report NL Final ENSREG |
| 06.31 | EU Stress ENSREG test Peer Review Final Report |
| 06.32 | Earthquakes en Folding HABOG |
| 06.33 | HABOG plant compliance with its current licensing basis |
| 07.0 | |
| 07.01 | Inspection Strategy for nuclear facilities, transport of nuclear material and radiation |
| 07.02 | <i>Inspection Program 2014</i> |

| | |
|-------------|---|
| 07.03 | Process description Inspection of nuclear facilities, transport of radioactive materials and Radiation |
| 07.04 | <i>Framework of Visions on Supervision</i> |
| 07.05 | Number not used |
| 07.06 | <i>Working Instruction Inspection Nuclear Installations</i> |
| 07.07 | Multi-annual plan 2014-2018 |
| 07.08 | <i>Multi year planning/Project plan inspection SZW - KFD</i> |
| 07.09 | <i>Example of inspection report</i> |
| 07.10 | <i>ILT-framework for uniform process inspection</i> |
| 07.11 | <i>Examples of proactive and reactive inspections</i> |
| 07.12 | <i>Multi-annual supervision plan 2009-2012 Research Location Petten (OLP)</i> |
| 07.13 | Number not used |
| 07.14 | <i>Example of a supervision signal</i> |
| 08.0 | |
| 08.01 | Enforcement Policy |
| 08.02 | Intervention Framework |
| 08.03 | <i>Process design Financial coercion order (LOD)</i> |
| 08.04 | <i>Process design Administrative coercion order</i> |
| 08.05 | <i>Working Instruction Revoking of the licence</i> |
| 08.06 | <i>Report of consultation KFD-FP d.d. 11 april 2012</i> |
| 08.07 | <i>Enforcement Arrangement 2012-2015</i> |
| 08.08 | Information on the use of KOMFORT (Catalogue for recording organizational and human factors upon Inspectins at site) |
| 09.0 | |
| 09.01 | Arrangements for Preparedness for a Nuclear or Radiological Emergency |

| | |
|-------|--|
| 09.02 | Application of The Management System for Facilities and Activities |
| 09.03 | The Management System for Nuclear Installations |
| 09.04 | Preparedness and Response for a Nuclear or Radiological Emergency |
| 09.05 | Safety Assessment and Verification for Nuclear Power Plants |
| 09.06 | Instrumentation and Control Systems Important to Safety in Nuclear Power Plants |
| 09.07 | Design of Fuel Handling and Storage Systems in Nuclear Power Plants |
| 09.08 | External Events Excluding Earthquakes in the Design of Nuclear Power Plants |
| 09.09 | Seismic Design and Qualification for Nuclear Power Plants |
| 09.10 | Protection Against Internal Fires and Explosions in the Design of Nuclear Power Plants |
| 09.11 | Design of Emergency Power Systems for Nuclear Power Plants |
| 09.12 | Design of the Reactor Coolant System and Associated Systems in Nuclear Power Plants |
| 09.13 | Design of Reactor Containment Systems for Nuclear Power Plants |
| 09.14 | Protection against Internal Hazards other than Fires and Explosions in the Design of Nuclear Power Plants |
| 09.15 | Design of the Reactor Core for Nuclear Power Plants |
| 09.16 | Radiation Protection Aspects of Design for Nuclear Power Plants |
| 09.17 | Fire Safety in the Operation of Nuclear Power Plants |
| 09.18 | Operational Limits and Conditions and Operational Procedures for Nuclear Power Plants |
| 09.19 | Modifications to Nuclear Power Plants |
| 09.20 | The Operating Organization for Nuclear Power Plants |
| 09.21 | Core Management and Fuel Handling for Nuclear Power Plants |
| 09.22 | Maintenance, Surveillance and In-Service Inspection in Nuclear Power Plants |
| 09.23 | Radiation Protection and Radioactive Waste Management in the Operation of Nuclear Power Plants |
| 09.24 | Recruitment, Qualification and Training of Personnel for Nuclear Power Plants |

| | |
|-------|--|
| 09.25 | Commissioning for Nuclear Power Plants |
| 09.26 | A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide |
| 09.27 | Ageing Management for power plants |
| 09.28 | Conduct of Operations at Nuclear Power Plants |
| 09.29 | Severe Accident Management Programmes for Nuclear Power Plants |
| 09.30 | External Human Induced Events in Site Evaluation for Nuclear Power Plants |
| 09.31 | Meteorological Events in Site Evaluation for Nuclear Power Plants |
| 09.32 | Geotechnical Aspects of Site Evaluation and Foundations for Nuclear Power Plants |
| 09.33 | Safety of Nuclear Power Plants: Design |
| 09.34 | Safety of Nuclear Power Plants: Operation |
| 09.35 | Deterministic Safety Analysis for Nuclear Power Plants |
| 09.36 | Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants |
| 09.37 | Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants |
| 09.38 | Safety Assessment for Facilities and Activities General Safety Requirements |
| 09.39 | Amended version of GS-G-4.1 Format and Content of the Safety Analysis Report for Nuclear Power Plants |
| 09.40 | Amended version of NS-G-3.5 The Management System for Nuclear Installations |
| 09.41 | Amended version of NS-G-1 1 Softwar for Computer Based Systems Important to Safety in Nuclear Power Plant |
| 09.42 | Amended version of NS-G-2 10 Periodic Safety Review of Nuclear Power Plants Safety Guide |
| 09.43 | Amended version of NS-G-2 13 Evaluation of Seismic Safety for Existing Nuclear Installations Safety Guide |
| 09.44 | Amended version of NS-G-3.1 External Human Induced Events in Site Evaluation for Nuclear Power Plant |
| 09.45 | Amended version of NS-G-3.2 Dispersion of Radioactive Material in Air and Water and Consideration of Population Distribution in Site Evaluation for Nuclear Power Plants Safety Guide |
| 09.46 | Amended version of NS-G-3.3 Evaluation of Seismic Hazards for Nuclear Power Plants |
| 09.47 | Amended version of NS-R-3 Site Evaluation for Nuclear Installations Safety Requirements |

| | |
|--------------|--|
| 09.48 | Amended version of SSG-3 Development and Application of Level 1 Probabilistic Safety Assessment for NPP |
| 09.49 | Amended version of SSG-9 Seismic Hazards in Site Evaluation for Nuclear Installations |
| 09.50 | Fundamental Safety Requirements - DSR- 2012 |
| 09.51 | Review on Fundamental Safety Requirements - DSR 2013 |
| 09.52 | Fundamental Safety Requirements - DSR- 2014 |
| 09.53 | Management and Organisation |
| 10.0 | |
| 10.01 | Nuclear Emergency Response Strategy |
| 10.02 | Process description Nuclear Accident Prevention Response |
| 10.03 | Process description NPK preparation |
| 10.04 | <i>Risks Serious Accidents Decree</i> |
| 10.05 | Number not used |
| 10.06 | <i>National Plan for Nuclear Emergency Management and Response</i> |
| 10.07 | National Nuclear and Radiological Response Plan ("NCS") |
| 10.08 | <i>National Manual on Decision-making in crisis situations</i> |
| 10.09 | <i>National Response Plan NPK</i> |
| 10.10 | <i>Enveloping events with categorie B objects</i> |
| 10.11 | <i>National response protocol for accidents involving B-objects</i> |
| 10.12 | <i>Communication on radiation accidents</i> |
| 10.13 | Security Regions Act |
| 10.14 | <i>Dutch regional nuclear emergency plan (Zeeland)</i> |
| 10.15 | <i>Year plan Education, Training and Practicing 2015 - National Plan for Nuclear Accident Control/National Crisis Plan Radiation Incidents</i> |
| 11a.0 | |

| | |
|--------------|--|
| 11a.01 | Number not used |
| 11b.0 | |
| 11b.01 | Self-evaluation Module Controle of Medical Exposures |
| 11b.02 | Individual Health Care Occupations Act |
| 11b.03 | Care Institutions Quality Act |
| 11b.04 | Radiological Procedures Expertise Requirements Regulation |
| 11c.0 | |
| 11c.01 | <i>Working instruction Inspection Transports of nuclear material</i> |
| 11c.02 | ADR= Agreement on Dangerous Goods by Road |
| 11c.03 | RID = Regulations concerning the International Transport of Dangerous Goods by Rail |
| 11c.04 | International Civil Aviation Organization (ICAO), Technical Instructions For The Safe Transport of Dangerous Goods by Air |
| 11c.05 | International Maritime Dangerous Goods Code |
| 11c.06 | Number not used |
| 11c.07 | European Agreement for International transport of hazardous goods by inland waterways (ADN 2013) |
| 11c.08 | <i>Radiological emergency response handbook</i> |
| 11c.09 | Number not used |
| 11c.10 | <i>Operational handbook Accident Control of Hazardous Substances</i> |
| 11c.11 | <i>practicing policy plan fire brigade Zeeland - mono disciplinary practicing</i> |
| 11c.12 | <i>Transport licence SCS Training & Consultancy B.V. - speciale arrangement</i> |
| 11c.13 | <i>Regulation on the Obligation to Report and Disclose Information regarding the Transport of Dangerous Goods by Air”</i> |
| 11c.14 | <i>Licence Manual procedure</i> |
| 11c.15 | <i>Inspection report 200-14-01-H92838</i> |
| 11c.16 | <i>Transport licence</i> |

| | |
|--------------|--|
| 11c.17 | <i>Regulation for the transport of dangerous goods by road</i> |
| 11c.18 | <i>Act for the transport of Dangerous goods</i> |
| 11c.19 | <i>Regulation for the transport of dangerous goods by rail</i> |
| 11c.20 | <i>Inspection program dangerous goods</i> |
| 11c.21 | Checklist of Council Directive 95/50/EG (annex 1) |
| 11c.22 | <i>Factsheet 1.12: Supervision Nuclear Energy Act (Audit IAEA 2014)</i> |
| 11c.23 | <i>yearplan transport inspections 2014</i> |
| 11c.24 | Working instruction for Inspection of consignments (by air) |
| 11c.25 | Number not used |
| 11c.26 | <i>Enforcement execution method Transport of Dangerous Goods Act by road</i> |
| 11c.27 | Number not used |
| 11c.28 | <i>Working instruction object inspection ILT/HGS</i> |
| 11c.29 | Number not used |
| 11c.30 | <i>Procedure summons hazardous goods transport by road</i> |
| 11c.31 | <i>Process description on object inspection</i> |
| 11c.32 | <i>Process description on administrative inspection</i> |
| 11c.33 | <i>Enforcement Policy ILT/Aviation</i> |
| 11d.0 | |
| 11d.01 | Policy reaction Evaluation Radiation Protection |
| 11d.02 | Evaluation of the Radiation Protection Framework |
| 11d.03 | Convenant Radon stand Still |
| 11d.04 | Convenant Radon stand Still - Annex 1 |
| 11d.05 | Basic safety standerds |

| | |
|-------------|--|
| 12.0 | |
| 12.01 | <i>Multi-annual approach occupational exposure 2012-2015</i> |
| 12.02 | <i>Inspection guideline for radioactive materials in metal and scrap</i> |
| 12.03 | <i>Handbook Follow-up of Reports</i> |
| 12.04 | <i>Reporting with regard to radioactive material and radiation in 2008 and 2009</i> |
| 12.05 | <i>Framework Agreement on Cooperation between the ministry of Infrastructure & Environment and the ministry of Finance (Customs) + Annex on activities Nuclear Energy Act.</i> |
| 13.0 | |
| 13.01 | Leaflet on the Activities of the Licencing Agency AgNI |
| 13.02 | Extension of Enrichment capacity and a limited Number of Changes to the Facilities |
| 13.03 | List of acronyms |
| 13.04 | Quick scan: regional emergency preparedness |
| 13.05 | Amendment of the licence for the lifetime extension (Long Term Operation) |
| 13.06 | Decision on MOX |
| 13.07 | Overview of operations for which NV EPZ is licensed |
| 13.08 | Text of the rules attached to the Nuclear Energy Act licence for Borssele NPP |
| 13.09 | Appointment of Inspectors and Fulfilment of Duties (Nuclear Energy Act) Decree 2013 |
| 13.10 | Extending the Design Lifetime Operational Lifespan of the Borssele Nuclear Power Plant: Assessment Report |
| 13.11 | Guide on the Security of Radioactive Substances |

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

| | |
|-----|--|
| 1. | INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006) |
| 2. | INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010). |
| 3. | INTERNATIONAL ATOMIC ENERGY AGENCY – The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006). |
| 4. | INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002). |
| 5. | INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014). |
| 6. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009) |
| 7. | INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009). |
| 8. | INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014). |
| 9. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012). |
| 10. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011). |
| 11. | INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003). |
| 12. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Safety Requirement Series No. NS-R-4, IAEA, Vienna (2005). |
| 13. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Safety Requirement Series No. NS-R-5, IAEA, Vienna (2014) |
| 14. | INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011) |
| 15. | INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012) |

| | |
|-----|---|
| 16. | INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002). |
| 17. | INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002). |
| 18. | INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002). |
| 19. | INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002). |
| 20. | INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007) |
| 21. | INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011) |
| 22. | INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014) |
| 23. | INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. SSG-25, IAEA, Vienna (2013) |
| 24. | INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006) |
| 25. | INTERNATIONAL ATOMIC ENERGY AGENCY - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999) |
| 26. | INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999) |
| 27. | INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999) |
| 28. | INTERNATIONAL ATOMIC ENERGY AGENCY - Radiological Protection for Medical Exposure to Ionizing Radiation, Safety Guide Series No. RS-G-1.5, IAEA, Vienna (2002) |
| 29. | INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005) |
| 30. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2006) |

| | |
|-----|---|
| 31. | INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010) |
| 32. | INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010) |
| 33. | INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010) |
| 34. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010) |
| 35. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010) |
| 36. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010) |
| 37. | INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010) |
| 38. | INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011) |
| 39. | INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel Specific Safety Guide Series No. SSG-15, IAEA, Vienna (2012) |
| 40. | INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014) |
| 41. | INTERNATIONAL ATOMIC ENERGY AGENCY - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002) |
| 42. | INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007) |
| 43. | INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008) |
| 44. | INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009) |
| 45. | INTERNATIONAL ATOMIC ENERGY AGENCY - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014) |

| | |
|-----|--|
| 46. | INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009) |
| 47. | INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radiation Sources, General Safety Guide No. GS-G-1.5, IAEA, Vienna (2004) |
| 48. | INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999) |
| 49. | INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Medical, Industrial and Research Facilities (1999) Safety Guide Series No.WS-G-2.2, IAEA, Vienna (1999) |
| 50. | INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No.WS-G-2.3, IAEA, Vienna (2000) |
| 51. | INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No.WS-G-2.4, IAEA, Vienna (2001) |
| 52. | INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No.WS-G-2.5, IAEA, Vienna (2003) |
| 53. | INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003) |
| 54. | INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Materials in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No.WS-G-2.7, IAEA, Vienna (2005) |
| 55. | INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008) |
| 56. | INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009) |
| 57. | INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006) |