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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

BELGIUM

Brussels, Belgium

1 to 13 of December 2013

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
BELGIUM

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

BELGIUM

Mission date:	*1 – 13 December 2013*
Regulatory body:	*Federal Agency for Nuclear Control (FANC)*
Location:	*Brussels, Belgium*
Regulated facilities and activities:	*Nuclear Power Plants, Research Reactors, Fuel Cycle Facilities, Radioactive Waste Facilities, Radioactive Sources, Medical Exposure, Occupational Radiation Protection, Control of Radioactive Discharges and Materials Clearance, Environmental Monitoring, Control of Chronic Exposures and Remediation, Decommissioning, Emergency Preparedness and Response, and Transport*
Organized by:	*International Atomic Energy Agency (IAEA)*

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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 10

I. INTRODUCTION 12

II. OBJECTIVE AND SCOPE 13

III. BASIS FOR THE REVIEW 14

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT 16
- 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY 16
- 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY 17
- 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE 21
- 1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY 23
- 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK 24
- 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS 27
- 1.7. PROVISIONS FOR DECOMMISSIONING AND MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL 28
- 1.8. COMPETENCE FOR SAFETY 30
- 1.9. PROVISION OF TECHNICAL SERVICES 31
- 1.10. SUMMARY 31

2. GLOBAL NUCLEAR SAFETY REGIME 33
- 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION 33
- 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE 34
- 2.3. SUMMARY 35

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY 36
- 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES 36
- 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES 38
- 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY 38
- 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS 39
- 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES 39
- 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL 40
- 3.7. SAFETY RELATED RECORDS 41
- 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES 42
- 3.9. SUMMARY 44

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY 45
- 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM 45
- 4.2. MANAGEMENT RESPONSIBILITY 47

4.3. RESOURCE MANAGEMENT 48
4.4. PROCESS IMPLEMENTATION 50
4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT 51
4.6. SUMMARY 52
5. AUTHORIZATION 54
5.1. GENERIC ISSUES 54
5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES 56
5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES 58
5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES 59
5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES 62
5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES 62
5.7. SUMMARY 63
6. REVIEW AND ASSESSMENT 65
6.1. GENERIC ISSUES 65
6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES 66
6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT 66
6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT 67
6.2.3. BASES FOR REVIEW AND ASSESSMENT 68
6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT 68
6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES 69
6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES 69
6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES 70
6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES 70
6.7. SUMMARY 70
7. INSPECTION 72
7.1. GENERIC ISSUES 72
7.1.1. INSPECTION APPROACHES, METHODS AND PLANS 72
7.1.2. INSPECTION PROCESSES AND PRACTICES 74
7.1.3. INSPECTORS 75
7.2. INSPECTION OF NUCLEAR POWER PLANTS 76
7.3. INSPECTION OF RESEARCH REACTORS 78
7.4. INSPECTION OF FUEL CYCLE FACILITIES 78
7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES 78
7.6. INSPECTION OF RADIATION SOURCES FACILITIES 78
7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES 80
7.8. INSPECTION OF TRANSPORT ACTIVITIES 80
7.9. SUMMARY 81
8. ENFORCEMENT 83
8.1. ENFORCEMENT POLICY AND PROCESSES 83
8.2. ENFORCEMENT IMPLEMENTATIONS 84
8.3. SUMMARY 84
9. REGULATIONS AND GUIDES 86

9.1. GENERIC ISSUES 86
9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES 88
9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES 88
9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES 89
9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES 90
9.6. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES 91
9.7. SUMMARY 93
10. EMERGENCY PREPAREDNESS AND RESPONSE 94
10.1. GENERAL REQUIREMENTS 94
10.2. FUNCTIONAL REQUIREMENTS 95
10.3. REQUIREMENTS FOR INFRASTRUCTURE 97
10.4. ROLE OF REGULATORY BODY DURING RESPONSE 99
10.5. SUMMARY 100
11. ADDITIONAL AREAS 101
11.1. CONTROL OF MEDICAL EXPOSURE 101
11.2. OCCUPATIONAL RADIATION PROTECTION 106
11.3. CONTROL OF DISCARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION 110
11.4. SUMMARY 111
12. INTERFACE WITH NUCLEAR SECURITY 112
12.1. LEGAL BASIS 112
12.2. REGULATORY OVERSIGHT ACTIVITY 113
12.3. INTERFACE WITH OTHER AUTHORITIES 115
12.4. SUMMARY 115
13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT 117
13.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY 117
13.2. TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT 119
13.3. PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT 123
13.4. CONCLUSIONS BY REVIEWED AREAS 124
APPENDIX I – LIST OF PARTICIPANTS 131
APPENDIX II – MISSION PROGRAMME 133
APPENDIX III – SITE VISITS 135
APPENDIX IV – LIST OF COUNTERPARTS 136
APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP) 139
APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT 149

APPENDIX VII – FANC REFERENCE MATERIAL USED FOR THE REVIEW 152
APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW.....160
APPENDIX IX – FANC ORGANIZATIONAL CHART.....162
APPENDIX X – BEL V ORGANIZATIONAL CHART 163

EXECUTIVE SUMMARY

At the request of the Government of Belgium, an international team of senior safety experts met representatives of the Belgium regulatory body, comprising the Federal Agency for Nuclear Control (FANC) and Bel V, to conduct an Integrated Regulatory Review Service (IRRS) mission from 2 – 13 December 2013. The purpose of the peer review was to review the Belgium regulatory framework for nuclear and radiation safety. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to the regulatory implications for nuclear safety in Belgium in light of the TEPCO-Fukushima Dai-ichi accident.

The review compared the Belgium 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 review team members and the Belgium counterparts in the areas covered by the IRRS.

The IRRS review team consisted of 18 senior regulatory experts from 14 IAEA Member States, one observer from the European Commission, one observer from the Pakistan Nuclear Regulatory Authority (PNRA), five IAEA staff members and one IAEA administrative assistant. The IRRS review 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 authorization, review and assessment, inspection, enforcement and development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposures; radioactive waste management and decommissioning; control of discharges, chronic exposure and environmental monitoring for public radiation protection; transport of radioactive materials; and interfaces with nuclear security, as well as lessons learned from the TEPCO-Fukushima Dai-ichi accident.

In addition, two policy issues were discussed: Leadership and management for safety – regulatory effectiveness, and justification for radiation exposure for medical purposes and consumer goods.

The IRRS review addressed all facilities and activities regulated by FANC/Bel V.

The mission included observations of regulatory activities and interviews and discussions with regulatory body staff, representatives from the Ministry of Home Affairs, a representative of the Ministry of Health, representatives from the Belgian Agency for Radioactive Waste and Enriched Fissile Materials (ONDRAF/NIRAS), and other organizations to help assess the effectiveness of the regulatory system. Inspections conducted by FANC/Bel V were observed at the Tihange nuclear power plant, SCK CEN research reactor, Belgoprocess waste management facility, IRE isotope production facility, Transrad radioactive material transport facility, AZ St. Maarten Duffel hospital, and Tivoli La Louvière radiotherapy facility. The IRRS team members observed the working practices during the inspections carried out, including discussions with licensee personnel and management. In addition, the IRRS team observed an emergency exercise at the National Crisis Centre (CGCCR) and the Tihange NPP.

FANC/Bel V provided the IRRS review team with advance reference material and documentation including the results of its self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS review team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of FANC and Bel V provided the fullest practicable assistance including an atmosphere of openness and transparency.

The IRRS review team identified good practices and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards.

The IRRS review team made the following general observations:

- In Belgium the protection of the public and the environment from ionizing radiation is addressed in the legal system;
- FANC and Bel V jointly implement the functions of the regulatory body as identified in the Belgium legal system;
- The regulatory body actively participates in the Global Safety Regime;
- The possible implications of the TEPCO Fukushima Dai-ichi accident on nuclear and radiation safety in Belgium were thoroughly assessed and the actions that may further enhance the nuclear and radiation safety in the country, including the results of the stress tests, were identified and scheduled for realization in an Action Plan;
- The self-assessment conducted in preparation for the IRRS mission was thorough and internally challenging;
- The regulatory body staff appears committed to assuring nuclear and radiation safety in Belgium.

The IRRS team recognized that Belgium faces challenges over the next several years, which include:

- Development of a national policy and strategy for nuclear and radiation safety including management of radioactive waste and spent nuclear fuel management;
- Developing and implementing a systematic review of the regulatory framework's organizational structure, competences and resources necessary to effectively carry out its mandated responsibilities;
- Updating Belgium's legislative and regulatory framework including regulations and guides;
- Clear separation of authority for regulating safety and those responsible for developing nuclear energy policy at the government level.

The IRRS review team identified strengths and good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to enhance the effectiveness of regulatory functions in line with the IAEA Safety Standards.

Among the strengths and good practices identified by the IRRS review team are the following:

- Transport of radioactive materials is well regulated;
- FANC's initiatives to review the issue of flaws in the Doel 3 and Tihange 2 pressure vessels was thorough and significant in terms of international collaboration;
- FANC is proactive in engaging with interested parties to promote optimisation and radiation safety in the medical sector;
- The regulatory body captures and analyses safety culture information during inspections at class I and IIa facilities.

The IRRS review 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:

- Providing regulatory guidance to licensees to enhance compliance with regulatory requirements;
- Providing internal guidance to enhance regulatory consistency in application of regulatory requirements;
- Further development and implementation of the regulatory body's Management System;
- Develop and implement communications systems with interested parties to ensure sharing of the basis for regulatory decisions.

The IRRS review 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 Belgium, an international team of senior safety experts met representatives of the Federal Agency for Nuclear Control (FANC) and Bel V, the regulatory body of Belgium, from 1 to 13 December 2013 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the missionwas to review the Belgium regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Belgium in March 2011. A preparatory mission was conducted 15-16 May 2013 at FANC Headquarters in Brussels to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by FANC and selected safety aspects.

The IRRS review team consisted of 18 senior regulatory experts from 14 IAEA Member States, 5 IAEA technical staff members, 1 IAEA administrative assistant and 2 observers. The IRRS review team carried out the review in the following broad 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 authorization, review and assessment, inspection, enforcement and development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposures; radioactive waste management and decommissioning; control of discharges, chronic exposure and environmental monitoring for public radiation protection; transport of radioactive materials; and interfaces with nuclear security. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to the regulatory implications of the TEPCO-Fukushima Dai-ichi accident in Belgium's framework for safety.

In addition, two policy issues were discussed: Leadership and management for safety – regulatory effectiveness, and justification for radiation exposure for medical purposes and consumer goods.

FANC and Bel V 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. The advance reference material was reviewed by the IRRS team members prior to the mission. The mission included observations of regulatory activities and interviews and discussions with regulatory body staff, representatives from the Ministry of Home Affairs, a representative of the Ministry of Health, representatives from the Belgian Agency for Radioactive Waste and Enriched Fissile Materials (ONDRAF/NIRAS), and other organizations to help assess the effectiveness of the regulatory system. Inspections conducted by FANC/Bel V were observed at the Tihange nuclear power plant, SCK CEN research reactor, Belgoprocess waste management facility, IRE isotope production facility, Transrad radioactive material transport facility, AZ St. Maarten Duffel hospital, and Tivoli La Louvière radiotherapy facility. The IRRS team members observed the working practices during the inspections carried out, including discussions with licensee personnel and management. In addition, the IRRS team observed an emergency exercise at the National Crisis Centre (CGCCR) and the Tihange NPP.

All through the mission the IRRS team received excellent support and cooperation from FANC and Bel V.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Belgium radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities regulated by FANC. 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 Belgium and other Member States from the knowledge gained and experiences shared through the evaluation of the effectiveness of the Belgium 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 Belgium, FANC and Bel V, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing Belgium, FANC and Bel V with a review of its regulatory programme and policy issues relating to nuclear and radiation safety, and emergency preparedness;
- Providing Belgium, FANC and Bel V with an objective evaluation of its nuclear safety, and emergency preparedness and response regulatory activities 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 FANC and Bel V staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Belgium, FANC and Bel V with recommendations and suggestions for improvement;
- 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 Belgium, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted 15-16 May 2013. The preparatory meeting was carried out by the appointed Team Leader Mr. Colin Patchett; Deputy Team Leader (at the time) Mr. Mark Shaffer; and the IRRS IAEA team representatives, IAEA Team Coordinator Mr. David Graves, IAEA Deputy Team Coordinator Mr. Stephen Evans, and IAEA Incident and Emergency Centre representatives Messrs. Jean-Francois Lafortune and Peter Zombori.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of FANC and Bel V represented by Mr. Jan Bens, Director General of FANC, and Mr. Benoit De Boeck, General Manager of Bel V, and other senior management and staff. 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 (limited);
- Waste facilities;
- Radiation sources and facilities;
- Decommissioning;
- Transport of radioactive material;
- Medical exposure control;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management;
- Regulatory implications of the TEPCO Fukushima Dai-ichi accident;
- Selected policy issues.

Mr. Bens and Mr. De Boeck made presentations on the national context, the current status of FANC and Bel V 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 Belgium in December 2013.

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

The FANC Liaison Officers for the preparatory meeting and the IRRS mission were Mr. Thierry Maldague, Mr. Simon Coenen and Mr. Yvan Pouleur.

FANC provided IAEA (and the review team) with the advance reference material for the review at the end of September 2013, including the self-assessment results. In preparation for the mission, the IAEA review team members conducted 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

An opening IRRS review team meeting was conducted on Sunday, 1 December 2013 in Brussels 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 provide guidance on the methodology for the review and the evaluation to the reviewers. The agenda for the mission was also discussed.

In addition, the IAEA Review Area Facilitator presented the expectations regarding misson report input and development, and for the module on the "Regulatory implications from TEPCO-Fukushima Dai-ichi Accident" that were to be applied during the mission.

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

The reviewers also reported their first impressions based on their initial review of the advance reference material.

The IRRS entrance meeting was held on Monday, 2 December 2013, with the participation of FANC and Bel V senior management and staff. Opening remarks were made by Mr. Jan Bens, Director General of FANC; Mr. Benoit De Boeck, General Manager of Bel V, and Mr. Colin Patchett, IRRS Team Leader. Mr. Jan Bens gave an overview of the Belgium context and FANCC activities and Mr. Simon Coenen gave an overview of the results of the self-assessment and the subsequent action plan prepared as a result.

During the mission, a review was conducted for all the subject areas with the objective of providing Belgium, FANC and Bel V 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 Review team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 13 December, 2013. The opening remarks at the exit meeting were presented by Mr. Jan Bens and were followed by the presentation of the results of the mission by Mr. Colin Patchett, the IRRS Team Leader. Closing remarks were made by Mr. James Lyons, IAEA, Director, Division of Nuclear Installation Safety.

Following the exit meeting, IAEA issued a press release and a joint IAEA and FANC/Bel V press conference was conducted.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

As Belgium is a member state of the European Union and Euratom (the European Atomic Energy Community), Belgium national policy and strategy for safety are framed by the Euratom Treaty and its directives (including directive setting basic safety standards, directive on medical exposure, directive on radioactive waste and spent fuel; directive on high-activity sealed radioactive sources, directive on nuclear safety…) and regulations (e.g. regulation on radioactive shipment within EU…).

The regulation of nuclear facilities and activities is a federal matter. The management of radioactive waste on the Belgian territory is organised at the federal level. The involvement of the regional authorities in the regulation of nuclear activities remains limited to consultation (for instance in the clearance from licence) and exchange of information, with the aim to ensure a coordinated treatment of the nuclear and non-nuclear environmental aspects.

Binding regulations are promulgated by the State institutions following the constitutional procedures. In hierarchical order, the enacted regulations can take the form of laws (approved by the Parliament), royal decrees (signed by the King and one or more of His ministers) and ministerial decrees (signed by one or more ministers). The policies and strategy which establishes the legal framework for nuclear and radiation safety are mostly stated in one law (of 15 April 1994) and several royal decrees (see section 1.2 below). The scope of this law is broad and sets the basis for specific regulations dealing with specific topics.

The current federal Government, in its government agreement of 1 December 2011, has formulated the commitment that the safety and security of nuclear installations will be an absolute priority for the Government. The Minister of Home Affairs also established a "general policy note", describing among other its major goals for her mandate on safety/security related topics, which was presented to Belgium Parliament.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Legislation and regulations express elements of the Belgium national policy for safety. The current Government coalition agreement formulated the commitment that the safety and security of nuclear installations will be an absolute priority. However, no unique document establishes a comprehensive national policy and strategy for nuclear safety.* *Various decisions related to management of radioactive waste have been made at different points in time. These decisions are not consolidated into a national policy and strategy for radioactive waste management and spent fuel. According to the European Commission Directive 2011/71/EURATOM, the development of such a national policy and strategy is needed.*	
(1)	**BASIS: GSR Part 1 requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
(2)	**BASIS: GSR Part 1 para. 2.3 states that** *"The 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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	implementing the national policy."
(3)	**BASIS: GSR Part 1 para. 2.28 states that 2.28.** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities"*
(4)	**BASIS: SSR-5 Req. 1 "Government responsibilities" states that** *"the government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need of disposal facilities of different types; specifications of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provisions and independent regulatory function related to a planned disposal facility".*
R1	**Recommendation: Government should formalize a comprehensive national policy and strategy for nuclear and radiation safety. Among others, the policy should include radioactive waste management and spent fuel management.**

In January 2003, a law on the phase-out of nuclear energy was promulgated, setting deadlines for operation of Doel and Tihange NPP as well as forbidding construction of new NPP. In December 2013, Parliament adopted a new calendar for the decommissioning of the different units.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Belgian (federal) Parliament is actively involved in establishing the national policy and strategy for nuclear safety by voting the necessary laws, for example the ones endorsing international conventions or needed to transpose European Union directives on safety related topics, and by adopting resolutions to suggest actions for the Government. It has set up a special Parliamentary commission for nuclear safety matters which, for example, was involved in the stress tests performed at Belgian NPPs as a consequence of the Fukushima Daiichi accident.

The basic Belgian legal texts regarding the safety of nuclear installations and radiation safety are:

- The Law of 15 April 1994 (amended) on the protection of the population and the environment against the hazards of ionizing radiation and on the Federal Agency for Nuclear Control (FANC). It sets out the basic elements for protecting the workers, the public and the environment against the adverse effects of ionising radiation and also creates the FANC;
- The royal decree of 20 July 2001 (amended) laying down the "General Regulations" regarding the protection of the public, the workers and the environment against the hazards of ionising radiation (GRR-2001) provides for the general principles set in the 1994 law. The GRR-2001 scope is very wide and covers practically all human activities and situations which involve a risk due to the exposure to ionizing radiation;
- The royal decree of 17 October 2003, supplementing the law of 15 May 2007 (on civil safety), defines a nuclear and radiological emergency plan for the Belgian territory as well as notification criteria from the operators to the Government. Emergency planning is a competence belonging to the Federal Minister of Home Affairs and his administrative services;

- The law of 22 July 1985 on nuclear liability ;
- The royal decree of 20 December 2007 on administrative fines;
- The royal decree of 24 March 2009 on the import, transit, and export of radioactive materials;
- The royal decree of 14 October 2011 on orphan sources;
- The royal decrees of 17 October 2011 on security. They address categorization and protection of documents, physical protection of nuclear materials, nuclear installations and transport, categorization of nuclear materials and definition of security zones in nuclear installations and nuclear transport organizations, security clearances and certificates, and regulating access to security zones, nuclear material or documents in specific circumstances;
- The royal decree of 30 November 2011 on the Safety Requirements for Nuclear Installations (SRNI-2011).

FANC devoted much effort to have all texts of legislation and regulations in force with regard to nuclear and radiation safety available on its website.

Currently, there are approximately 40 on-going regulatory initiatives under drafting; one fourth of them have already been sent to the competent Minister. Topics selected for new or amended legislation or regulations include, for example, stating more explicitly that the licensee has the prime responsibility for safety, clarifying BelV and Authorized Inspection Organizations (AIO) roles and status, setting additional requirements for research reactors or waste storage/disposal facilities.

For example, recognising that the current regulations contained in the general regulations of 2001 and the nuclear installation regulations of 2011 do not adequately address the staged licensing process applicable to a radioactive waste disposal facility, the FANC has developed a revised authorisation process to be applied for disposal facilities. The IRRS team noted that, while the revised authorisation process for disposal facilities has been developed in the form of a draft regulation, it has not been formally approved and issued for implementation.

Another example is the requirements for decommissioning currently specified in the GRR-2001. FANC has developed draft regulations on decommissioning based on the WENRA safety reference levels (SRLs) for decommissioning, intended to be published as a royal decree supplementing the SRNI-2011.

FANC cannot promulgate binding legislation unless such regulations (and guides) are of a specific technical nature and if it is foreseen by royal decrees. FANC has rarely made use of this possibility and only on narrow technical issues. Currently there are about 20 FANC decrees mostly related to the medical sector but no FANC decrees giving technical requirements for nuclear safety. SRNI-2011 Article 13.2 gives FANC the possibility to develop a decree only concerning the contents of safety analysis report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *In the self-assessment performed in preparation of this IRRS mission, FANC recognizes the need for several updates of regulations and legislation, some of them being in the late phase of drafting, i.e. already sent to the Government, to enhance and have a more effective regulatory framework for safety.*

Within the current legal provisions, there is nothing that prevent the Minister to introduce changes in the draft without FANC knowing.

Currently there are very limited possibilities for "FANC decrees" setting technical requirements for nuclear safety although such decrees do exist for medical activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety."*
(2)	**BASIS: GSR Part 1 Para. 2.7 states that** *"The government has the ultimate responsibility for involving those with legitimate and recognized interests in its decision making. However, the government shall ensure that the regulatory body is able to make decisions under its statutory obligation for the regulatory control of facilities and activities, and that it is able to perform its functions without undue pressure or constraint."*
(3)	**BASIS: GSR Part 1 Para. 2.8 states that** *"...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".*
(4)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
R2	**Recommendation: The Government should provide in consultation with the regulatory body a more expedited, prioritized process to issue or amend regulations for the safety and security of nuclear facilities and activities. If making changes to regulations proposed by the regulatory body or impacting the regulatory body, the Government should consult the regulatory body.**
R3	**Recommendation: The Government should broaden the authority of the regulatory body to issue binding technical regulations (e.g. FANC decrees) for nuclear facilities and activities.**

Currently FANC can only complete inspections of activities on licensed facilities or premises where equipment generating ionising radiation is located.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no legal provisions which give the regulatory body the right to make inspections at contractors or subcontractors associated with an authorized party. In practice, Bel V can perform controls only if the authorized party agrees. The proposed licensing regime for waste disposal facilities contains new provisions to allow inspections but, if adopted, it would still not cover procurement of equipment to already operating nuclear installations or other new nuclear installations.*	
(1)	**BASIS: GSR Part 1 para. 2.13 (b) states that** *"The regulatory body shall be conferred with the legal authority to require an authorized party or an applicant, whether a person or an organization, to make arrangements to provide:* *(b) Access, solely or together with the authorized party or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R4	**Recommendation: Government should ensure the regulatory body has legal authority for inspection at designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party or applicant.**

Besides the public authorities, key actors in nuclear and radiation safety are:

- authorized inspection organisations (AIOs), which employ recognized experts (i.e. experts accredited by FANC), for oversight of class II and III activities and facilities. AIOs were established in the late 1950's when no technical competence was available within the public authorities. Recognition by the State became mandatory by a royal decree in 1963. The 1994 law establishing FANC maintained AIOs on a transitory basis (but without deadline), to allow time for FANC to be staffed with appropriate competences and resources. AIOs are contracted (and paid) by authorized parties. AIOs do not have enforcement power;
- The Scientific Council for Ionizing Radiations. It is in particular involved in licensing of class I facilities and recognition of experts. It can also provide advice, upon request of the Government, FANC or on its own initiative;
- Health Physics Control Department (HPD). The 1994 Law requires each authorized party to benefit from a HPD which is responsible in general terms for organising and supervising the necessary measures to guarantee compliance with the legislation, regulations and licence conditions. HPDs report to the facility manager. The HPD needs to be in-house for Category I facilities but can be outsourced to an AIO for Category II and III facilities. In-house HPD should be headed by a recognized expert.

The 1994 law also enables FANC to use AIO for oversight purposes: "*Under its own responsibility, the FANC may, for the completion of certain missions, collaborate with organisations, that it has especially recognised to this end…*". As the 1994 law set similar tasks for HPDs and AIOs, including checking compliance with regulatory requirements, proposals for a more transparent, sustainable relationship between FANC, Bel V and the AIOs, have been initially submitted by FANC in 2009.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For class II and III facilities, GRR-2001 allows the authorized party to assign the HPD to the FANC, which may (and in practice does) delegate this to Authorized Inspection Organizations. Adapted regulations have been proposed by FANC and are currently being re-evaluated (statute of Bel V, responsibility of the independent institutions for health physics control). Relevant stakeholders have also been asked to provide their input.* *FANC has recognized since several years that it would be valuable to clarify in the legislation and regulations the expected roles of Bel V and Authorized Inspection Organizations (AIO) and their interfaces with FANC and authorized parties. FANC proposed a legal reform of the organisation for health physics control.*	
(1)	**BASIS: GSR Part 1 para. 2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
(2)	**BASIS: GSR Part 1 para. 2.9 states that** *"No responsibilities shall be assigned to the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."
R5	**Recommendation: Government should update the regulatory framework to:** - **ensure that the authorized party responsibility for health physics department cannot be provided by FANC or Bel V;** - **clarify the roles of AIO and their interfaces with the regulatory body and the authorized parties.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The FANC, together with its technical subsidiary Bel V (see below), constitute the regulatory body according to the Belgium report to the Convention on Nuclear Safety. Nevertheless, some decisions on safety matters do not legally rest with FANC, such as the promulgation of binding legislation/regulation and the licensing of class I nuclear facilities (the King issues the licence). FANC has a key role in the preparation of these legislations/regulations and licences.

The Law of 15 April 1994 creates the FANC as the public interest organisation having legal personality and enumerates the various missions of the FANC, including:

- To propose and prepare new regulations related to this law;
- To review the license applications for nuclear facilities;
- To grant licenses for specific facilities, except those with the highest risk (class I);
- To perform safety and security assessment of nuclear facilities and conduct inspections in those facilities;
- To perform radiological surveillance of the territory;
- To provide technical assistance to the Ministry of Home Affairs in case of nuclear emergencies;
- To gather scientific and technical documentation in the field of nuclear safety and to stimulate and coordinate R&D; and
- To issue neutral and objective information to the public.

The 1994 law also enables delegation of some of the missions of the FANC to organisations that FANC has recognized or to legal entities that it has created to that end. Delegations are of two kinds:

- The first relates to certain missions of the health physics department that each licensee has to set up. The recognition of those organisation is based on criteria to be defined by the FANC (see AIO in section 1.2);
- The second addresses missions delegated to the legal entities created by FANC. Bel V was established to this end in September 2007 as a FANC non-profit subsidiary. The majority of the BelV Board is composed of members of the FANC Board.

The GRR-2001 specifies a number of tasks to be performed by the FANC, which may delegate tasks to Bel V to perform supervision activities of some facilities. In practice, this is the case for the class I and class IIa facilities.

The FANC remains fully responsible for the results of the work done by Bel V (and the FANC could decide to end the outsourcing and to perform the currently outsourced tasks by its own staff).

In addition, FANC performs review and assessment of facilities of all classes and grants licences for class II and III facilities.

Independence of the Regulatory Body

FANC reports to the Federal Minister of Home Affairs. Other State-related organisations involved in the use of nuclear energy, such as the "Centre d'Etudes Nucléaires" (SCK•CEN) or the Belgian Agency for Radioactive Waste and Enriched Fissile Materials (ONDRAF/NIRAS) or the Institute for Radioelements (IRE) report to the Ministry of Economic Affairs as well as to the Minister for Energy. In the current Belgium government there is no Minister of Energy, but only a State Secretary for Energy who exercises his functions under the responsibility of the Minister of Home Affairs. FANC also reports to the Minister of Home Affairs, who is responsible for promulgating regulations on nuclear safety and involved in licensing class I facilities.

Nuclear power plants are operated by a private operator (Electrabel).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC is a public body which report to the Parliament via the Minister of Home Affairs. This Minister has in its responsibility the competence of the State Secretary of Energy responsible for the energy policy and some of the licensees. Even though "de facto" it doesn´t appear to be an undue influence of the energy policy makers on the regulatory decisions, this situations should be improved.* *ONDRAF/NIRAS was established in 1980 when ONDRAF/NIRAS was not an authorized party and FANC did not exist. The GRR2001 requires FANC to conclude an agreement with ONDRAF/NIRAS with a view to mutual consultation on aspects of radioactive waste management which may affect the exercise of competences by both organisations. ONDRAF/NIRAS has to approve the decommissioning plan, even the ones of the facilities it operates or will operate, although decommissioning licence is issued by the regulatory body. The establishment of waste acceptance criteria belongs to ONDRAF/NIRAS. From discussions with FANC and ONDRAF/NIRAS staff, it appears there is confusion on the roles of each organization and interfaces.*	
(1)	**BASIS: SF-1 requirement 3.11 states that** *"In the event that the licensee is a branch of government, this branch must be clearly identified as distinct from and effectively independent of the branches of government with responsibilities for regulatory functions."*
(2)	**BASIS: GSR Part 1 requirement 4 states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making"*
(3)	**BASIS: GSR Part 1 para.4.9 states that** *"To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities…"*
R6	**Recommendation: The Government should establish appropriate provisions to ensure a clear separation of authorities responsible for regulating safety from bodies responsible for nuclear energy policy (i.e. the relationship between State Secretary for Energy and the Minister of Home Affairs).**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R7	**Recommendation: The Government should review the current allocation of roles and responsibilities of ONDRAF/NIRAS and the regulatory body to ensure separation of roles and responsibilities of both organizations so that the regulatory body decisions are not unduly influenced by prior governmental or ONDRAF/NIRAS decisions.**

The FANC:

- is an independent governmental body. Its legal statute is in itself a guarantee that it can make independent regulatory judgements within its legal competences;
- is directed by a Board whose members, appointed by royal decree taken after consultation of the Council of Ministers, must be independent from any operator of a nuclear facility. The FANC general manager is appointed by royal decree for a fixed mandate of 6 years. He can only be dismissed under exceptional circumstances;
- can organize its internal decision-making and can recruit its staff with sufficient autonomy;
- has legal personality. This means that FANC can defend its position before court against other interested parties when needed.

The supervision of FANC by the Ministry of Home Affairs is provided through a governmental commissioner (also appointed by royal decree) who attends the Board. His task is to verify that FANC's activities and decisions are fully compatible with its legal competences. On his/her proposal, the Minister may annul FANC decisions. This happened twice in FANC history, but only on procedural aspects and not on "technical" decisions taken by FANC.

FANC decisions relating to the restart of Doel-3 and Tihange-2 after several months of shutdown following the detection of flaws in their reactor vessels are a clear example of the capacity and authority of the regulatory body to make independent judgements which are respected by the Government. The Government sought information from FANC on this issue and on the timing to allow (or not) restart. The decision on whether safety was ensured and therefore a restart was possible remained within FANC.

FANC and Bel V are not financed through the State budget. Bel V charges the authorized parties according to the review and assessment and inspection activities performed. FANC funding is primarily based on annual taxes on authorized parties or applicants as well as fees on the occasion of the application for a license, recognition or registration.

The IRRS team concluded that FANC demonstrates effective independence in regulatory decision making, within the frame set by the current Belgium legal framework, but that some amendments to the legal framework would consolidate its *de jure* independence (see R7).

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

Currently the prime responsibility for the safety by the authorized party is rather implicitly ensured by some regulatory provisions, the clearest being the royal decree of 17 October 2003 (establishing the nuclear and radiological emergency plan for the Belgian territory) or SNRI-2011. FANC recognizes a more explicit statement in the legislation would be welcomed and has prepared a corresponding amendment to the 1994 law.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Currently the requirement concerning the licensee's prime responsibility of safety is not included explicitly in the law. There is a draft proposal to update the regulations on this part.*	
(1)	**BASIS: GSR Part 1 Requirement 5 states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as o demonstrate such compliance."*
R8	**Recommendation: Government should explicitly assign the prime responsibility for safety to the person or organisation responsible for a facility or an activity.**

Authorization processes are established by the 1994 law and GRR-2001 for practices involving ionising radiations, graded according to the class (I to III) of the activity or facility. Modifications to the facilities or activities or to the licenses as well as termination of activities are also framed by these binding texts.

As for determining what measures have to be implemented to ensure safety for a facility or an activity, the GRR-2001 states that the Health Physics Department (HPD) is "responsible in general terms for organising and supervising the necessary measures to guarantee compliance with the provisions of this regulation and the decrees and decisions of the FANC". More generally, the GRR-2001 tasks the HPD with the "analysis of the necessary measures to prevent any incident, accident, loss or theft of radioactive or fissile material".

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

Ministers (or State Secretary) involved and associated Federal Public Service (FPS)

In the federal government, the Minister of Home Affairs is politically accountable for nuclear safety matters. In addition to supervising the FANC, this Minister is also responsible for:

- regulations (promulgation);
- licensing of class I facilities;
- emergency response planning and coordination of response in case of an emergency (nuclear or not);
- appeal against decisions of the FANC, including appeal to licenses for class II and III facilities;
- the Scientific Council for Ionizing Radiation.

Other Ministers of the federal government and other governmental institutions have some competences relating to the safety and security of nuclear installations, the protection of the workers or the public, for example:

- The Minister of Energy and the Minister of Economy are responsible for policy on the nuclear fuel cycle, the management of spent fuel and radioactive waste, the export control on nuclear sensitive technology, and the State funding of the nuclear research institutions. The Minister of Economy is also responsible for the nuclear insurance;
- The Minister of Employment is responsible for the health protection of workers, including from occupational radiation exposure;

- The Minister of Public Health is responsible for the medical applications of ionizing radiation. Medical use of ionizing radiations is a topic where many actors, including FANC, are involved;
- The Minister of Agriculture is responsible for monitoring the food chain for radioactive substances.

Interface and Cooperation with FANC

The mechanisms for coordination between the public authorities are generally set in the legislation itself. With several of them, the FANC has cooperation agreements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Several authorities, namely FANC, FPS Health, NIHDI (National Institute for Health and Disability Insurance), FAMHP(Federal Agency for Medicine and Health Products), have a role in regulating medical exposure by ensuring the safety of patients undergoing medical exposures. There are agreements in place between FANC and each of these authorities. However the legislation does not clearly specify the responsibility and functions of each authority.*	
(1)	**BASIS: GSR Part 1 para. 2.18 (3) states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as applications of radiation in medicine. "*
R9	**Recommendation: The government should specify in legislation, the respective functions and responsibilities of all authorities involved in the regulatory oversight of medical exposures and patient safety to ensure effective national co-ordination and cooperation in applying regulatory requirements.**

Some aspects of sealed radioactive source regulation, such as exports of sources, are managed by the regional governments. The export license of radioactive sources is only requested in Belgium according to the Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of export, transfer, brokering and transit of dual-use items and Council Regulation (Euratom) No 1493/93 on shipments of radioactive substances between Member States of the EU. The 3 Belgian regions (Flemish, Walloon and Brussels-Capital) are responsible for delivering the license of export of dual-use items after taking advice of an Advisory Committee composed of representatives of regional and federal authorities including FANC.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC is involved in the authorization process of export of sealed radioactive sources when the export authorisation is dual-use goods, even if such dual-use goods licensing process is assigned to regional government offices. Communication and reporting by the regional governments regarding export of sources appears to be non-mandatory.*	
(1)	**BASIS: CoC 23 states that** *"Every State involved in the import or export of radioactive sources should take appropriate steps to ensure that transfers are undertaken in a manner consistent with the provisions of the Code and that transfers of radioactive sources in Categories 1 and 2 of Annex 1 of this Code take place only with the prior notification by the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	exporting State and, as appropriate, consent by the importing State in accordance with their respective laws and regulations."
R10	**Recommendation: For the export of radioactive sources, the regulatory body and regional government offices should jointly develop a formal process, either through regulations or by communication protocols or MoUs, wherever necessary, to harmonize processes and ensure there are no regulatory gaps or overlaps between the different organizations.**

A royal decree details how "conventional" pressure retaining components regulations are to be implemented for components in nuclear installations as well as the respective roles of FANC and the authority responsible for "conventional" pressure retaining components. For fire protection matters, FANC is in principle responsible for oversight if the fire could impair safety of the facility. More generally, the FANC mandate covers every aspect which contributes to nuclear or radiation safety at an authorized facility. Other aspects, such as conventional occupational safety are not explicitly within FANC's mandate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *At a class I or IIa facility, when a Bel V inspector detects a deviation or an issue related to a topic outside of the regulatory body mandate, the usual practice is to report it to the licensee but not to report it to the responsible authority for this matter (even through an informal way such as an E-mail or a phone call).*	
(1)	**BASIS: GS-G 1.3 para 3.21. states that** *"In addition to the regulatory body, other governmental bodies may participate in the regulatory process according to national practices. The regulatory body should establish and maintain liaison throughout the lifetime of the facility with other relevant governmental bodies, and should develop and, where practicable, formalize working procedures with such bodies, whether at the national, regional or local level. Such bodies may undertake their own inspections of the facility, and it may be appropriate for the regulatory body to conduct joint inspections with one or more of them. In planning an inspection programme and determining a specific inspection plan, the regulatory body should consider whether inspectors from these bodies should participate in the inspection."*
(2)	**BASIS: GS-G 1.3 para 3.22. states that** *"It is particularly important that there should be liaison with other governmental bodies when enforcement action is contemplated. The regulatory body should keep the relevant governmental bodies informed since these bodies may be considering taking enforcement actions under different legal provisions and, if so, co-ordination of the enforcement actions should be considered. Similarly, the regulatory body should be advised of any enforcement actions under consideration by other bodies."*
(3)	**BASIS: GS-G 1.3 para 3.23. states that** *"The areas which may be inspected by other governmental bodies should be identified. The latter could include but are not limited to:* • *environmental protection authorities;* • *authorities responsible for public liability issues;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	• *authorities for physical protection and/or safeguards;* • *authorities for planning the use of water resources and land;* • *authorities responsible for public and occupational health and safety;* • *fire protection authorities;* • *transport authorities;* • *law enforcement bodies;* • *bodies with responsibilities for civil engineering structures and buildings, and electrical and mechanical equipment;* • *other bodies with responsibilities for emergency preparedness;* • *other bodies with responsibilities for limits on releases of radioactive effluent;* • *other regulatory authorities, particularly those performing similar functions."*
(4)	**BASIS: GS-G 1.3 para 3.24. states that** *"The regulatory body should be aware of the relationships between the operator and other governmental bodies such as may be determined by national legislation, regulations and practices."*
S1	**Suggestion: The regulatory body should consider :** - **enhancing interfaces with the relevant governmental bodies having responsibilities for oversight of authorized facilities on domains outside of the regulatory body mandate to ensure timely communication on inspection findings and, whenever appropriate, joint inspections;** - **increasing regulatory body staff awareness on interfaces and, where applicable, existing agreements, with these other governmental bodies.**

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

The GRR-2001 established the need for an authorization for numerous activities and facilities, including some involving natural radiation sources. Such approach limits the occurrence of unregulated radiation risks and unforeseen events and allows FANC to exercise its enforcements powers.

Orphan sources

To stimulate the recovery of orphan sources in materials to be recycled (metal scrap) and non-radioactive waste, a special surveillance system has been established in some industrial sectors. Facilities where orphan sources may be found have been identified and have been required (regulation published at the end of 2011) to install appropriate monitoring equipment. The financial costs to treat the recovered sources as radioactive waste are covered by a special fund managed by ONDRAF/NIRAS (See also section 5.4).

Remediation of sites contaminated by radioactive substances

The FANC has made a proposal for a legal initiative that should facilitate interventions on sites contaminated by radioactive substances, to impose remediation or restrictions on land-use, based on the principles of justification, optimization and dose limits.

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

Decommissioning

Every owner or operator of a nuclear installation is responsible for the future dismantling and/or decommissioning of his installations at the termination of normal operations. ONDRAF/NIRAS verifies that the owner/operator undertakes timely the necessary steps in order to carry out the dismantling programme. The owner/operator has to submit his decommissioning programme to ONDRAF/NIRAS for approval. The radioactive waste resulting from the dismantling is subject to the management of ONDRAF/NIRAS according to the same principles as the waste generated during normal operation.

Some nuclear installations are in the phase of dismantling following a decision of the operators (Belgonucleaire, FBFCi, Thetis research reactor, BR3 reactor). According to the phase-out law of 2003, as amended in December 2013, decommissioning work at some NPP's will start soon after 2015. The decommissioning of facilities needs a separate authorization (GRR-2001).

The law of 11 April 2003 ("on the provisions for the decommissioning of nuclear power plants and the management of fissile material irradiated in these plants") sets out the obligations of the licensee of the NPPs (Electrabel) for the financial provisions for decommissioning the plants after their legal lifetime. These provisions are entrusted to Synatom (see below) even if the operator (Electrabel) remains responsible for the actual decommissioning works. A Governmental commission, in which the FANC and ONDRAF/NIRAS are represented, supervises this decommissioning fund.

On request of the owner/operator, ONDRAF/NIRAS can be tasked with the dismantling of a nuclear facility. This is the case for the dismantling of some historical state-owned installations (e.g. former Eurochemic plant, the former waste processing and storage installations of the SCK•CEN). These operations are executed by its industrial subsidiary Belgoprocess. ONDRAF/NIRAS can also be in charge of the dismantling of a facility in case of bankruptcy of its operator.

ONDRAF/NIRAS is also in charge of establishing, every 5 years, a national inventory of all nuclear installations and sites which could represent a potential nuclear liability, known as the 'national inventory of potential nuclear liabilities'. The inventory, which also contains an estimation of the decommissioning/dismantling and remediation costs, is publicly available on the ONDRAF/NIRAS website.

The application for a decommissioning license, which includes the safety analysis report for decommissioning, has to be submitted to FANC for review. The ONDRAF/NIRAS regulations relating to decommissioning of nuclear facilities requires also that the operator develop a final decommissioning plan. This final decommissioning plan has to be submitted to ONDRAF for review and approval. FANC is not involved in this process.

Radioactive waste management

Radioactive waste in Belgium is defined as waste that has radioactivity in excess of the clearance levels established by the regulatory body (FANC). Radioactive waste is classified in accordance with a three tier system as follows:

- Category A: Low- and medium-level short-lived waste.
- Category B: Low- and medium-level long-lived waste.
- Category C: Long-lived high-level waste.

The current national policy in Belgium is that all radioactive waste produced in the country shall be disposed of in land-based repositories. Radioactive waste generated during routine operations of nuclear facilities in Belgium is processed and conditioned on-site by the operator of the relevant facility or ONDRAF/ NIRAS in central processing and conditioning facilities located mainly in Dessel (North-East of Belgium).

Whilst various decisions have been taken over the years relating to management of spent fuel and radioactive waste management, a single comprehensive and cohesive document detailing the Belgium national strategy and policy for the management of all radioactive waste and spent fuel, does not exist.

At the moment, no radioactive waste disposal facilities are in operation in Belgium. In 2006, the Government approved in principle a proposal of ONDRAF/NIRAS to build a surface disposal facility for short-lived low and intermediate level waste (category A) and ONDRAF/NIRAS has submitted an application for the construction and operation license of such a facility. As for the management of high level and long-lived waste, ONDRAF/NIRAS has developed a national plan and submitted it to the Government for approval. A decision by the Government is still pending. As for radium-bearing waste, a plan has been announced by ONDRAF/NIRAS.

On 23 June 2006, the Belgian federal Government selected the municipality of Dessel for the location of a surface repository for low- and medium-level short-lived radioactive waste. The Government requested ONDRAF/NIRAS to:

- continue the development of the technical integrated disposal project in Dessel,
- carry on the local partnership participation process,
- to develop a framework to guarantee the project's safety and financing, and to
- provide for the financing of the associated socio-economic aspects.

In its decision of 2006 on the disposal of category A waste in a surface disposal facility, the Belgium Government charged the FANC with the development of a specific licensing regime for disposal facilities and of guidance documents for ensuring safety (short-, medium- as well as long-term) with respect to disposal, and to have a close follow-up of the activities of ONDRAF/NIRAS concerning the subject. This specific licensing regime is not yet established and the general licensing regime for class I facilities is being used.

ONDRAF/NIRAS has, in January 2013, submitted to FANC an application for the construction and operation of a near surface repository for Category A waste. Said application is currently being evaluated by the regulatory body.

Spent fuel management

According to ONDRAF/NIRAS regulations, spent fuel is not regarded as radioactive waste. Consequently its management is not automatically subject to the competence of ONDRAF/NIRAS, as long as it is not declared as waste by the owner/producer.

The management of the spent fuel of the NPPs is a competence of Synatom (a subsidiary of the power plant operator Electrabel), in which the Belgian State has special voting rights. Synatom, owner of the fuel, has to comply with the obligations in respect of financial provisions for the management of the spent fuel as set in the law of 11 April 2003.

In 1993, the Parliament decided to temporarily ban all further reprocessing and to stimulate research on direct disposal of the fuel. Meanwhile, the spent fuel generated by the nuclear power plants is kept in onsite interim storage facilities (except for the fuel already reprocessed). These interim storage facilities

are licensed class I facilities operated by the nuclear power plant operator. R&D on underground repository is currently performed near SCK•CEN.

As evidenced above, various decisions related to the management of radioactive waste have been made at different points in time. These decisions should be consolidated into a national policy and strategy for radioactive waste management. The national policy on radioactive waste management has to:

- set out the preferred options for radioactive waste management.
- reflect national priorities and available resources and has to be based on knowledge of the waste to be managed (e.g. knowledge of the inventory and of waste streams) now and in the future.
- assign responsibilities for various aspects of radioactive waste management, including regulatory overview..
- outline arrangements for ensuring the implementation of the national policy.
- provide for the coordination of responsibilities.
- be compatible with other related strategies such as strategies for nuclear safety and for radiation protection.

The national policy and strategy should be developed within the framework of the national policy for safety recommended and discussed in section 1.1. Furthermore, a recommendation relating to coordination and defining the roles of involved parties is provided in recommendation R7 in section 1.3.

1.8. COMPETENCE FOR SAFETY

Belgium has a long history for nuclear applications since the creation, in 1950, of the Atomic Energy Commission. Consequently, measures for the development of necessary competence for operation and for regulation of facilities and activities, i.e., research centre, universities, scientific cycles, are in place in Belgium and have been for several decades.

The SCK•CEN is the national research centre in the field of nuclear energy that was created in the 1950s in Mol. Research facilities, training facilities and research reactors are available at this centre. Training is one of its statutory missions. The SCK•CEN offers specialized services to the nuclear and non-nuclear industry, the medical sector and the authorities.

As a joint effort to maintain and further develop a high quality programme in nuclear engineering in Belgium, the Belgian Nuclear Higher Education Network (BNEN) was set up in 2001 by six Belgian universities and the SCK•CEN. The BNEN created a 60 ECTS "Master of Science in Nuclear Engineering" programme (ECTS=European Credit Transfer and Accumulation System, 1 ECTS=30 hours of education). Several Belgian universities also organize training programmes in radiological protection at the "Master" level. Several technical high schools also provide training courses in radiological protection and/or nuclear technology.

Finally, Belgian experts (both from the regulatory body and from the operators) and technicians can also be trained in foreign countries, for example at the French INSTN.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The 1994 law assigns to FANC the responsibility of initiating and coordinating research and development work and establishing special relations with public organizations operating in the nuclear field, with scientific research circles as well as relevant international authorities. Scientific Council of Ionizing Radiation may also express opinion on R&D. For the past years, neither FANC nor the Scientific Council has fully used the possibilities offered by the regulatory framework to express*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
their views on R&D needs for regulatory purposes. Some research programs are nevertheless performed in relation to medical exposures and geological disposal.	
(1)	**BASIS: GSR Part 1 para. 2.35 states that** *"The building of competence shall be 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. Competence shall be built, in the context of the regulatory framework for safety, by such means as:* - *Technical training;* - *Learning through academic institutions and other learning centres;* - *Research and development work."*
(2)	**BASIS: GSR Part 1 para. 2.38 states that** *"Development of the necessary competence for the operation and regulatory control of facilities and activities shall be facilitated by the establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety."*
S2	**Suggestion: FANC, with the support of the Scientific Council if needed, should consider identifying its radiation and nuclear safety research needs periodically and notifying relevant parties so that appropriate associated research programmes are developed.**

1.9. PROVISION OF TECHNICAL SERVICES

The FANC operates a network of monitoring stations, known as TELERAD, located over the entire national territory, in particular around the most important Belgian nuclear sites and along the Belgian borders in the vicinity of foreign nuclear installations. The network is intended to detect environmental contamination in normal and accident circumstances.

The various types of personal dosimeters and their read-out systems used by the operators to protect their employees are subject to prior approval (recognition) by the FANC. The services that collect and interpret the dosimetry data on behalf of the operators also need such a prior recognition.

1.10. SUMMARY

In Belgium, supervision of the protection of the public and the environment against the dangers of ionizing radiation is performed at the federal level. A Special Parliamentary commission for nuclear safety matters has been established. In the Federal Government, the Minister of Home Affairs is politically responsible for safety matters and hence supervises the FANC which became operational in 2001 and acts as the regulatory body together with its technical subsidiary Bel V, created in 2008. The 1994 law (amended) and several royal decrees establish the mandatory requirements for nuclear safety, nuclear security and radiation protection in Belgium. This framework enables the FANC and Bel V to perform their duties without undue influence from the Government and other interested parties. The FANC mandate is extensive but nevertheless requires interfaces with several other Federal services on issues such as emergency preparedness and response, waste management or medical exposure.

As for radioactive waste and spent fuel, two organizations (ONDRAF/NIRAS and Synatom) have the mandate to ensure, at the national level, long term management.

Areas of improvement identified by IRRS team deal with:

- Formalising a comprehensive national policy for safety, including on radioactive waste and spent fuel, and explicit assignment of the prime responsibility for safety to the authorised party;
- Process to issue regulations in a more efficient manner;
- Legal basis for inspection at suppliers or contractors facilities;
- Responsibility for HPD and AIO roles and interfaces with FANC;
- Allocation of responsibilities and interfaces within the governmental bodies; and
- FANC inputs to the research and development programme for safety.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

International legal tools

Belgium is a contracting party of relevant international treaties and conventions that establish common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and radiation for peaceful purposes and that provide for an effective coordinated international response to a nuclear or radiological emergency, including:

- the Convention on Nuclear Safety;
- the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- the Convention on Early Notification of a Nuclear Accident.

As a member of the European Union, Belgium has to transpose into the national legal framework the European Directives, the most important being the Directive setting the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, the one setting a community framework for the nuclear safety of nuclear installations and the one on the safe management of radioactive waste.

Codes of conduct published by IAEA

Belgium made a "political commitment" to work following the recommendations of the Code of Conduct on the Safety and Security of Radioactive Sources but did not make a commitment on the associated Guidance on Import and Export of Radioactive Sources. The Code of Conduct on the Safety of Research Reactors is used as an important reference.

Use of and participation in development of IAEA Safety Standards

Belgium participates actively in the development of IAEA safety standards and in the enhancement of harmonized approaches for safety as well as for exchange of regulatory experience. A member of the Scientific Council is also a member of the IAEA Commission on Safety Standards (CSS), and FANC staff are members of Radiation Safety Standards Committee (RASSC), Transport Safety Standards Committee (TRANSSC), and the Radioactive Waste Safety Standards Committee (WASSC). The Bel V general manager is a member of Nuclear Safety Standards Committee (NUSSC).

FANC has a policy document (GD010-09) concerning the development of regulations and guides and a procedure (PC005-02) concerning the development of regulations. One of the primary inputs for FANC in developing draft regulations is the WENRA reference safety levels which are established after considering, in particular, IAEA safety requirements. However, IAEA safety guides are mostly considered on a case by case basis, with FANC relying on the fact that the FANC staff drafting regulations have often been involved in drafting IAEA safety standards (see section 9 suggestion S16).

International peer reviews

OSART missions were held in 2007 at Tihange NPP and in 2010 at Doel NPP with subsequent follow up respectively in 2009 and 2012. Both sites undergo a peer review by WANO on a three year basis with a follow-up in between.

In addition to the current IRRS, an IPPAS mission (physical protection) is foreseen for 2014. Belgium underwent the post-Fukushima EU stress test peer review. Furthermore, the FANC management system requires to benefit from an IRRS mission, consistent with the European Directive 2009/71/Euratom.

Belgian experts volunteer to participate in IRRS and in other peer review missions such as OSART missions or EU stress test peer review. A Belgian pool of experts available for performing IRRS missions has been established and is maintained.

Multilateral and bilateral cooperation programmes

In addition to IAEA and various OECD/NEA committees and working groups, FANC and BelV take part in a number of organizations, working groups and committees important for enhancing harmonized approaches for safety as well as for exchange of regulatory and operating experience including the following: ENSREG, WENRA, HERCA, EACA and European Clearinghouse on NPP operating experience feedback. In addition, the Belgium NPP operator is a member of WANO, Westinghouse Owners Group and Framatome Owners Group.

As for bilateral cooperation, the FANC signed cooperation agreements with several foreign regulators, e.g. the French Safety Authority (ASN), the USNRC and Luxembourg. With the ASN, the FANC and Bel V have established an active cooperation with several meetings each year as well as cross-inspections. A tripartite working group has been recently established between members of FANC, Bel V, ASN and ENSI (Switzerland) to discuss specific regulatory topics (such as long term operation of NPPs).

In the area of emergency preparedness and response, cooperation agreements with neighbouring countries (France, Luxembourg, and the Netherlands) are also in place.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Reporting of operating and regulatory experience

Belgium regulation (SNRI-2011) requires the licensees of the NPPs or of other class I facilities authorized after 2011 to have a process to collect and review the operational feedback, from their own installation and from other similar installations (foreign installations included), and to disseminate this information to relevant national and international organisations.

Event notification to the regulatory body is a licence condition for each operator of class I, II and III facilities. FANC guidance defines the events to be reported.

Receiving of information from other States and authorized parties, dissemination of lessons learned and their use

In addition to domestic operating experience, the main sources of foreign operating experience information for FANC and BelV are IAEA or OECD/NEA databases and publications, EU Clearinghouse, as well as information published by foreign regulatory bodies (e.g. USNRC, French ASN). Any other information can be also used on condition that it is issued by a reliable and official source.

For class I and IIa facilities, for which Bel V performs regulatory surveillance as requested by FANC, Bel V has a formal process to review international operating experience feedback (OEF), select the ones warranting an in-depth analysis, or notify the relevant authorized parties and provide the feedback to international systems for OEF. FANC recently formalized its process to manage OEF, which relies largely on BelV work. For class IIb and class III industrial facilities and activities, FANC carries out OEF activities with relevant input from international events as well as dissemination to international forum.

OEF inputs, process and goals are not documented in detail in the FANC management system for transport activities and for medical activities and facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For the reactor pressure vessel flaws issue of the Doel 3 and Tihange 2 reactors in 2012, FANC decided to benefit from international expert advice, as well as to increase transparency and cooperation with potentially interested countries, set up several working groups to review the licensee safety assessment and action plan.*	
(1)	**BASIS: GSR Part 1 para. 3.2 (e) states that** *"The features of the global safety regime include:* *(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 establish and maintain a … means for making available to others lessons learned from operating experience and regulatory experience.*
GP1	**Good Practice: The creation by FANC of several international working groups to review the issue of flaws in Doel 3 and Tihange 2 pressure vessels represents a major initiative to address a new and significant safety issue.**

2.3. SUMMARY

The IRRS team concluded that Belgium and FANC fulfil their international obligations and actively participate in the relevant international arrangements, including international peer reviews.

The IRRS team concluded that a system is in place for use and dissemination of international operating and regulatory experience in order to contribute to safety. The FANC response to the issue of flaws in Doel 3 and Tihange 2 pressure vessels could be considered as exemplary. When Bel V has a lead role (class I and IIa facilities), FANC involvement in OEF activities is limited and is focused on ensuring BelV's OEF process is effective.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

FANC has been operational since 2001. The only legal requirement regarding its structure is the separation between regulation development activities and the surveillance and inspection activities. Article 28 of the FANC law has allowed the FANC to outsource some of its legal tasks to Bel V. These tasks mainly comprise the review and assessment of licence applications, the safety analyses of class I nuclear facilities, and the supervision of the operator. Bel V works mainly for FANC but also performs some smaller tasks related to international cooperation and support activities. Although it is not forbidden, in practice Bel V does not work for the Belgian licensees. The relations between FANC and Bel V are formalized in a "management agreement". There are regular meetings between FANC and Bel V in areas of inspections, review and assessment (large projects) and cross-cutting issues (e.g. R&D and regulations). Only FANC nuclear inspectors have enforcement powers. If needed, Bel V inspectors can contact FANC for enforcement actions.

Both FANC and Bel V have their own Board of Directors. The boards have about 14 members and at least 2/3 of the members of the Board of Bel V are common with the Board of the FANC. The mission of the FANC Board of Directors is stated in the FANC law. Financial and strategic committees report to the board and the board makes decisions, e.g. staffing plans, budget and strategy. The board also nominates the directors of FANC departments.

For matters related to high risk facilities (i.e. class I), an expert group, the Scientific Council for Ionizing Radiations, is established, pursuant to article 37 of the FANC law. Its mission has a clear status and is described in relevant articles of the GRR-2001. The Scientific Council is composed of 16 highly-skilled experts (internationally recognized experts, experts with a large professional experience, university professors, etc.), each having voting rights and who are appointed by the FANC supervising minister. The Scientific Council does not perform itself the safety evaluation or technical studies, but may request the opinion or advice of any external expert (or organization) it deems appropriate. Article 11 of the royal decree of 18 December 2002 on the Scientific Council as well as the internal regulations of the Scientific Council prevents conflicts of interest for its members in providing its advices.

In the licensing process of class I facilities, the report of the Scientific Council should be included in the dossier that FANC submits to the Ministry in support of the decision making proposal. If the Scientific Council report recommends not issuing an authorization, this recommendation must be followed by the Minister and consequently the Scientific Council has the capacity to introduce a veto in the process, being part of the safety regulatory decision making process. On the other hand, the Minister is not obliged to incorporate the Scientific Council or FANC conditions included in their reports; he can modify or delete. This also implies that the Minister is part of the safety regulatory decision making.

For personal licences and recognitions in the medical field a medical jury intervenes (see Section 11.1).

FANC has approximately 150 workers and Bel V approximately 80 workers. Those staffs have increased more than 50% between 2006 and 2013. One reason has been the anticipated retirement of some part of the staff and another reason has been to recruit new staff to oversee the new FANC activities (e.g. security). The taxes collected from the licensees have been raised accordingly. There seems to be some room for improvement on an overall and long term staffing plan and a technical competence management plan at the FANC (see Sections 3.3 and 4).

Bel V assesses its annual workload based on the information of the known activities and the history of working hours. About 60-65% of the workload is reserved for oversight activities, the rest can be used for activities such as international cooperation and R&D. The staffing plan for the next year is produced based on this assessment and Technical Responsibility Centres (TRCs) are used for defining the needed competences for the possible new recruitments. As a result of the recent resource planning for year 2014, Bel V has started recruiting five new workers.

FANC is currently finalizing the new strategic plan for the next 9 years. It takes into account internal factors (e.g. retirement and competence analysis of the staff) and external factors (e.g. decommissioning or licensing of facilities). There will be also a new mid-term plan (3 years) provided for years 2014-2016. FANC also prepares an annual operational plan where the next year's activities are presented in more detail. This mid-term or annual operational plan does not include the staffing plan which will be developed later. Bel V does not have its own strategic or global operational plans even though they have one for inspection activities. Bel V is included in the strategic plan concerning the organizational structure and the long term resources (financial, material, personnel), but the Bel V activities have not systematically been included in the strategic plan.

FANC is financed directly by the licensees (e.g. annual taxes, administrative fines, authorization fees). The costs cover all regulatory activities including environmental monitoring, emergency preparedness, research and international cooperation. There is no money coming from the government budget.

Bel V invoices to the licensees the working hours carried out for inspections and analyses based on the contract between Bel V and the licensee. Currently those contracts have not any legal recognition as a public service but are treated as private contracts in the same way as any other services provided to the licensees. This is not coherent with the Bel V regulatory role. There was one case identified where the Bel V oversight activities of the waste facilities are not financed by ONDRAF/NIRAS. ONDRAF/NIRAS is paying for the oversight in annual taxes to FANC but there is not a mechanism to transfer this money to Bel V. There is also not a contract between Bel V and ONDRAF/NIRAS for invoicing the working hours for the oversight work. In order to preserve the regulatory role and independence, its functions and financing should be clarified in the legislation. A draft of the royal decree on Bel V and an update of the Nuclear Act and GRR-2001 have been prepared for this purpose.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The safety regulatory decision making process involves several organizations including, FANC, Bel V, the Scientific Council for Ionizing Radiations and even the Minister, and in this sense all of them can be considered as part of the regulatory body. Even though all roles and responsibilities are assigned in the legal framework, except in the case of Bel V and AIOs, not all these organizations fulfil the criteria required for a regulatory body (e.g. independence, competence, resources, safety culture, ...). A systematic review on the way in which the regulatory body, taking into account the different actors involved in the regulatory process, discharge its responsibilities has not been carried out. Similarly, a systematic process for analyzing the resources and competences needed for all of them is not in place.*	
(1)	**BASIS: GSR Part 1 para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fullfil its statutory obligations efectively."*
R11	**Recommendation: The regulatory body should develop and implement a process for carrying out a systematic review of its organizational structure, competences and**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	resource needs to effectively discharge its current and future reponsibilities.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The legal framework of the regulatory body and its independence has been reviewed in Section 1.3. In Section 3.1 a systematic analysis of the way in which the different actors taking part in the regulatory decision making process fulfil the criteria required for a regulatory body, including their independence, has been recommended. In addition to that, some other aspects have been reviewed.

FANC is directed by a Board. A Government commissioner attends the meetings of the Board of Directors to verify that FANC fulfils its legal missions. The members of the Board of Directors are appointed by royal decree, on the proposal of the Council of Ministers. No special technical expertise in nuclear safety or radiation protection is required to be a member. The Governance charter of the Board is published on the FANC web site. The Board, which meets approximately six times per year, focuses on:

- the overall strategy for long and short term, with the approval of the mid-term and annual operational plan;
- the staffing and personnel employment conditions of the FANC;
- the financing of the FANC.

The Board approves the annual budget and the staffing of the FANC. It nominates and evaluates the senior management. The Board delegates the management of the FANC to the General Manager, who is appointed by royal decree for a fixed term of 6 years. The General Manager is responsible for the functioning of FANC, deals with all technical issues and takes the regulatory decisions without the intervention of the Board of Directors. However, there is no provision to prevent any undue influence of the Board of Directors or any of its members on the safety decision making. This should be taken into consideration when performing the systematic review recommended in Section 3.1.

The need for a legal recognition of the Bel V functions and funding has also been addressed in Section 3.1.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

At FANC, each department determines the number of staff and the competences it requires, according to the mid-term and annual Operational Plan (POP) and other foreseeable workload (like pre-licensing projects), based on past experience. Resources are adapted accordingly. A formalized system describing the competences required for each position is currently being developed. A systematic process for allocation of resources taking into account the safety significance of the different issues is not in place. A relevant example is the situation of the Health Protection Section, in which only 2.5 full-time equivalent inspectors are available for 7,740 medical installations and 15,462 medical practitioners. The global review of the organizational structure, competences and resources recommended in Section 3.1 should contribute to a balanced allocation of human resources and competences. This subject is reviewed also in Section 4.3 and an additional suggestion is included in relation with the competence management system.

The recruitment process is described in procedure PC003-01 of the management system. Each job description specifies the required core technical competencies. All positions are offered publically for application and are also open to internal candidates. Specific assessments of the applicants are done as appropriate looking not only at technical competencies, but also at behavioural and/or managerial competencies, which are evaluated with the support of one external consultant. Training needs for

newcomers are identified after assessment with respect to the required competencies. A tutorial plan is defined.

An annual budget is foreseen for staff training and knowledge management needs. Training of staff consists of multiple and diverse external training courses as well as internal training. Currently this plan is not systematically based on the competence analysis for each position.

For foreseeable departures, the recruitment is initiated, depending of the importance of the position and of the required experience, up to two years in advance of the actual departure, so that the new staff member can fully benefit from "on the job" training with the leaving staff member. In addition, after retirement, staff can be hired as external consultant for maintaining and transferring the accumulated expertise and knowledge.

At Bel V, the competence needs (both number of staff and required competencies) are periodically evaluated and reported by the head of each Technical Responsibility Centre (TRC). A systematic way of analysing the competences required for each position is not in place yet but a new system is being developed, taking into account the IAEA SARCoN2 (Systematic Assessment of Regulatory Competence Needs) system. This subject has also been reviewed in Section 4.3 and a suggestion to finalize and implement the competence management system and to establish a formal and sustainable training programme has been provided.

The annual evaluation may lead to announcement of new positions, internal job rotations or adapted training for the actual staff members. The recruitment process is described within process A08 "Manage and Develop Human resources". If no internal expertise is available, vacancies are published through the Bel V website and selected jobsites, mentioning the job description as well as the required competencies and qualifications.

The TRC Annual Reports, as well as the staff's Individual Development Plans, indicate training needs in the short and long term. The Technical Training Manager is in charge of the elaboration and follow-up of an annual training programme. Currently this plan is not systematically based on the competence analysis for each position.

Bel V experts involved in the control activities of nuclear facilities have to be accredited by the FANC as experts in health physics, in accordance with the criteria and procedure of article 73 of GRR-2001. Within FANC, a similar process for recognising experts as FANC nuclear inspectors has been developed. Currently, there are about 7 FANC inspectors and 15-20 Bel V inspectors qualified.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

For matters related to high risk facilities (i.e. class I), an expert group, the Scientific Council for Ionizing Radiation, is established, pursuant to article 37 of the FANC-law. Its role and responsibilities have been discussed in Section 3.1.

For personal licences and recognitions in the medical field a medical jury intervenes (see Section 11.1). This medical jury can also give advice for all questions related to radiation protection in the medical or occupational field. For justification questions the High Health Council can be consulted.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There are several formal mechanisms of communications with the authorized parties: reporting, control and approval of some decisions of the Health Physics Department, communications in the framework of the licensing process, inspection reports, meetings, and follow-up of action plans. There is also informal communication and meetings. Meetings can be organized at the request of authorized/applicant parties or at the FANC/Bel V's initiative.

Meetings are planned between authorized parties and FANC/Bel V at regular frequencies. Evidence suggests that the relationship is strong and results in a proper definition and closure of actions. In particular, controls at class I facilities are followed by structured and detailed discussions between the proponents/stakeholders. Currently the relationships between FANC/Bel V and the class I licensees shows that there is no need to apply hard enforcement measures. However changes in licensee culture could affect this relationship and the need for enforcement.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

FANC decisions and positions are drafted, reviewed and approved by different staff members at different hierarchical levels and approved by the process owner (ranging from the head of the section/department up to the FANC general manager for high risk facilities).

Bel V has different mechanisms in place to improve the consistency of regulatory decisions. There are Technical Responsibility Centres (TRCs) where the TRC coordinator ensures the consistency of the positions that are taken within the concerned technical area. There are also four global project managers who verify Bel V safety positions between different projects. In addition, there is also a Safety Issue Committee (CIS) comprising of seven high level experts. This Committee meets at least two times per year and also whenever needed. The committee can give their position to major safety issues which are not urgent. For urgent matters, the steering committee of Bel V can give their position.

The graded approach relies on classifying different facilities and their related regulations, review and assessment and inspections. Within one class of facilities, the graded approach is said to be used in practice by giving more resources to the most safety significant issues but this has not yet been systematically documented in FANC or Bel V. Currently there is a FANC Nuclear Industrial Facilities Section procedure relating to the application of the graded approach to planned and reactive activities. It gives a relatively good framework for prioritizing different regulatory activities and could be used as an example for all activities in both organizations.

A graded approach to authorisation of practices within the medical sector based on radiological risk is not formally applied. The same level of regulatory control applies to all practices, radiotherapy, nuclear medicine, radiology, dental and veterinary, through a licensing system. The FANC is currently required by the law to license 100% of all practices within the medical sector. However, in practice, more time and resources are allocated for licensing the more complex facilities, for example radiotherapy and nuclear medicine applications. FANC is looking into improving the effectiveness of the regulatory body by employing different instruments like information campaigns, or a risk-oriented prioritisation of inspections.

The mandatory advice of the Scientific Council is needed for licensing decisions of the highest risk facilities. FANC can also ask advice from the Scientific Council concerning other issues related to class I facilities, authorization of class II and III facilities or regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is some room for improvement in the consistency of the regulatory actions and decisions. Policy documents are currently under development in the FANC management system with the aim of laying down more formal policies and criteria for regulatory body's actions, judgements and decisions. There is a need to give more detailed guidance (e.g. internal inspection and assessment guides) so that the regulatory staffs are able to make consistent decisions.*	
(1)	**BASIS: GSR Part 1 para. 4.26 states that** *"The regulatory process shall be a formal*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based."
R12	**Recommendation: The regulatory body should give more detailed internal guidance for inspections, review and assessment to improve the consistency in its decision making.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Within one class of nuclear facilities, the principle of graded approach is used in practice by giving more resources to most safety significant issues but this has not yet been formalized and systematically documented in FANC or Bel V management systems.* *Currently there is a FANC Nuclear Industrial Facilities Section procedure relating to the application of the graded approach to planned and reactive activities. It gives relatively good framework for prioritizing different regulatory activities and could be used as an example for all activities in both organizations.* *In the medical and industrial sector, the law requires to license 100% of all practices.*	
(1)	**BASIS: GSR Part 1 para. 4.26 states that** *"The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control; for the highest associated radiation risks, it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization."*
S3	**Suggestion: The regulatory body should consider formalizing and systematically documenting the use of graded approach for allocating resource according to risk.**

3.7. SAFETY RELATED RECORDS

Written records of the results of the inspections, enforcement, licensing activities, safety review and assessments are kept within the regulatory body. FANC has a central information system (CIS) for storing the documents in electronic format. Currently CIS includes all documents related to authorization processing and their final decisions (documents in electronic format from year 2001). CIS will be supplemented with the inspection reports in January 2014. Currently all inspection reports from year 2004 can be found in another database. There is also a plan to include all archives in electronic format to this new CIS system. Bel V does not have access to the FANC document management system.

Bel V document management system includes all inspection reports, meeting reports, some technical documents, and a database for actions to be taken by the licensees. Previously Bel V did not produce its own safety assessment report concerning their assessment work. This has been now clarified in the FANC/Bel V note describing the process for work requests by FANC to Bel V in the field of review and assessment for specific projects. The note defines that Bel V sends the draft deliverables to FANC for evaluation before finalising them. FANC will prepare a decision taking into account all deliverables from Bel V or other bodies (e.g. advisory bodies). In the future, the Bel V assessment reports will be stored in the Bel V document management system.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

FANC has a wide programme to communicate and inform its different stakeholders. The web page contains abundant information on events and relevant issues as well as background information on general matters, information about the radiation risks of different facilities and activities. A specific space is devoted to laws and regulations. The web page allows asking questions to the FANC. The results of the measurements performed by the TELERAD network are also available on the FANC web site. Even though, some valuable information is not available to the public, such as the list of members of the Board of the Directors and their curricula as well as the Director General curriculum,

An annual report is submitted every year to the Parliament. This report is published on the FANC web site, together with the Bel V annual report. In addition to the governmental commissioner that attends the Board of Directors meetings, a liaison officer within the office of the Minister of Home affairs (the supervising Minister of the FANC) is appointed by the FANC. This contact point facilitates the communication with the supervising Minister.

The public is consulted ("public inquiry") in the frame of the licensing process of high risk facilities (class I and some class II), with the possibility to attend information meetings organized by the FANC.

Even though there is a wide range of communication activities carried out by FANC, there is not in place a transparent decision making process that provides to the public and stakeholders the elements that support its relevant regulatory decisions.

A variety of forums are established to communicate and interact with licensees, adapted to the specific needs of each industrial or medical sector. In the vicinity of nuclear facilities, local communities organize regular meetings to which they also invite the regulatory body. Proactive local communications originating from the regulatory body does not seem to take place.

A local representative is appointed by the FANC in the Mol-Dessel area (nuclear research centre, waste treatment and storage facilities, fuel cycle facilities) ("FANC antenna") to inform the local community and to organize specific meetings with interested groups as needed. But local representatives have not been appointed in other nuclear facilities, and periodic meetings with local committees that are open to the public do not occur. The practice of FANC appointing a local representative in the Mol-Dessel area should be considered for other areas.

Communication of events related to radiation or nuclear safety with the INES scale is systematically and on a structural manner used in Belgium. FANC has written guidance/directives which are applicable to all the industrial class I, II and III facilities and which precisely identify the type of events which have to be notified to the FANC, Bel V or other institutions, the delay (time allowance) to notify the events and the INES applicability for the event. In parallel, FANC has set up specific conventions between the regulatory body, the AIOs and the licensees of the class I installations and the highest risk class II installations to use INES as a communication tool to the public. This convention is on a voluntary basis, and all the concerned licensees participate in it. Events that are classified at level 1 or higher on the INES scale, or

level 0 which have a media interest, are published on a dedicated web page on the web site of the FANC.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC carries out a wide range of communication activities but there is not in place a transparent decision making process, providing to the public and stakeholder the elements that support its relevant regulatory decisions (e.g. decision documents and assessment reports).*	
(1)	**BASIS: GSR Part 1 para. 4.66 states that:** *The regulatory body shall establish provision for effective mechanisms of communication... This communication shall include constructive liaison such as: (d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public.*
S4	**Suggestion: FANC should consider establishing a transparent decision making process, providing to the public and stakeholder the elements that support its regulatory decisions.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current public/stakeholders engagement process related to approval of decommissioning strategies and site end states is considered to be limited. Recognizing that this matter is a subject that is of concern to stakeholders and in particular the general public, the regulatory body should establish processes for engaging with a broader spectrum of stakeholders, including public living in the vicinity of the nuclear facilities.*	
(1)	**BASIS: GSR Part 1 Req. 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: GSR Part 1 para. 4.67 states that** *"The regulatory body, in its public informal activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media….In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities"*
(3)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include:* - *Reviewing the initial decommissioning plan and reviewing and approving the final decommissioning plan before allowing decommissioning activities to be commenced;* *Giving interested parties an opportunity to provide comments on the plan before it is approved."*
S5	**Suggestion: The regulatory body should consider the establishment of a clearly defined process and criteria for engagement with a broader spectrum of stakeholders and gathering of public input on decommissioning actions and the final end state of the site.**

3.9. SUMMARY

The regulatory body functions are performed mainly by FANC that delegates some activities to Bel V and other Authorized Inspection Organizations. The Scientific Council for Ionizing Radiations has a role and participates in the safety regulatory decision making. An integrated and systematic assessment of the way in which all these organizations discharge their regulatory responsibilities and the resources and competences needed has to be performed.

FANC is financed directly by the licensees (e.g. annual taxes, administrative fines, authorization fees). Bel V invoices to the licensees the working hours carried out for inspections and analyses. Legal support should be provided to Bel V functions and funding in order that its regulatory tasks can be fulfiled with the due authority and independence. The competence management is being improved in FANC and Bel V. Based on it, a formal and sustainable training programme should be developed.

In order to ensure more consistency in the decision making, more detailed regulatory guides have to be developed and internal guidance for review and assessment should be provided. A formal and systematically documented use of a graded approach should be implemented, assigning more resources to the most safety significant issues.

FANC has a wide programme to communicate and inform its different stakeholders, but current public/stakeholders engagement process related to the radioactive waste management and disposal facilities should be reinforce engaging with a broader spectrum of stakeholders (in particular the public living around the proposed site of disposal facilities).

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The FANC, together with its technical subsidiary Bel V, constitute the regulatory body. Besides these public authorities, key actors in nuclear and radiation safety are AIOs and other organizations as explained in Chapters 1 and 3. These actors do, even in a limited way, ensure regulatory tasks. This is subject to a specific recommendation (see recommendation R5). Currently the AIOs perform supervision tasks of the HPD of some lower class installations (II B, III). The FANC has submitted a regulation project that structures the regulatory tasks so that in the future, AIOs should not perform regulatory tasks.

Since 2008 the FANC has had a quality management system that conforms to ISO 9001:2008. A complete review of the management system started in 2012 after the 2011 self-assessment with the aim to be compliant with IAEA Safety Requirements, GS-R-3. Some aspects of GS-R-3 are not yet covered, e.g. safety culture within the FANC organization and the graded approach. The re-worked management system was successfully recertified to conform to ISO 9001:2008 in October 2012. The FANC intends to keep both the ISO certificate and meet compliance with GS-R-3. The management system describing the processes at the FANC is well documented. It does not, however, describe the processes for the regulatory functions at the regulatory body level and for other organizations with regulatory functions.

Since 2001, Bel V has developed its own management system in light of their specific role. The Bel V Quality Management System is certified under quality standard ISO 9001:2008. Bel V's management system aims to be an Integrated Management System as defined in the IAEA Safety Standard GS-R-3. Some aspects of GS-R-3 are not yet covered, e.g. safety culture within the Bel V organization and the graded approach.

The cooperation between the FANC and Bel V works well in practice. They maintain periodic meetings for coordination and progress review purposes. For instance, they inform each other on training opportunities, they agree on the participation on international working groups and exchange the obtained information. There is a management agreement between FANC and Bel V, and Bel V reports to FANC in a structured manner. There is no coordination of the management systems of the FANC and Bel V.

The cooperation with the AIOs can be improved; e.g. the reporting of the inspection findings to FANC needs to be improved. Currently, the FANC puts no requirements on the management systems at the AIOs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The FANC management system describing the processes at FANC, is well documented. It does, however, not describe the processes for the regulatory functions at the Regulatory Body as a whole and the other organizations with regulatory functions*. *Although the FANC puts requirements on the AIOs and Bel V, there is no policy for the management systems of all organizations performing regulatory functions, nor is there a coordination of the management systems of these organizations.*	
(1)	**BASIS: GS-R-3 para. 2.1 states that** *"The main aim of the management system shall be to achieve and enhance safety by bringing together in a coherent manner all the requirements for managing the organization".*
(2)	**BASIS: GS-R-3 para. 2.4 states that** *"The organization shall be able to demonstrate the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	effective fulfilment of its management system requirements".
(3)	**BASIS: GS-R-3 para. 3.9 states that** *"Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed".*
(4)	**BASIS: GS-R-3 para. 3.12 states that** *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved".*
(5)	**BASIS: GS-R-3 para. 6.1 states that** *"The effectiveness of the management system shall be monitored and measured to confirm the ability of processes to achieve the intended results and to identify opportunities for improvements".*
R13	**Recommendation: FANC should include in its management system, a process that allows FANC to oversee and review the activities of Bel V and all other organizations performing regulatory functions, to ensure coherence and effectiveness of all regulatory functions including those carried out by FANC, and to identify opportunities for improvements.**

The concept of continuous improvement is being applied to the FANC organization, to the management system, and to the individual workers at FANC. In preparation for this IRRS mission, the FANC performed two consecutive self-assessments using the IAEA self-assessment tools.

All staff members contribute to the identification of non-conformities. Responsibility on the solution of non-conformity is clear. The corrective and preventive actions are regularly monitored, and the status of the non-conformities is discussed with the senior management during the Management Review. Currently, an annual Management Review is conducted on the quality aspects, including results of internal/external quality audits, corrective/preventive actions, non-conformities, complaints, and customer satisfaction surveys.

Each staff-member (including the management) is expected to actively participate in the improvement process of the management system by having a questioning attitude and making constructive proposals. All staff members are asked how they contribute to the goals of the organization. In the future, personal objectives will be aligned with the goals in the Strategic Plan.

GS-R-3 requires the management system to be used to promote and support a strong safety culture. For management systems within the regulatory body, safety culture would include, for example, timely decision making and prioritising safety issues and resources used. At present, safety culture is not being addressed explicitly in the management systems of either FANC or Bel V.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The safety culture within the Regulatory Body itself is not being addressed explicitly.*	
(1)	**BASIS: GS-R-3, para 2.5 states that** *"The management system shall be used to promote and support a strong safety culture"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R14	**Recommendation: The regulatory body including Bel V, and all other organizations performing regulatory functions, should develop and implement a common safety culture policy.**

The FANC processes of licensing, inspection, review and assessment, or management of modifications rely on a graded approach by classifying different types of facilities. For nuclear facilities, the safety implications of the regulatory tasks are assessed in order to determine priorities and allocate the necessary resources to perform the tasks. For other facilities, the use of the graded approach could vary from one section/activity to the other.

Within some areas, further improvements in the application of the graded approach can be made, e.g. in the authorisation process for transport of low risk radioactive material (see Sections 3.6 and 5.6).

4.2. MANAGEMENT RESPONSIBILITY

In FANC, the responsibility of the General Manager and the management team regarding the establishment, implementation, assessment and continuous improvement of the management system are included in the governance document, GD002-01.

Until last year, the management system was approached at the level of departments, and there was no structured and formal approach for the management system at the level of the organization. The senior managers have individually taken initiatives regarding their departments (definition of responsibilities, scope of activities, performance measurements, and internal and transversal meetings), trying to further improve the management/quality system. Coherence across departments is being enhanced by formulating policies at the organizational level, e.g. a policy for licensing leads to harmonisation of the separate licensing procedures. Coherence at the organizational level is also promoted by horizontal mentoring where a new department head will be mentored by a colleague department head.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Until last year, there was no structured and formal approach for the management system at the level of the organization. The senior managers have individually taken initiatives regarding their department (definition of responsibilities, scope of activities, performance measurements, and internal and transversal meetings), trying to further improve the management/quality system.*	
(1)	**BASIS: GS-R-3 para. 3.1 states that** *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."*
S6	**Suggestion: FANC should consider continuing the development and implementation of an integrated management system. This should include processes for assessment and continuous improvement.**

There are in place some means to collect and address expectations of interested parties and to communicate with stakeholders. Round table discussions are organized and online forums are dedicated to stakeholders on the FANC website. FANC collects feedback from customers and stakeholders with questionnaires, customer satisfaction inquiries, and personal contacts with the senior management. The

results of this feedback are reviewed and improvements are planned where appropriate. The FANC also has a dedicated area on its website where members of the public can submit their questions or complaints.

In accordance with ISO requirements and IAEA requirements, a mapping of activities and their related governance documents/intention plans (strategic plan -IP002-01) and operational plans/policies has been set up. The policies are made available to all staff members through the quality documentation system on the intranet.

In Bel V the management's commitment to the development and improvement of the management system is included in its Quality Management System. Bel V is also committed to provide high quality services satisfying its customer's requests. At every level of the organization, those responsible for a process or sub-process perform measurements (verification) of service conformity and customer satisfaction, and evaluate the service. For the person responsible for the process, this is the feedback report. The Management Review checks how each process works, evaluates the functioning of Bel V and identifies possible improvements.

The FANC is not seen by Bel V as a customer, but as part of the regulatory body to which Bel V also belongs. To satisfy the FANC means to fulfil the missions that have been delegated to Bel V and to participate in the realization of the Regulatory Body's tasks.

Bel V defines its annual plan giving priority to the tasks required by the FANC. Projects for other Regulatory Bodies are occasionally accepted, and are a matter of lesser priority.

Bel V defines the inspections to be performed to ensure complementarities with the inspections conducted by the FANC, and schedules inspections so as to spread the workload between the experts entrusted with these inspections.

The monitoring of the Bel V Quality Management System is performed through internal/external audits, bimonthly Quality System reviews, by measuring and assessing the functioning of the processes to ensure that they have been established and are maintained, by identifying areas for improvement, by analysing the conformity of the service, and by assessing corrective and preventive actions.

4.3. RESOURCE MANAGEMENT

A FANC strategic plan for the 9 coming years has been set up with safety strategic goals. This strategic plan will be translated into a 3 years operational plan and finally into an annual operational plan including budget. The new strategic plan and the 3 year and 1 year operational plans will be implemented in a consistent way with down-streaming of the operational objectives to the departments, sections and individuals (through the annual assessment exercise). This will allow a periodic revision of the resources deployment.

The annual budget is prepared taking into account the logistic costs, the operational plan and manpower costs. It is approved and monitored by the Board of Directors. In the framework of the management system and specifically of the new strategic plan, 3 year plan and operational plan, the annual budget will also integrate future needs (resources), regulatory context changes and new constraints.

Up to now, a systematic process for allocating resources across issues, taking into account a graded approach according to the safety significance, is not in place. At the FANC, no records are kept of actual time spent on specific activities. As a result, there is no experience base for coupling regulatory objectives to required resources. Bel V does, however, monitor the actual time spent on activities; this serves as a basis for their financial accountability.

As required in the Act on the well-being of workers in the performance of their work and the royal decree of 27 March 1998, the FANC has an Internal Service for Prevention and Protection at work; the service

reports directly to the General Manager. The service assists the employer, the management, and the workers to ensure the implementation of measures relating to the well-being, health, and safety of the workers. This includes personal protection measures, radiation dosimetry, ergonomics, issues from violence, harassment and sexual harassment at work. Related costs estimates are included in the annual budget.

In Bel V there is a continuous evaluation of needs in terms of staffing, recruitment, lifelong learning, participation in working groups (e.g. R&D) and other areas.

The human resources management has identified the skills required (role definition), the qualification criteria and functional or organizational dependence, and establishes for each staff member a programme of basic technical training and specific training with a view to the development of the skills that need to be acquired.

The resources to be implemented are evaluated on the basis of a staffing plan and evaluations of the functioning of processes. The staffing plan takes account of present and future needs with a view to the completion of tasks and projects.

Bel V experts involved in the control activities of nuclear facilities have to be accredited by the FANC as health physics experts in accordance with the criteria and procedures of article 73 of GRR-2001. The same procedure is also used for some FANC inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *At the FANC, no records are kept of actual time spent on specific activities. As a result, there is no experience base for coupling regulatory objectives to required human resources at the FANC. Bel V does, however, monitor the actual time spent on activities.*	
(1)	**BASIS: GS-R-3 para 4.1 states that** *"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".*
S7	**Suggestion: The FANC should consider gathering information on actual time spent on specific regulatory activities to improve the planning and management of resources.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *At FANC, each department evaluates the number of staff and the competences it requires, according to the mid-term and annual Operational Plan and other foreseeable workload, based on past experience. Resource needs are discussed at the FANC Management Team and submitted if appropriate to the board of directors. A formalized system describing the competences required for each position is currently been developed. An annual budget is foreseen for staff training and knowledge management needs. Training of staff consists of multiple and diverse external training courses as well as internal training. Currently this plan is not systematically based on the competence analysis for each position.* *At Bel V, the competence needs (both number of staff and required competencies) are annually evaluated and reported by the coordinator of each Technical Responsibility Centre (TRC). A systematic way of analysing the competences required for each position is not in place yet but the human resources*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
process is being adapted to include the IAEA SARCoN2 system in the evaluation of competences. The TRC (Technical Responsibilities Centres) Annual Reports, as well as the staff's Individual Development Plans, indicate training needs and a training plan is annually prepared. Currently this plan is not based on the systematic analysis of the competence needs for each position.	
(1)	**BASIS: GSR Part 1 para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of specific training"*
S8	**Suggestion: The regulatory body should consider finalizing and implementing the competence management system that is being developed and establish a formal and sustainable training programme based on it.**

4.4. PROCESS IMPLEMENTATION

The FANC core processes and related support processes have been identified by the FANC management team and were integrated into the existing quality system in 2008 by an external consultant. The 2012 review of the management system resulted in a new mapping of the management system and integrating governance documents, intention plans (strategy, operational objectives), and operational and support processes.

The interfaces between interacting FANC processes are identified and the process owner is responsible to verify the consistency of the process. For transversal operational processes, the responsibility for approving the procedures is with each senior manager in charge of the fields of activities concerned. In particular, for core business processes, a Managing Director is the owner of the process and has the responsibility to ensure that all parties concerned are involved in the development and approval of the procedure.

Documentation of the FANC management system is described in the documents PC001-01 and GD001-02. The core operational processes include licensing, inspections, incident and accident management, environmental surveillance, security, enforcement, development of regulations and guides, international relations, and projects and development. The core support processes relate to human and financial resource management, communication, ICT management, legal affairs, and record and information management. The process description for the management of organizational changes will be available by the end of 2013.

Bel V Quality Manual Chapter 4 identifies all core and support processes. QM level 2 includes all procedures and level 3 instructions and forms. Process examples include managing accounts and projects, performing conformity checks and inspections, and managing and developing human resources. Bel V has developed a process chart for its work processes with the interactions.

The responsibilities of different actors of the FANC management system can be found in PC001-01. Also Bel V has defined the roles of different actors.

The output records of FANC regulatory activities include licenses, recognitions, approvals and inspection reports. The procedure PC001-01 stipulates that each FANC procedure must contain a specific section where the requirements related to the records produced by the process are listed. Within the management system, a specific policy (GD005-02) describes the requirements related to the retention of records.

Bel V has set up an automated system for the generation of standard documents with unique numbering; templates are adapted to requirements that include the formal method of approval.

Electronic document management was described in Section 3.7.

The FANC has developed several means for internal communication documented in the policy on communication (GD004-02). At the level of the organization, there are monthly lunch time sessions, meetings, and electronic newsletters. At the level of the FANC sections, there are regular section meetings. External communication to the stakeholders is done, for example, via meetings, workshops, reports, and the FANC website.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

FANC process owners are in charge of the improvement of the process and their efficiency through periodic reviews (Key Performance Indicator (KPI) results, self-assessment, independent assessment, internal and external assessment and management review). The management review is performed annually. GD002-02 states that a systematic review of the process should be done at least every 2 years. Currently, the management review covers only quality aspects (audit results, corrective/preventive actions, non-conformities, complaints, customer satisfaction surveys) and not financial and operational aspects which are planned to be included in the future. See Suggestions S6 and S7 in previous sections.

There is a series of KPIs developed for the older version of the FANC management system. In the frame of the new management system, two quality documents (GD002-02 and PC002-02) establish rules and requirements to the definition of KPIs linked with the mid-term and short-term objectives of the operational plan.

At the Bel V, those responsible for a process perform measurements, evaluate the process and create a feedback report. The management review checks how each process works, evaluates the functioning of Bel V and identifies possible improvements. Bel V has recently developed its system of KPIs where different activities are given specific indicators and associated target values.

Since 2008 the FANC has a quality management system that conforms to ISO 9001:2008. The certification in 2008 was performed by an independent inspection body for certification, and was repeated in 2012. The FANC has recognised some improvement needs in the self-assessment of the management system and is considering an independent assessment. The FANC shows the commitment to conduct an IRRS missions every 10 years.

Bel V organises internal/external audits and bimonthly Quality System reviews. The results of the internal audits are reported to the process manager and to the steering committee (SC). The SC decides what actions should be taken and the responsibilities. Afterwards the actions are validated and their effectiveness checked. Once a year, an inspection body for certification conducts an external audit in conformance with ISO 9001:2008.

All FANC staff members have the duty to inform the Quality Assurance (QA) section of all non-conformities. It is the responsibility of the process owners to define the most adequate action to be undertaken. The section head or the department head is responsible to implement the solution and to inform the QA section. A process has been implemented to identify the situations presenting a potential risk of non-conformance in regulatory activities and processes (PC009-06). The status of the non-conformities are regularly monitored by the QA unit and discussed in the Management Review meeting.

Bel V also has procedures to handle non-conformities and corrective actions. Monitoring of non-conformities and corrective actions is included in the Bimonthly Quality System Reports submitted to the

Steering Committee, in the Management Representative's Reports, and in the Management Review Reports.

Opportunities for improvements of the Management System include the Management Review, non-conformances, customer complaints, customer satisfaction, training and exercises of the emergency response organizations.

The FANC reports on a quarterly basis to the Board of Directors. The quarterly report shows the progress of internal and external activities, and the financial budget. For standard activities, a set of key performance indicators (KPIs) is being used, e.g. the number of internal audits, and the number of license applications received. For non-standard activities, such as the evaluation of the yearly dose of the public, project specific KPI's are defined during a feasibility phase. These KPI's are reported in the 3 month intermediate reports, and the projects and their status are discussed every three months in the Project Management Board in order to set priorities and to adapt to large changes in the circumstances (such as Fukushima). The resulting status is reported in the quarterly report to the Board of Directors.

KPI's are derived from the overall objectives in the strategic plan and the yearly plan. The reference levels for the TELERAD KPI's are traceable to management decisions of 2008 and earlier. The quarterly report contains, in addition to the KPI's, a chapter on ad-hoc topics arranged per department.

Bel V has a similar approach of quarterly reporting to their Board of Directors.

At the FANC, a Management Review is conducted once a year. The Management Review covers only the quality aspects (results of internal/external quality audits, corrective/preventive actions, non-conformities, complaints, customer satisfaction surveys). The FANC has planned to integrate two other aspects into the management reviews: the financial aspect and the operational aspect. The financial aspect will be focused on resources, and the operational aspect will focus on the ability of the FANC to accomplish its objectives.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The FANC yearly Management Review covers the quality aspects of the Management System: results of internal/external quality audits, corrective/preventive actions, non-conformities, complaints, customer satisfaction surveys.* *The FANC has planned to expand the management reviews to include resources and the ability of the FANC to accomplish its objectives.*	
(1)	**BASIS: GS-R-3, Glossary states that** *"A Management Review is a regular and systematic evaluation by senior management of an organization of the suitability, adequacy, effectiveness and efficiency of its management system in executing the policies and achieving the goals and objectives of the organization".*
S9	**Suggestion: The regulatory body should consider including the financial and operational aspects in the Management Review, to ensure that the strategic objectives of the regulatory body are met.**

4.6. SUMMARY

The regulatory body in Belgium is composed by the FANC and Bel V. Several other actors do, even in a limited way, ensure regulatory tasks. It is recommended to include in the FANC management system a process that allows FANC to oversee and review the activities of Bel V and all other organizations

performing regulatory functions to ensure coherence and effectiveness of all regulatory functions, including those carried out by FANC, and to identify opportunities for improvements.

The Regulatory Body does not yet address safety culture for itself. The regulatory body, including Bel V and all other organizations performing regulatory functions, should develop and implement a common safety culture policy.

The recommendations and suggestions expressed in other modules such as 3.1, 3.6 and 12.1 should also be considered in the improvement of the management system

Both the FANC and Bel V have an established Action Plan to follow-up the self-assessments. The IRRS review team encourages the FANC and Bel V to fully and timely implement the Action Plan.

5. AUTHORIZATION

5.1. GENERIC ISSUES

According to article 16 of the FANC law of 15 April 1994 all facilities where radioactive materials or other radiation sources are present have to be authorized. Similar provisions exist for transport and medical activities. According to this law, the FANC is in charge of the investigation of the conditions necessary for safety.

In application of the FANC law, the royal decree of 20 July 2001 laying down the General Regulation on Radioprotection (GRR-2001) contains several provisions regarding the authorization of facilities and activities:

Article 3 of the GRR-2011 describes the categorization of facilities and activities into 4 classes according to their inherent risk:

- Class I facilities include nuclear reactors (both power reactors and research reactors), facilities where fissile materials are used or stored in quantities exceeding half of their minimum critical mass, spent fuel reprocessing facilities, and facilities for the collection, treatment, conditioning, storage or disposal of radioactive waste.
- Class II comprises the facilities where radioactive substances are produced from irradiated fissile materials and where they are packaged for sale, particle accelerators, facilities where any quantities (lower than in class I) of fissile substances are used or stored, facilities using X-ray equipment operated at a peak voltage higher than 200 kV and facilities where quantities of radioactive nuclides of which the total activity is larger than "class II values" are used or stored.
- Class III comprises the facilities where are used or held quantities of radioactive nuclides where the total activity ranges between the "exemption values" and "class II values", the facilities using X-ray equipment operated at a peak voltage of 200 kV or less.
- Class IV comprises the facilities using very low quantities of radioactive substances (i.e. below the exemption values) or using equipment emitting ionising radiation at a very low dose rate.

The facilities in which natural or depleted uranium and natural thorium are used or stored, are categorised in class IV providing the corresponding quantities are equal to or less than respectively 5 MBq and 50 kBq (otherwise they belong to class III). Mobile and/or temporary activities like gammagraphy and mobile X-ray equipment are also regarded as classified facilities as are the fixed facilities.

The licensing process is designed according to which class the facility/activity belongs to and therefore follows implicitly a graded approach. The FANC policy document GD010-04 defines the generic guidelines and basic principles for the licensing of facilities and activities.

Licenses are needed for constructing and operating facilities, for modifications of the facilities, for personnel, for dismantling of facilities and for the disposal, and recycling or re-use of radioactive waste. The process for applying for licenses, the involved authorities, the notification, publication and appeal procedures are also described per class of facilities.

Finally, the GRR-2001 contains provisions for the transfer of the construction and operating license and for the suspension and withdrawal of licenses.

Noting the concerns raised following the bankruptcy of Best-Medical, the regulatory body should undertake a review of the suitability of all applicants for new licenses and in the case of transfer of existing licenses. The attributes of the applicants to be considered for adequacy should include, inter alia,

the management system and safety culture programme; the resources and support for safety during operations; the provisions of resources for termination of operations, decommissioning and site rehabilitation or remediation; and the provisions for resources for waste management. A project to obtain the necessary change in the actual legal provisions is on-going.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Class I facility licence is issued by the King, after advice of the Scientific Council and class II and III facilities licenses are issued by FANC. According to GRR-2001, a class I licence transfer requires prior approval of FANC. A class II or III licence transfer requires prior notification to FANC, which has to acknowledge having received the notification. "Partial" transfer of a licence is also envisaged by the regulations. Whatever the facility class, no update of the licence, stating the new licensee name, is mandatory.* *In accordance with the procedure for licensing and acceptance of class II and III facilities, a partial transfer of a license is classified as administrative change of the facility, which leads to the delivery of a new license. In the new license the old license will be abrogated.*	
(1)	**BASIS: GSR Part 1 para. 2.14 states that** *"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. Responsibility for safety may be transferred to a different authorized party when there has been a declared change, approved by the regulatory body, of general responsibility for a facility or activity"*
R15	**Recommendation: The Government should update provisions so that a licence transfer is explicitly approved by the regulatory body after appropriate review.**

The regulatory body is not involved in the site selection phase for new nuclear facilities, but performs the site review and assessment when the application for a construction and operating license (for details please refer to chapter 5.2 and 5.3) is submitted.

For changes to the surroundings of an existing nuclear facility there is the need for the regulatory body to evaluate possible impacts of the changes on the nuclear facility (e.g. creation of new installations in the surroundings that would increase the risk of a particular accident on the nuclear facility). Practical examples of such changes have shown the benefit for the local, regional or state authorities authorizing the changes in the surroundings to coordinate with the regulatory body for the nuclear installation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory body is not formally involved before the decision for approving changes in the close surroundings of an existing nuclear facility is taken by the relevant authorities. The regulatory body has to evaluate how these changes may impact the safety of an existing nuclear facility.*	
(1)	**BASIS: GSR Part 1 requirement 23 states that** *"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."*
(2)	**BASIS: GSR Part 1 para. 4.29 states that** *"Different types of authorization shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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).”
(3)	**BASIS: GSR Part 1 para. 4.44 states that** *“Any proposed modification that might significantly affect the safety of a facility or activity shall be subject to a review and assessment by the regulatory body.”*
R16	**Recommendation: The government should update provisions so that the regulatory body is formally involved in the review and assessment of the impacts on the nuclear facility due to changes in its surroundings, before these changes are approved by the relevant authorities.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES

The operating nuclear power plants, the existing research reactors and some of the fuel cycle facilities were authorized before the creation of the FANC following a review and assessment methodology based on regulatory guidance from the country of origin of the installation.

Currently, licenses for class I facilities are granted by a royal decree signed by the King, but the entire licensing process is coordinated by the FANC. This coordination includes the review and assessment (for details see chapter 6) of a license application in collaboration with Bel V, ensuring the consultation of all relevant advisory bodies (including public consultation) and the drafting of the license decision. The class I licenses are granted for an indefinite time period, however the requirement to perform a periodic safety review (PSR) every 10 years is a standard license condition for all class I nuclear facilities and is now included in the royal decree of 30 November 2011 on the safety requirements for nuclear installations (SRNI-2011).

The licensing procedure for class I facilities is essentially a 2-step process: in a first step, a construction and operating license is granted which allows the licensee to start constructing its nuclear facility. In a second step the construction and operating license is confirmed by a royal decree which allows the licensee to start the nuclear operation of the facility. The major items in this 2-step process are as follows:

- Step 1: construction and operating license
  - submittal of the license application
  - review and assessment of the license application (including the preliminary safety analysis report and the environmental impact assessment report) by the regulatory body;
  - preliminary advice of the Scientific Council;
  - public inquiry, advice of the municipal authorities and of the provincial executives;
  - international Consultation (EURATOM treaty, neighbouring countries);
  - final advice of the Scientific Council;
  - final decision (royal decree).
- Step 2: Confirmation of construction and operating license (essentially a license for commissioning and start of operation)
  - commissioning report by Bel V;
  - royal decree to allow operation of the class I facility.

For procedural matters appeals are possible to the administrative court after the license is issued. In case of disagreement on technical matters the applicant can request a hearing by the Scientific Council during the licensing procedure.

It is interesting to note that the regulatory body is not involved in the decision of siting of new nuclear installations. The siting decision is made by the political authorities and does not require a prior safety assessment. The regulatory body has to evaluate the site-related aspects as part of the review of the construction and operating license application.

Regarding the design information that needs to be submitted, generic guidance is provided by GRR-2001, and more detailed guidance can be provided by the regulatory body during a pre-licensing procedure.

One of the conditions of the license is that the safety analysis report be kept up to date with any changes in the design or with operation conditions. Proper control of plant modifications is established including the requirement of prior approval by FANC of major modification applications (see also review and assessment in chapter 6).

Certification of personnel is the responsibility of the licensee, and experts of Bel V participate in the certification committee (with a practical veto power). The head of the licensee's Health Physics Department (responsible for radiation protection, nuclear safety and security) has to have a class I license issued by FANC after consultation with the Scientific Council. Other plant personnel involved in the Health Physics Department may also have a class I license. Manager qualifications are established in the safety analysis report.

The regulatory body has a specific role to play in the authorization process. The FANC is coordinating the overall process, as it receives the applicant's submittal and is tasked with putting together the advices of the various involved authorities (especially the Scientific Council and the local/regional authorities), but it also performs a safety review and assessment of the application in collaboration with Bel V.

The FANC activities of review and assessment of the license application are not explicitly foreseen in the GRR-2001; therefore FANC has started an internal review project aiming at defining improvements in the licensing process to be included in the legislative framework (specifically drafting a proposal for changes in Art. 6 of GRR-2001). Such improvements may include the explicit mentioning of the review and assessment activities of the regulatory body in the licensing process, the official introduction of the pre-licensing process (see below), the step-wise specification of the commissioning process with involvement of the Scientific Council, the explicit link to the PSAR requirements as contained in the SRNI-2011, the detailed specification of the contents of the license, and the extension and modernization of the means for public enquiry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The role of the regulatory body related to review and assessment of a license application in the authorization of class I facilities is not explicitly included in the GRR-2001 royal decree describing the licensing regime.* *As concerns the step of the confirmation of construction and operating license, it is presentation of the case in front of the Scientific Council, which is not explicitly foreseen in the GRR-2001 royal decree.*	
(1)	**BASIS: GSR Part 1 requirement 23 states that** *"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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	a notification process."
R17	**Recommendation: The government should explicitly include the regulatory body and its activities of review and assessment, including specifying the conditions necessary for safety, in the legal framework describing the licensing regime.**
S10	**Suggestion: The government should consider including the advice of the Scientific Council in the procedure for confirmation of the construction and operating license.**

For large projects aiming at the construction and operation of complex nuclear installations or relying on new technologies, FANC has established a so-called "pre-licensing" procedure. Although not required by law or decree, the pre-licensing phase is always initiated by the prospective applicant on a voluntary basis. It does not foresee the participation of other stakeholders than the applicant.

The modalities and objectives of the pre-licensing phase are described in detail in a FANC note of 2011 (2011-04-09-MSC-5-3-2-FR). The objectives of the pre-licensing phase are to inform the future applicant on the regulatory body's expectations such that no unexpected results or delays would appear during the licensing phase. For new technologies the pre-licensing phase also gives the regulatory body the possibility of acquiring the technical expertise needed for the evaluation of the application. At the end of pre-licensing the applicant should have reached a proper understanding of the expected safety, radiological protection and security argumentations that have to be developed and submitted during the licensing phase. A well-defined framework for future exchanges between the future applicant and the regulatory body would have been established. Further observations related to the identified need of issuing guidelines (including the pre-licensing phase), please refer to chapter 9 (see recommendation R23).

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Recognising that the current regulations contained in the general regulations of 2001 and the nuclear installation regulations of 2011 do not adequately address the staged licensing process applicable to a radioactive waste disposal facility, the FANC developed a revised authorisation process to be applied for disposal facilities. This was developed as a draft royal decree and is currently in the process of being approved. The process proposed foresees a number of distinct licensing stages including:

- review of the siting and design culminating in an initial construction and operation licence
- update of the construction and operation licence authorising emplacement of waste
- approval of closure of the facility following completion of the waste emplacement period
- period of surveillance and monitoring of the disposal facility after closure
- release of the site from regulatory control.

It is required that each licensing stage will be supported by an appropriate update of the safety case for the disposal facility. The IRRS team noted that while the revised authorisation process for disposal facilities was developed in the form of a draft regulation, this has not been formally approved and issued for implementation. Further observations related to the expediting and finalisation of draft regulations have been included in chapter 1.2 (see recommendation R2).

Further, consistent with the IAEA safety standards, the FANC has recognised that there are important interdependencies in various steps of waste management, in particular requirements on predisposal waste management that are influenced by the disposal option chosen. In this regard the FANC has included

requirements on the facility that will produce the disposal monoliths based on their initial findings from a review of the near surface disposal facility safety case.

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES

Medical facilities and practices

While the regulations define the categories of facilities into 4 classes (see Module 5.1), the FANC has established two further sub-categories for internal purposes, namely class IIA and IIB. Class IIA includes cyclotron facilities and class IIB includes among others radiotherapy and nuclear medicine facilities. Class III includes dental, veterinary and radiology practices.

Following the authorization of a new medical facility, the licensee must notify the FANC at least thirty calendar days in advance of the commencement of the practice. Furthermore, prior to the first clinical use of the radiation equipment, the FANC requires a commissioning report to be completed by the AIO which includes an acceptance report from health physics and medical radiation physics.

The AIO sends the commissioning report to the licensee and in the accompanying letter, they stipulate that the FANC has one week to comment on the report. In that period, the FANC reviews the report for quality and completeness. If there are any issues, the FANC corresponds with the licensee to follow up. If there are no issues, the facility licence is deemed operational for use however there is no written or verbal confirmation issued to the licensee by FANC.

In 2012 FANC began carrying out periodic checks to establish if there are any installations for which a commissioning report has not been received.

During the inspection witnessed by team members it was evident that a new piece of radiation equipment was in use by the facility however a commissioning report was not received by FANC. This would demonstrate a weakness in the authorisation process which should be reviewed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no formal process for confirming the authorisation of facilities in the medical sector prior to first clinical use following receipt of the reception report.* *There are an extensive number of licensees in the medical sector, which would require the mentioned confirmation prior to first clinical use. This would require a significant administrative burden on the regulatory body.*	
(1)	**BASIS: GSR Part 1 para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: CoC 21 (b) states that** *"Every State should ensure that its regulatory body: …* *(b) has the financial resources and the facilities and equipment necessary to undertake its functions in an effective manner;"*
S11	**Suggestion: The regulatory body should consider introducing a formal documented process for confirming the authorisation of facilities in the medical sector following the**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	commissioning process.

Other radiation sources facilities

The regulator has established strong outreach to sorting centres, container parks, landfills, waste incinerators and scrap metal facilities to encourage the detection and recovery of orphan sources. All facilities have to meet minimal requirements (training, vigilance procedures). They have received training by the FANC to recognize common items that could typically house an orphan radioactive source. Some facilities have to install a portal detection system (landfills, waste incinerators and scrap metal facilities with an annual turnover more than 25,000 ton). If such radioactive sources are found in these facilities, an intervention can be done by appropriately trained personnel, unless measured dose rates exceeds some limits. The FANC will allow the facility to temporarily store the source in question, along with providing radiation protection and security tips on how to store the source. After a few months of storage, the site will be subject to a control from an AIO. These controllers will then prepare the source for shipment, and ensure that it gets shipped by ONDRAF/NIRAS. The entire cost of disposal for orphan sources is covered by an insolvability fund. In addition to these measures, seaports are equipped with portal monitors that can detect radiation in incoming shipments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC has engaged in outreach, education and has provided financial means to parties involved to assist in the detection and recovery of orphan sources*	
(1)	**BASIS: CoC 22 (o)states that** *"Every State should ensure that its regulatory body is prepared, or has established provisions, to recover and restore appropriate control over orphan sources"*
GP2	**Good practice: FANC has been proactive in ensuring those likely to encounter orphan sources are educated and assisted both legally and financially to ensure the safe detection, storage and recovery of orphan sources.**

For authorization of class II and III facilities, a licence application is received, and its contents are scanned electronically. Each step in the review process, from administrative information to technical assessments, is carefully tracked in the software database, allowing anyone to see exactly who is responsible for each section to be reviewed, and whether or not the review has been completed. This diligent tracking of the entire process allows the regulator to be fairly responsive to any internal delays, and ensures all persons involved are aware of when an authorization request has been received. Source transfers, imports and exports are not included in this database.

Some aspects of sealed radioactive source regulation, such as exports of sources are managed by the regional governments. The export license of radioactive sources is only requested in Belgium according to the Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of export, transfer, brokering and transit of dual-use items. The 3 Belgian regions (Flemish, Walloon and Brussels-Capital) are responsible for delivering the license of export of dual-use items after taking advice of an Advisory Committee composed of representatives of regional and federal authorities including the FANC. There does not appear to be proper sealed source tracking when the transfer is an export.

Source transfers within Belgium or imports of sources to Belgium, despite going through an internal authorization process, do not generate an automatic notification entry into the high active sealed source tracking database. Rather, a separate notification ("life course sheet") from a licensee to the FANC is required for the change to be made. This second notification, in addition to the transfer authorization requirement, is not always performed by some licensees, and has resulted in at least one case of a category I source being transferred without any notification being generated. Given that the recipient of the source is also required to provide notification of receipt, any transfer should always generate a notification from the shipper and receiver. This double notification provides a redundancy in the process. However, if a source is being sent to ONDRAF/NIRAS for disposal, ONDRAF/NIRAS is not required to notify FANC of receipt of the source given that it is considered a disposal, and not an active inventory source. Thus, when sources are sent for disposal, redundancy in notifications is lost, greatly weakening the sealed source tracking process.

FANC has recently upgraded its software for category I and II sealed source tracking. It is now in the form of an elaborate Excel worksheet. The tracking system captures many details about an individual source, and is updated by way of notifications of sources transfer from licensees. The worksheet has some weaknesses in preventing accidental modifications to the data, and there are concerns as to how backups are generated and protected.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are some deficiencies in the internal communication and tracking of sealed sources, namely:* *Transfer authorizations granted by FANC are not communicated to the high activity sealed source tracking group. In absence of this information, sealed source tracking is entirely dependent on the licensee providing a second notification confirming the transfer has taken place.* *If a high activity sealed source is transferred to ONDRAF/NIRAS for disposal, ONDRAF/NIRAS is not required to notify the sealed source tracking group within FANC about the receipt of such a source. In these cases, correct tracking of a given sealed source rests entirely on the correct notification of the shipper to FANC.* *In terms of security and error proofing of the worksheet, it should be noted that data can be inadvertently erased or modified without such errors being readily evident, which could lead to information losses.*	
(1)	**BASIS: CoC 22 (g) states that:** *"Every State should ensure that its regulatory body establishes systems for ensuring that, where practical, radioactive sources are identifiable, and traceable, or where this is not practicable, ensures that alternative processes for identifying and tracing those sources are in place."*
R18	**Recommendation: The regulatory body should increase the robustness in the sealed source tracking process and traceability of sources. More specifically, the following points of improvements are recommended:** **a) Increase reporting requirements to ensure sources cannot get transferred without a notification being made in the sealed source tracking system.** **b) Harmonize the tracking and reporting requirements to ensure sealed source transfer notifications are generated, both by the sender and recipient, regardless of the destination or purpose of the transfer including shipments for disposal.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	c) Transfer authorizations should also be internally communicated to those tracking sealed sources. **d) Implement additional measures to protect the Sealed Source Tracking Database file and its software back-ups from accidental over-writes, deletions or edits. Creating automated records of any changes made to the database itself would also be very helpful.**

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The FANC has undertaken a review of the regulatory framework on decommissioning to implement the WENRA SRLs for decommissioning into the Belgium regulatory framework. In this regard, new regulations have been drafted but are not yet approved.

Currently, the FANC does not review the initial decommissioning plan and its regular updates. This activity is undertaken by ONDRAF/NIRAS. Further, the license application for decommissioning/dismantling includes parts of the final decommissioning plan and not the entire document. The IRRS team also found that it is unclear how the decommissioning plan will be updated should the regulatory body require changes in the decommissioning strategy as part of the license approval. Compliance with the requirements of the IAEA safety standards should be further developed. The regulatory body should in particular be able to ensure consistency of the final decommissioning plan with the requirements of the decommissioning license.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *It was not evident that all the responsibilities as per WS-R-5 para. 3.6 have been discharged by FANC, in particular:* *i. the regulatory body does not specifically review and approve the initial and final decommissioning plans. The task has been assigned by law to ONDRAF/NIRAS.*	
(1)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include:* *- Reviewing the initial decommissioning plan and reviewing and approving the final decommissioning plan before allowing decommissioning activities to be commenced;*
R19	**Recommendation: The regulatory body should:** **a) review the safety related aspects of the initial decommissioning plan and its regular updates** **b) review and approve the safety related aspects of the final decommissioning plan.**

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

Belgium has established the following legislation pertaining amongst others to the safe transport of radioactive material:

- Law of 15 April 1994 and the implementation of this law in:
- Royal decree of 20 July 2001 (GRR-2001)

Articles 3 and 18 of the Law of 15 April 1994 stipulate the responsibility of the FANC for the transport of radioactive material.

Article 57 of GRR-2001 requires that transport activities shall comply with the provisions laid down in international modal agreements and regulations governing the carriage of dangerous materials and that these may only be performed subject to a preliminary license. Since these modal agreements are transpositions of the IAEA transport regulations for each mode of transport (air, sea, road railway and inland waterways), it can be concluded that all provisions in TS-R-1 Regulations for the Safe Transport of Radioactive Material are addressed in the authorization process (e.g. shipment, special arrangement, package design, radioactive material in special form).

During the interview with transport experts from the Belgian counterpart on this issue it was mentioned that a revision of Chapter VII of GRR-2001 is under planning. The revision would entail a simplification of the authorization process for low-risk radioactive materials. Since it has not yet been decided how this can be done in the most effective manner, all options are kept open, but an exemption from the licensing requirement is no longer excluded. The planned revision of Chapter VII of GRR-2001 aims at establishing and/or improving the graded approach in all regulatory areas and for all modes of transport. Simultaneously there is a trend to make a transition from a repressive approach in the regulation towards a preventive approach. This implies that in transport activities more emphasis is placed on registration of carriers on one hand, and to focus more on inspections and compliance audits. The FANC intends to perform a consultation with its stakeholders on the proposed revision at several phases during the revision process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The above formulation in article 57 of GRR-2001 does not permit to deviate from the general requirement of a license for a transport activity. Variations exist in the type of license (general, specific or special), depending on the frequency of shipments and on the activity of the material. In all cases, irrespective of the source strength, a license procedure must be undertaken.* *It is questionable whether this is in compliance with the graded approach demanded in article 1 of GSR Part 1 and with FANC's own policy regarding a graded approach, which is adopted in many other areas.*	
(1)	**BASIS: GSR Part 1 para 4.33 states that** *"Prior to the granting of an authorization the applicant shall be required to submit a safety assessment …the extent of regulatory control applied shall be commensurate with the radiation risks…"*
S12	**Suggestion: The regulatory body should consider the introduction of a system in which a notification procedure for transports of low risk radioactive material would replace the present licensing requirement.**

5.7. SUMMARY

Although Belgium has decided not to build any more nuclear power plants, an authorization process is well established for approving modifications to the existing plants and for construction as well as operation of other facilities, such as new research reactors and waste disposal facilities. The IRRS Team considers that an area where improvements should be implemented is related to the approval of changes in the surroundings of an existing nuclear site: an evaluation of the impact of the changes on the nuclear facilities should be performed by the regulatory body before approval for those changes is granted by the relevant authorities.

A revision of the royal decree of 20 July 2001 (GRR-2001) to explicitly describe the role of the FANC and Bel V in the authorization process will provide a further optimization for the existing situation.

The adoption of a pre-licensing approach may compensate for the lack of a comprehensive system of guides related to detailed design requirements, especially for complex installations using new technologies, such as the MYRRHA research reactor and the waste disposal facility under examination for which the applicant has limited previous licensing experience.

A revised authorisation procedure for waste management facilities has been developed by the FANC but has not been approved for implementation. Expediting the finalisation of draft regulations is an area of improvement which is more generally addressed in Chapter 1.

Within the medical sector consideration should be given to formalising the process of confirming the final authorisation of facilities prior to first clinical use following commissioning testing of the radiation equipment.

The FANC's outreach to stakeholders regarding the search and retrieval for orphan sources is proactive and commendable. In terms of sealed source tracking of in-use sources, several areas which are not in compliance with IAEA requirements were noted for improvement in the overall tracking process. Many of these problems are recognized internally by the regulatory body but have yet to be corrected. More effort should be dedicated to resolve the issues.

As concerns the authorization of decommissioning activities, the FANC should review and approve the safety related aspects of the decommissioning plans.

The planned revision of the royal decree of 20 July 2001 related to transport would result in a simplification of the authorization process for transport with a shift of emphasis from licensing to registration and inspection. The IRRS team suggests that the revision be implemented with the necessary emphasis.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Review and assessment is a necessary function of the regulatory body and is carried out mainly during the authorization process and for plant modifications. Further safety reviews are linked to PSRs and reactive actions in case of non-conformity notifications or are triggered by findings during inspections. The depth of the review of the related documentation depends on the class of the facility or activity, as established in GRR-2001, and follows the application of the graded approach principle.

Within the regulatory body most of the review and assessment for the nuclear power plants, the fuel cycle facilities and the research reactors is performed by Bel V. It was noted however that review and assessment of the new licence application for the proposed near surface disposal facility is undertaken primarily by the FANC with input by Bel V.

Recently an optimization review by the FANC and Bel V has started with the goal of fostering a common understanding of the respective roles in the area of review and assessment. An opportunity for improvements was identified in the coordination between FANC and Bel V; the adopted countermeasures are documented in the draft FANC/Bel V note 2013-11-10-FD-5-4-012-EN "Review and assessment – Process for work requests by FANC to Bel V".

The types of documents subject to review and assessment are very diverse. Some documents are related to inspection activities (submittals for modifications of the installations, justifications for continued operation, operational events to be analysed, etc.). Other documents are related to projects, such as periodic safety reviews (PSR), the Stress Tests analyses, and additional important projects such as steam generator replacements (sometimes linked to a request for power increase). Further submittals are related to licensing of new installations or dismantling activities.

Operating experience feedback

For class I and IIa facilities, for which Bel V performs regulatory surveillance as requested by the FANC, Bel V has a formal process to review operating experience feedback (OEF), select the ones warranting an in-depth analysis or notify the relevant authorized parties with requests for action if needed. Results provide for quarterly summary operating experience feedback review reports as well as an annual domestic operating experience review report. The FANC recently formalized its process to manage OEF, which relies largely on Bel V work. OEF is also used as an input in the inspection planning process.

Within the frame of continuous improvement Bel V has identified at the beginning of 2013 areas for improvement in its operating experience programme and proceeded to implement solutions. Therefore it has introduced an internal committee for work coordination, updated the Bel V note Q070300-01-00-p-org-e on managing OEF and extended the procedure for dissemination of OEF to the licensee (e.g. with the use of operating experience examination request letters and operating experience information letters). Improvements in the coordination of work with the FANC have also been put into place, copying to the FANC the quarterly reports issued by Bel V on OEF and the inspection reports documenting the meetings with the licensees on this subject. Proposals for a modification for the FANC guidance related to the notification criteria are being discussed. In particular the time frame and exact content of the event reports produced by the licensee need to be more precisely specified.

For class IIb and III industrial facilities and activities as well as for transport of radioactive material, the FANC carries out its OEF activities. The IRRS team was provided with examples of letters sent to relevant authorized parties following up on foreign and domestic operating experience. The FANC

recently formalized its process to manage OEF on class IIb and III industrial facilities and activities. This process covers both domestic and international OEF (gathering and disseminating), actions towards the authorized parties and other stakeholders (including authorized inspection organizations) and potential improvements to the Belgian regulatory framework.

Compared to the procedures for OEF in class I and IIa, as well as in class IIb and III industrial facilities, the FANC is using a less structured approach to analyse and disseminate domestic and international operating experience from medical and transport activities. The FANC recognized that OEF inputs, process and goals are not documented in detail in its management system for transport activities and for medical activities and facilities.

The regulatory body is aware of the importance of evaluating OEF and will pursue the planned improvements with the necessary emphasis.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS, RESEARCH REACTORS and FUEL CYCLE FACILITIES

6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The review and assessment activities of Bel V are regulated by the process A06 ("Deliver expert services in nuclear safety and radiation protection") of the Bel V management system. Close interfaces exist with the processes A02 ("Managing projects") and A04 ("Conducting control during operation"), because a large majority of the requests for review and assessment activities are coming from the Processes A02 and A04. A formal step of second verification (documented via a second signature) in the evaluations provides the necessary quality control. The processes are fully documented.

The assessment and approval process for modifications is carried out in accordance with the impact of the modification on the safety of the facility. Following Art. 12 of the GRR-2001, the regulatory body has to be notified of every modification or extension of the installation and has to decide whether a new license is necessary or not. A FANC note (006-029 herz/rév.2), with the objective of assuring consistency in decision making, details the criteria for categorizing the modifications in:

- Important modifications which require a change of the license;
- Non-important modifications which do not require a change of the license but need formal approval by Bel V;
- Minor modifications which need only to be notified to the regulatory body.

Coordination meetings with the FANC, Bel V and the licensees take place regularly to discuss running and upcoming projects, especially with regards to their categorization of modifications. The Bel V inspectors get regular notifications from the licensee and consult with the FANC in case of doubt as to which category applies for a particular modification.

The bulk of modifications where regulatory approval is required falls under the category of non-important modifications and Bel V has initiated an effort to apply a graded approach in review and assessment for this category of modifications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *Within the group of "non-important modifications" as defined in the FANC note 006-029 there are practical attempts to apply a graded approach for class I facilities which need to be formalized in an official document.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach"*
(2)	**BASIS: GSR Part 1 para. 4.40 states that** *"The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 para. 4.28 states that** *"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."*
R20	**Recommendation: The regulatory body should review its guidance to perform review and assessment of "non-important modifications" of class I facilities in order to clearly identify the criteria for a graded approach.**

As regards periodic safety reviews (PSR) these were required from the beginning as a licensing condition for nuclear facilities and further demanded with the issuance of the SRNI-2011 for all class I facilities. The regulatory body has correspondingly a long experience in review and assessment of PSRs which was described in the FANC note 2010-095 (recently revised in 2013) setting down the process of such reviews. It applies to all class I facilities including those whose dismantling lasts sufficiently long (i.e. 10 years after the most recent PSR). The process is divided into three phases and is based in content on the IAEA Safety Guide NS-G-2.10, now SSG-25. The licensee can propose a limitation in the scope of the analysis to be performed based on a graded approach principle. Such limitation always has to be approved by the regulatory body. The follow-up of the PSR results and actions to be taken by the licensee is established with the third phase of the process, the implementation phase.

It can be concluded that the regulatory body has established legal provisions and regulatory guidance to perform review and assessment of the safety of class I facilities over the lifetime of the facility, including dismantling activities, within comprehensive programmes for periodic safety reviews based on SSG-25.

6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The main effort related to review and assessment for nuclear installations is performed by Bel V staff, mainly the members of the NRA (Nuclear Safety and Radiation Protection Assessment) Department and the NRP (Nuclear Safety and Radiation Protection Projects) Department.

Besides the hierarchical structure, Bel V has a transversal structure organized in Technical Responsibility Centres (TRCs). These TRCs were created in the 1990s, with the objective to use the staff based on their specific competence as effectively as possible independently from hierarchical affiliation. About 20 TRCs are operating. The goal is to involve all people having expertise in a technical domain in review and

assessment work for that domain, wherever the staff member is positioned in the Bel V organization chart. Also staff members of the FANC may be integrated into a TRC. External experts can also be hired to work with the TRCs.

Concerning the use of advisory bodies/committees, the role of the Scientific Council of the FANC is to be mentioned. This Scientific Council is involved during the licensing process for new installations or dismantling projects and certification of class I experts, and is also informed on the progress and final results of the PSR for the class I facilities.

Following the assessment process in the management system of Bel V, the needs for training and further education are identified in order to ensure that the necessary competencies are available. Each year a provisional training programme (with internal as well as external training activities) is set up. The training programme is coordinated by a Technical Training Manager whose function is defined within the Bel V management system.

6.2.3. BASES FOR REVIEW AND ASSESSMENT

A list of documents to be submitted by the applicant is defined in GRR-2001 for class I facilities. As a part of this, the general content of the initial safety analysis report is defined. The FANC verifies the acceptability and completeness of the application documents, while the safety analysis report and associated technical documents are mainly reviewed by Bel V.

For NPPs, the principles and criteria are mainly based on the Regulatory Guides from the USNRC, but also the design and operational safety principles as described in the SRNI-2011 are applicable.

For projects with a specific/innovative character which are presently in a pre-licensing phase (see module 5 - Authorization) an important effort is put into discussing with the future applicant the basis for the design and the subsequent review and assessment, including the needed scope and level of detail of the safety demonstration to be provided.

6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT

The scope of the review during the initial licensing process is based on the prescribed content of the safety analysis report. For nuclear power plants the USNRC Regulatory Guide 1.70 was followed. For other class I facilities adaptation was done as necessary. For waste disposal facilities, the long-term safety assessment is also verified.

The assessment by Bel V includes verification of fulfilment of regulations, comparison with similar facilities and performance of independent calculation (with independent tools and models or with the same tools as the licensee). Both deterministic and probabilistic methods are used.

Previous assessments of PSRs were based on IAEA NS-G-2.10 where the following safety factors are reviewed: plant design; actual condition of SSCs (systems, structures and structures); equipment qualification; ageing; deterministic safety analysis; probabilistic safety analysis; hazard analysis; safety performance; experience feedback; organization and administration; procedures; human factors; emergency planning; radiological impact on the environment. The new IAEA SSG-25 guidance has been adopted for future reviews.

Because of a decision of the government that the operation of Doel 1 and 2 NPPs will be limited to 40 years, the licensee has started a new project concerning the end of power operation of Doel 1 and 2 (2015) and the subsequent phases (shutdown of each unit, fuel removal from reactors, fuel removal from spent fuel pools, dismantling). Bel V is performing review and assessment of files submitted by the licensee with respect to this new situation.

Review and assessment activities related to long term operation (LTO) of the NPPs started some years ago with the objective of taking up the issue in the fourth PSR for the Belgian class I facilities. The FANC and Bel V together published a strategy note (Note 008-194, rev.2) on LTO describing the scope and depth of the required submission. Meanwhile, review has been performed on the licensee's submissions concerning design upgrades and ageing.

As a further example of review and assessment activities in a large scale project, the Belgian regulatory body reviewed the licensees' report of the European Stress Tests performed for all class I facilities (e.g. NPPs, research reactors and fuel management facilities). Compared to the ENSREG specifications for the stress test, an extension of scope was applied for the Belgian facilities to man-made events, namely aircraft crash, toxic and explosive gases and blast waves, and external attacks on computer based controls and systems. The review and assessment conducted by the regulatory body led to the identification of further analysis needs, but also to concrete hardware back-fitting actions. All actions are included in an action plan for follow-up by the regulatory body, who also reports internationally to the ENSREG peers and within the frame of the international obligations linked to the IAEA Conventions. The IRRS Team, recognizing the ambitious scope and scheduling of the actions included in the action plan, underlines that emphasis and prioritization by the regulatory body can be very instrumental to adequate implementation of the actions.

6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The review and assessment process followed for waste management facilities is generally consistent with what is followed for other class I facilities (see section 6.2 above). It was noted however that review and assessment of the new licence application for the proposed near surface disposal facility is undertaken primarily by the FANC with input by Bel V. Recommendations relating to the allocation of responsibilities between the various organisations involved in the regulation of nuclear facilities are covered in Chapter 1.

FANC had initiated a pre-licensing process in support of the anticipated licence application for the near surface disposal facility. As part of this process the FANC developed a number of guides that were intended to assist the applicant with the development of the required safety case in support of the license application. The FANC developed a set of regulatory evaluation criteria to be used as part of the regulatory review of the individual chapters of the safety case documentation.

6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

Medical facilities and practices

The FANC performs review and assessment mainly during the licensing process of facilities within the medical sector, where the licensing process for the different practices is the same. However the level of review is carried out according to the practice and the associated risks, which is linked to the information that has to be provided by the applicants demonstrating the safety arrangements in place. In practice more time and resources are allocated for reviewing the more complex facilities, for example radiotherapy and nuclear medicine applications. The FANC reviews the submitted documentation, which has also been reviewed and signed off by the AIO, and once satisfied of the safe operation of the practice a facilities license is issued. Documentation relating to applications for individual licensing of radiologists and other relevant clinicians incorporates a review of the submitted training and activity record. The results and decisions of reviews are held with the licensee file.

Other radiation sources facilities

The review and assessment of Category 1, 2 and 3 source facilities at the onset is an in-depth process of evaluating the radiation protection programme, the site suitability and licensee competence for receiving an authorization. Of note, is that for all applicants seeking to obtain their first authorization, the community within a given radius of the intended facility is notified of the license. A public hearing is held prior to issuing any authorization for class I and some class II facilities. This also applies to medical facilities.

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The review and assessment process for authorization of decommissioning for nuclear facilities of class I is generally consistent with what is described in section 6.2 above.

Up to now, the initial and final decommissioning plans are submitted to ONDRAF/NIRAS for review and acceptance. The review performed by ONDRAF/NIRAS is not a comprehensive review of the expected content of the decommissioning plans. ONDRAF/NIRAS provides the licensee with an advice on the decommissioning plans. The primary aim of this advice is to verify that:

- the dismantling techniques foreseen are well established,
- the wastes generated by dismantling actions are well defined and have elimination routes,
- the estimation of the cost of dismantling activities and waste management has been properly addressed.

The FANC does not currently undertake an in-depth review of the decommissioning plan. The IRRS team noted that with the current arrangements there is confusion regarding the roles of ONDRAF/NIRAS and the regulatory body. Recommendations regarding clarification of roles have been made under chapter 1 of this report and recommendations regarding the authorisation and review process are included in section 5.5.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Since the safety during transport of radioactive material is primarily ensured by the design of the package, review and assessment of applications for transport licenses is mainly achieved by reviewing and assessing the technical aspects of a package and the source specifications such as special form material or low dispersible material. These design aspects include issues such as mechanical properties, thermodynamics, criticality, radiation protection etc. Many foreign designs are submitted to the FANC for certification or validation and require to be assessed by the regulatory body.

A document promoted on the FANC website (PDSR Guide, http://www.fanc.fgov.be/GED/00000000/2600/2632.pdf) is meant to assist both the applicant and the FANC reviewer. It contains unique information on the licensing process and the requirements for a successful application. It enables the applicant to check which documents in support of his application are expected by the regulatory authority. At the same time the reviewer/assessor at the FANC could trust that the information supplied is complete. This would usually prevent or diminish the administrative burden to request additional information. The document includes many references to applicable paragraphs in IAEA Safety Guide No.TS-G-1.1 in the case that more detailed guidance on technical elements is necessary.

6.7. SUMMARY

Review and assessment for class I facilities is mostly performed by Bel V, while the FANC intervenes when review and assessment are related to changes of the license. Very recent improvements in the

coordination and definition of roles between FANC and Bel V will be further formalised and documented in the respective management systems.

The type of documents subject to review and assessment is very diverse in scope and content and the regulatory body applies a graded approach which it is recommended for further optimization with the definition of suitable criteria.

Belgium has a long tradition with periodic safety reviews for all class I facilities and covering all lifetime phases including dismantling as an application of a graded approach. As some of these facilities are approaching forty years of operation, the issues related to long term operation (mechanical as well as design ageing) have been taken up within the periodic safety reviews.

The review and assessment process for evaluating the suitability of radiation source facilities has been examined and found to be adequate.

The safety assessment of certain models of transport packages, required for certification and validation of these packages, is reviewed and assessed by the FANC. In order to assist both the regulatory body and the applicant of a license for a specific package design, the FANC has placed a guidance document with detailed information on its website with drawings specifications, calculations and other supporting documents for all types of packages.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

The regulatory body has developed and implemented a programme for the inspection of related facilities. This programme includes the definition of a 3-year strategy for class I facilities (so called "GIC"). The strategy is used to design an annual plan for the inspection of all class I facilities. The annual plan is then delivered by a qualified team of regulatory staff including inspectors and nuclear inspectors. Inspections are either announced or unannounced, and in a category of proactive or reactive as a function of established criteria and circumstances.

The graded approach to inspections takes into account the nuclear and radiological risk as evidenced in the strategy developed.

The regulator body (the FANC and Bel V) has a clear delineation of inspection functions; sharing of information, inspection functions and results is appropriate between the organizations; no appearance of redundancy or lack of efficiency or effectiveness could be detected in the working relations.

Inspection methods are typical of those expected at regulatory bodies; they include documentation review, events review, interviews and field visits, and the monitoring and sampling of activities or parameters.

The team finds it useful to describe the term "inspection programme". For the IAEA, the inspection programme consists of a complete list of compliance verification activities, specific and detailed acceptance criteria, with frequency of delivery of the activity. The programme can also be risk informed. More specifically for the FANC and Bel V the programme is above this "GIC".

The inspection programme for class I facilities is considered by the team to be too general, in terms of depth of review. While high level thematic inspections subjects are described, the level of description of the inspection procedures is insufficient to assure that all inspectors will perform harmonized inspections and will gain a complete picture of all aspects of the inspected area. The Regulatory Body has not developed inspection criteria or specific guide sheets (checklists) that would normally define detailed acceptance criteria for the element being inspected. The team was told that this practice is acceptable to the regulatory body; discussions with management of Bel V reveal that this practice is adequate as it prevents the inspector from blindly delivering an automatic eyes closed tick box verification of specific conditions; a second reason given is that the inspectors are well trained and carry around knowledge of technical specifications, therefore the FANC and Bel V do not believe that they need descriptive work instructions.

There is no evidence to suggest that the regulatory body has taken action to validate the scope of its mandate. The programme currently covering the class I facilities reviews processes and structures, systems and components in a risk-based manner. However the regulatory body does not verify specifically or systematically plant systems, system elements and components for critical functions such as reactor trip, standby systems or containment isolation. Such a review might also uncover areas not inspected, in their mandate, such as shift turnover. The inspection programme does not explicitly specify basic frequency requirements as it should.

The regulatory framework clearly indicates the areas of responsibility of the regulatory body; however, these areas do not cover all elements which form part of the safety-security envelope. Therefore, other governmental organizations share functions (with or without Memorandum of Understanding), in emergency preparedness, fire protection, radioactive waste, pressure boundary, and conventional health

and safety. However, the regulatory body does not share information directly with the organizations responsible. For example, the regulatory body, while delivering inspections, might identify obvious findings that are not within its area of competence, and report directly to the licensee without feedback about the corrective actions, and without capacity for enforcement.

Joint inspections, or scheduled programmed meetings with other governmental organizations, are exceptional instead of being the norm. There are no interfaces with other governmental organizations sharing elements of safety. Through Bel V, the regulatory body maintains a continuous relationship with class I licensees and a good knowledge of the status of open action items; inspections in the field are followed at site by activities of coordination with the licensee's HPD and regular integration of results. Regularly during inspection closure meetings, a summary of reviews and authorizations are shared with the licensee.

The licensees recognize the independence of the regulatory function while performing inspections, and emphasize that the regulatory body does not substitute for the licensee in this function.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For class I facilities, since there is no baseline frequency consideration on delivering inspections, the Regulatory Body cannot demonstrate with its annual, middle term and long term Inspection Plans, that its inspection programme covers all area of the mandate of GDO10-02 governance document. The inspection programme does not include specific verification of systems and components availabilities and transitions of states. Examples include also reactor shift personnel turnovers and considerations to counterfeit components.* *Some high level inspection criteria exist, however there is no detailed guidance to carry out more targeted inspections with appropriate acceptance criteria.*	
(1)	**BASIS: GSR Part 1 Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 para 4.52. states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 Requirement 32 states that** *"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."*
(4)	**BASIS: GSR Part 1 para 4.62. states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	associated with the facilities and activities, in accordance with a graded approach."
R21	**Recommendation: The regulatory body should review the scope of its inspection programme to ensure that it is comprehensive and covers all areas relevant to safety and includes appropriate acceptance criteria**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The inspection programme may appear to take into account the radiological risk and apply a graded approach. However, the programme does not stipulate the frequency of inspections in accordance with the risks associated with facilities and activities in some areas such as, radiation sources and facilities in the medical sector. There is an exception for transport activity.*	
(1)	**BASIS: GSR Part 1 para. 4.50 states that** *"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. 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."*
R22	**Recommendation: The regulatory body should ensure the inspection programme considers radiological risk and specifies the frequency by which facilities are inspected, in accordance with a graded approach for radiation sources and facilities in the medical sector (classes IIb and III).**

7.1.2. INSPECTION PROCESSES AND PRACTICES

Inspectors benefit from guidelines and procedures that define their work.

Observations of inspections show effectiveness and a few areas for improvement:

- The inspection reports should be clear as to who makes a statement, based on what information
- Some inspection facts should be collected
- The inspector should be able to take videos or pictures to support as evidence for efficiency purposes.

Reporting the results of inspection is done in acceptable ways including oral reporting at closure meetings at the termination of the inspection followed by inspection reports sent to the licensee.

Recording of the complete inspection file is very efficient and the team witnessed efficient retrieval by the regulatory body staff.

Corrective actions are clearly identified in reports, and meticulously followed through closure in letters and references as well as meetings. Overall results and ad hoc trending is used at the regulatory body to define the following strategy and possible fleet wide inspection scopes for the future.

For class I facilities the current content of inspection reports tends to be a long list of issues, descriptions of follow up of old items and current findings in the field. While this content allows a reader to capture a

global picture on themes, the separation of functions of authorization, review, licensee intentions, and compliance verification seems non-uniform. Inspection reports also contain information given by the licensee and other parties. In that case, it may be difficult to know the origin of the statement and to know if this information has been verified independently by the inspector.

The regulatory body should review their inspection training to ensure that authors of inspection reports clearly delineate between statements made by the regulatory body versus those made by the licensee or reported by other parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Currently there are no regulatory requirements concerning the safety culture programmes of the licensees (see Sect. 9.1), so the topic is not included formally in the inspection programme. However, the regulatory body has developed an expectation on inspectors to target safety culture observations in the delivery of their activities. This is considered a difficult area to enforce, since the criteria can be subjective. The regulatory body has developed tools that enable capture of observations of safety culture, during its oversight activities. The regulatory body has trained its inspectors in its use, and has developed an analysis process based on the data collected.*	
(1)	**BASIS: GSR Part 1 para 4.53. states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *—Structures, systems, components and materials important to safety;* *—Management systems;* *—Operational activities and procedures;* *—Records of operational activities and results of monitoring;* *—Liaison with contractors and other service providers;* *—Competence of staff;* *—Safety culture;* *—Liaison with the relevant organization for joint inspections, where necessary."*
GP3	**Good practice: The regulatory body has developed a methodology and training for the inspection of class I and class IIa facilities to capture, analyse and report observations of safety culture.**

7.1.3. INSPECTORS

The decree 20/07/01, governance document GD010-03 and practice properly frame the functions, powers and responsibilities of the FANC inspectors. The practice shows that there are two different categories of staff performing compliance verification inspections. Nuclear inspectors carry full authority for enforcement and administrative policing. Despite the existence of the decree and governance, the team was made aware that Bel V inspectors cannot collect evidence in the delivery of administrative compliance verification activities.

For class I facilities, a Ministerial Order published in April 2008 established the list of nuclear inspectors "*Arrêté ministériel du 14 avril 2008 fixant la liste nominative actualisée des inspecteurs nucléaires*". This ministerial order implements a list of 23 inspectors which superseded the previous ministerial order issued in 2005. Since 2008, the list of inspectors has not been updated to take into account the turnover of the FANC employees. Since 2008, 30% of the FANC nuclear inspectors have left the Agency. From the remaining nuclear inspectors, 9 inspectors are still in charge of nuclear inspections. Up to now, for the

waste management section, only one inspector has the status of nuclear inspector. For the section on "Nuclear Facilities", six inspectors perform inspections but no one has the status of nuclear inspector. According to the Belgium legal and regulatory framework, only nuclear inspectors have enforcement power.

The FANC has not updated the list of employees in charge of inspections and submitted it to the government for endorsement as nuclear inspectors through a new ministerial order.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Considering that the list of nuclear inspectors has been endorsed by a Ministerial order issued in 2008 and observing that the current turnover of FANC employees is such that the inspectors being in a position to perform enforcement actions is limited, an update of the nuclear inspectors list should be undertaken by FANC.*	
(1)	**BASIS: GSR Part 1 para. 2.5 (10) states that** *"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 :* *(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach.*
(2)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include:* • *Implementing inspection and review of decommissioning activities and taking enforcement actions in case of non-compliance with safety requirements."*
(3)	**BASIS: WS-R-5 para. 8.9 states that** *"The regulatory body shall make arrangements for and shall implement inspection and review of the decommissioning activities to ensure that they are being carried out in accordance with the decommissioning plan and with other requirements for which the regulatory body has oversight responsibility. Whenever safety requirements and conditions for authorization are not met, the regulatory body shall take appropriate enforcement actions."*
S13	**Suggestion: The government should consider allowing the director general of FANC to authorize nuclear inspectors.**

7.2. INSPECTION OF NUCLEAR POWER PLANTS

In order to accomplish its task, the IRRS team reviewed all documents submitted, interviewed FANC and Bel V managers, accompanied and witnessed an inspector in his routine control observations at the station, and the programmed follow up meeting with the station HPD. The team also interviewed the station management and HPD department management.

FANC is responsible for monitoring and control for public authorities regarding nuclear safety and protection against ionising radiation. Inspections and controls are to be carried out by the FANC and Bel V under the responsibility of the FANC. The purpose of the "general FANC inspection and control policy concerning compliance with GRR-2001" is to check that the activities conducted by the licensee are performed safely. The above mentioned inspection policy aims at controlling that the licensees:

- use a management system and a policy focusing on safety and radiation protection as well as on their continuous improvement. The necessary measures shall be taken to prevent possible accidents and to limit their consequences.
- employ qualified and well trained personnel.
- aim for (and maintain) safety, reliability and quality in the design, construction, operation, maintenance, shutdown and decommissioning of his facilities/installations.
- are capable of demonstrating that he complies with all provisions of the regulation and operating conditions of the licences.
- use a system enabling to learn lessons from past experience in Belgium and abroad.

The inspections and controls are part of the same system that the FANC and Bel V use jointly to carry out an "integrated safety assessment" of the licensee's activities.

By means of these inspections and controls, the FANC and Bel V, among other things,:

- make sure that the licensee of a facility meets his legal obligations and has a sufficient/acceptable safety level;
- support the continuous improvement of safety and radiation protection;
- identify sufficiently early the first signs of a possible degradation of the level of safety and/or radiation protection and inform the licensee.

These inspections and controls do not exempt the licensee from its obligation and responsibility with regards to the safety of his facilities/installations and the protection of its employees, the public and the environment. The inspections and controls include the following: investigations, studies, observations, measurements, and tests carried out by or for the FANC/Bel V. In the aim of continuous improvement, the FANC and Bel V use a QA system.

When problems, failures or infringements are observed via these inspections and controls, they inform the licensee.

Bel V controls:

- enable the overview of the operation of the health physics department of the licensee and the approval of certain favourable decisions of this department;
- enable a FANC action in the event of an obvious degradation or of non-compliance with obligations.

The FANC inspections:

- ensure the general monitoring of the nuclear sector in Belgium (monitoring of the licensees of nuclear industrial facilities, of licensees of other facilities corresponding to class II and III, of Bel V, of recognised inspection organisations, etc.);
- enable, via targeted actions, the assessment of the level of nuclear safety or radiation protection for a given field of activity and the implementation of improvement actions;
- enable, on the basis of feedback and the development of international standards, the assessment of the adequacy of the regulatory context and the proposal of improvements and/or the enactment of ad hoc guidelines;
- guarantee (if necessary) the use of policing powers.

7.3. INSPECTION OF RESEARCH REACTORS

In order to accomplish its task, the IRRS team reviewed all documents submitted, interviewed the FANC and Bel V managers, accompanied and witnessed an inspector in his routine control observations at the station, and the programmed follow up meeting with the station Health Physics Department. The team also interviewed the station management and HPD department management.

The same inspection arrangements apply for research reactors as at nuclear power plants.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

Since the only fuel cycle facility is decommissioned, please refer to the section on waste and decommissioning.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

IRRS team members accompanied an inspection performed by Bel V at the predisposal waste management facilities operated by Belgoprocess at Dessel. The inspection agenda included

- review of the status of modifications being undertaken at the site,
- follow-up of corrective actions related to reported events,
- a facility walk down and conformation of compliance to a selection of items extracted from the facility technical specifications.

The IRRS team members observed that the inspector demonstrated good knowledge of the facility and current issues and the interactions with the licensee were cordial and 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 by the FANC and Bel V. 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 FANC and Bel V. Recommendations related to this are included in module 1.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES

Most sealed source inspections are conducted by Authorized Inspection Organizations. While the licensee is required to maintain inventory checks on-site, the AIOs cannot compare this inventory with what the regulatory sealed source tracking system indicates they should have. By having direct access to the sealed source tracking system, the AIOs would be easily able to detect any unreported acquisitions or transfers of such sealed sources when conducting on-site inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Authorized Inspection Organizations do not have access to the licensee's sealed source inventory when conducting controls. Thus, an unreported Category 1 or 2 sealed source transfer may not be detected by the AIO during on-site controls.*	
(1)	**BASIS: CoC 22(h) states that** *"Every state should ensure its regulatory body ensures that inventory controls are conducted on a regular basis by persons with authorizations."*
S14	**Suggestion: The FANC should establish procedures to ensure Authorized Inspection Organizations (AIOs) verify the validity of the Category I and II sealed source**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	inventory when conducting on-site controls.

During the IRRS mission, team members accompanied FANC inspectors on two inspections which included a Radiotherapy Department and a Nuclear Medicine Department. A medical physicist expert, from the FANC Health Protection Section, in each of the relevant medical applications assisted the inspector in carrying out the inspections.

Based on the observations during these visits, together with the contents of the FANC Inspection Checklist (Manual), it can be concluded that the inspection visits were well structured and professionally conducted, and covered the requisite items in GS-R Part 1 para. 4.53. The format of the inspections observed was: an initial meeting with the licensee of the facility and an authorised practitioner supported by the Prevention Officer from the hospital who is responsible for health and safety aspects of persons at the hospital. At this meeting the regulatory and licence requirements of the facility were scrutinized and discussed, including other relevant authorizations, qualifications and radiation protection training of key personnel (medical practitioners, health physicists, medical radiation physicists and auxiliaries), health physics reports, personnel monitoring, and radiation protection of the patients. The meeting was followed by an inspection of the facility itself. A debriefing meeting was held at the end of the inspection to summarise the inspector's findings, deviations, deficiencies and good practices. An inspection report will be issued within 28 days of the inspection.

An inspector training programme exists which includes modules of observation, supervision by a pilot inspector and competence sign off is documented and records are maintained.

It appears that the regulatory system places great reliance on AIOs to carry out the requirements of the health physicists and medical radiation physicists set by FANC. The FANC inspector's role is to ensure that these have taken place as required. It was noted that licensees have responded to actions required by the FANC that the AIO was to do the particular action. It is important that the role of the AIO is fully understood by the licensee. It was noted that the AIOs have a double role of performing control checks on behalf of the FANC and also providing services to licensees. As a symptom of this the reports of the control checks carried out by the AIO often specify actions that fall under the role of the AIO.

An inspection programme is developed for the proactive inspections for medical licensees. The existing planned inspection programme (2011-2013) is coming to the end of its lifecycle. This programme was developed at an internal workshop attended by all staff of the section which considered aspects such as quality, efficiencies and priorities. The inspection programme may appear to take into account the radiological risk and apply a graded approach. However, the programme does not stipulate the frequency of inspections in accordance with the risks associated with the facilities and activities (see Recommendation R22). FANC performs both announced and unannounced inspections of medical practices using radiation. FANC also performs inspections as a result of an incident or complaint raised. Inspectors issue an inspection report following the inspection.

IRRS team members noted from witnessing the inspection that one facility had several significant non-compliances identified by the FANC inspector. The particular medical facility had not been inspected since 2005 highlighting the lack of periodic inspections and established frequencies for which facilities should be inspected. In addition it was identified that a QA programme on one specific type of radiation equipment had not been carried out since 2008 which may be attributed to the lack of regulatory oversight in the form of on-site inspections. Furthermore it is important to note that when the AIO performs control checks quarterly of radiotherapy facilities these checks do not cover patient protection aspects or checks on QA programmes. These illustrate that inspectorate capacity should be of concern.

There are 2.5 full-time equivalent inspectors within the Health Protection Section of FANC, while there are 7,740 medical installations licensed. There appears to be no documented evidence of an evaluation of the staff complement and inspectorate capacity required to discharge the duties of the inspection body effectively. Please refer to recommendation R11 in Module 3.1.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

The inspection for decommissioning facilities follows the same principles as the inspection for class I facilities.

On completion of decommissioning the operator shall demonstrate that the end state criteria as defined in the decommissioning plan and any additional regulatory requirements have been met. The nuclear facilities cannot be released from regulatory control until approval by the regulatory body. According to WS-R-5, a final inspection shall be performed prior to this formal approval. This kind of final inspection needs in practice to be performed by in-situ sampling for radiological measurements. A suggestion regarding training programmes is made in section 4.3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Considering that the termination of the license for nuclear facilities implies that the regulatory body normally performs a thorough on-site inspection to ensure that the criteria of the final end-state status, both physical and radiological, of the facility and site have been met and are consistent with the final decommissioning plan, the inspectors in charge of such inspections need the support of other departments within FANC. There is currently no process to ensure that this assistance is provided*	
(1)	**BASIS: GS-G 1.1 para; 5.1 states that "***In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts."*
S15	**Suggestion: For inspections relating to final release of sites from regulatory control, the regulatory body should consider formalising its training programmes covering the relevant inspection areas and establishing effective coordination arrangements in cases where expertise is provided from other departments within FANC.**

7.8. INSPECTION OF TRANSPORT ACTIVITIES

The inspection programme for transport follows a graded approach and includes all types of inspections (announced, unannounced, reactive, and proactive). All parties involved in a transport chain (consignor, carrier and consignee) are subjected to inspections which are focused on mainly 3 areas of interest: administrative (license, transport documents), equipment and conveyance, radiation protection.

Inspections are carried out by FANC staff only; however joint inspections occur incidentally with inspectors from other countries (e.g. joint inspections have been carried out with an inspector from ASN (France)).

For carriers of radioactive material, the FANC has developed an inspection programme (document SP 007-02) that follows a graded approach. It implies that each licensed carrier is inspected at a frequency determined by the risk, nature and frequency of the transports undertaken. It typically takes into account the following items:

- Transport of nuclear materials
- Holding one or several transport licenses
- Holding one or several special transport licenses
- Quantity and type of packages being transported
- Nature and scope of transport operations
- Previous incidents and accidents
- Results and observations from previous inspections
- Nationality and size of the company, complexity and diversity of the action proposed by the carrier
- Means of transport (number and type) used by the carrier

The minimum frequency of inspections is once in 5 years since this ties in with the maximum period for which a transport license is granted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC has established an inspection programme for carriers (document SP 007-02) for ensuring compliance with the regulations in the area of transport of radioactive materials. It is exemplary for the graded approach, which has been adopted for many regulatory functions exercised by the regulatory body in Belgium.* *It has also attracted the attention of regulatory authorities in other countries (e.g. in France, an overview was given in ASN's monthly journal CONTROLE nr.193).*	
(1)	**BASIS: GSR Part 1 para. 2.5 (10) states that** *"The legal and regulatory framework for safety shall set out the following:* *Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach"*
GP4	**Good Practice: The inspection programme for carriers of radioactive materials is graded based on risk and is recognized by other countries as a good practice.**

7.9. SUMMARY

The FANC and Bel V deliver the inspection programme for class I and IIA facilities; while the FANC and the AIOs deliver it for the class II and III facilities and activities. The planning and delivery of inspections are a shared responsibility for class I and IIA between the FANC and Bel V. Appropriate communication allows for a good exchange of information between the two organizations. The 3-year Integrated Inspection and Control Strategy using past inspection results and operational feedback is evidence of such good communications.

Strengths were seen in the overall delivery of inspections of transportation and in the observation and evaluation of safety culture attributes at class I and IIA facilities.

While the methods of inspections are typical of inspection practices in other countries, the scope of coverage needs to be reviewed to consider a more focused verification of safety functions such as the availability of safety related systems and components. The team also determined that the use of risk arguments and a graded approach could help in guiding the frequency of minimum coverage of inspections.

Implementation of inspections in the field, with exceptions noted in the area of transportation, needs guidance with more specific and detailed acceptance criteria to ensure proper decision making, uniformity from inspector to inspector, fair delivery of the inspection and for knowledge transfer purposes.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

The different enforcement tools and powers of the Regulatory Body are described in the FANC Law of 1994 as well as in the royal decree of 20 July 2001 on the powers and appointment of members of the inspection section of the FANC. The enforcement tools are further described in the royal decree of 20 December 2007 laying down the terms of the simplified administrative procedure for paying administrative fines and in the royal decree of 20 December 2007 laying down the terms of the administrative procedure for paying administrative fines.

According to the legislation, the nuclear inspectors are auxiliary officers of the Public Prosecutor's criminal investigation department. The FANC has about 15 nuclear inspectors. Bel V inspectors do not have enforcement powers. This could lead to delays in the delivery and implementation of enforcement measures in cases of non-compliance that the licensee refuses to correct.

The different enforcement measures are:

- Warning
- Confiscation
- Measure intended to render sources harmless
- Withdrawal/revocation/modification/suspension of the license
- Simplified administrative fines imposed by the FANC
- Administrative fines imposed by the FANC
- Prosecution recording for courts

Enforcement can also include financial and prison penalties according to the Law of 1994.

The simplified administrative fines are issued directly by the FANC and concern mainly infringement to the transport regulations. The standard administrative fines are issued by the FANC after the Prosecutor gives the approval to pursue the administrative process on the basis of FANC reports.

As for the facilities in the medical sector, regulations allow for a formal system of administrative fines for infringements of a limited nature. This is a very formal system which is not manageable for individual infringements of medical licensees but is used in specific situations. Other tools of enforcement and ensuring compliance include inspections of licensees and also an arrangement with the National Institute for Health and Disability Insurance (NIHDI). The arrangement allows the FANC to communicate with NIHDI if there are infringements with certain licensees, for example dental and radiology licensees.

According to the Law of 1994, the nuclear inspectors have the power to take on the spot any suitable measures to neutralise sources of ionising radiation which could endanger public health or the environment.

Evidence shows that training of the FANC nuclear inspectors in the area of enforcement has been given properly.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *Whereas there is evidence of graded approach for the standard administrative fines, there is no guidance to help nuclear inspectors and FANC decide about the nature of the enforcement measure: warning, simplified administrative fines, confiscation, withdrawal /revocation /modification*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
/suspension of the license.	
(1)	**BASIS: GSR Part 1 para. 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."*
S16	**Suggestion: FANC should consider improving its decision making process for enforcement in order to ensure consistency.**

The FANC has issued an internal instruction which supports the decision-making for the amount of standard administrative fines. This amount is decided on a risk-based approach considering the potential consequences of the infringement and its probability of occurrence. The calculation of the amount also considers safety culture aspects as well as the licensee's responsibility for safety in the enforcement (e.g. recurrence of infringement or intentional breach of the regulations).

The FANC has issued a process which clearly explains the decision making process and the applicable criteria for fixing the amount of standard administrative fines. This amount takes into account a risk based approach (taking into account the potential consequences and the probability of occurrence of the risk) and the safety culture aspects and the licensee's reaction for safety in the enforcement. This system is unique because it considers simultaneously the risk and the relevant safety culture aspects.

Most regulatory bodies deal with the problem that prosecutors do not always prosecute the infringements suggested by them. Moreover; the treatment of prosecution is a long lasting process. For the Belgian system of administrative fines however, the FANC convened clear practical modalities with the prosecutors in Belgium to guarantee the effectiveness and speed of this enforcement tool. The amount is fixed in a transparent manner.

This system of administrative fines seems to be an effective enforcement tool because the prosecutors apparently follow on the FANC administrative fines. Thus the application of the fine can be concluded in short time periods.

8.2. ENFORCEMENT IMPLEMENTATIONS

For certain precise infringements the FANC inspectors can propose a simplified procedure, provided that the financial amount of the sanction remains below € 2500 (royal decree of 20 December 2007 on simplified administrative sanctions). In Annex 1 of this decree, a list of events of non-compliance with transport requirements is included together with corresponding fixed fines.

Infringements of specific requirements related to the vehicle, to the transport package or to the documents during transport operations by the carrier have been directly coupled to the amount of the fine. The regulatory body is commended for good implementation of the enforcement procedure.

8.3. SUMMARY

Belgian legislation contains appropriate provisions for the Regulatory Body to take enforcement measures in a graded approach where the action is commensurate to the safety significance.

It provides also for the nuclear inspectors to take immediate actions on the spot in case of acute health and safety issue.

The nuclear inspectors are involved in the recommendations to the prosecutor for possible prosecution and there is evidence that the nuclear inspectors are properly trained in the enforcement area.

The graded approach is properly and clearly explained for standard administrative fines but is not reflected in the decision-making process as for the nature of the enforcement measure to be taken.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Belgian legal framework consists of the FANC law (15/04/1994), which establishes the authority of the FANC as the Belgium nuclear regulator, the GRR-2001 (20/07/2001), which covers the licensing procedure, supervision, radiological protection requirements, medical applications, transport, consumer products, radiological surveillance, and emergency planning, the royal decree on emergency preparedness and response (17/10/2003), the SRNI-2011 (30/11/11) which covers generic safety requirements for nuclear installations of class I and specific safety requirements for NPPs, and the royal decree on import, export and transit (24/03/2009). Still under development are specific requirements for waste disposal facilities, decommissioning activities, and storage of radioactive waste and spent fuel. These requirements will be included in an update of the SRNI-2011.

The FANC cannot promulgate binding regulations unless such regulations are of a specific technical nature and if it is foreseen by law or by royal decrees. The FANC has rarely made use of this possibility and only on narrow technical issues. Currently there are about 20 FANC decrees mostly related to the medical sector but no FANC decrees giving technical requirements for nuclear safety. SRNI-2011 Article 13.2 gives FANC a possibility to develop a decree only concerning the contents of the safety analysis report.

In addition, there are non-binding guides providing recommendations, expectations and guidance on how to comply with regulations. Drafting of the process for establishing generic guides has been initiated. The process for establishing specific guides is available (PC006-21). Until now, not many regulatory guides have been published. For new nuclear facility projects currently in the pre-licensing or licensing phase, the regulatory body has approached the issue in a more systematic way creating for the specific facilities at hand (e.g. the MYRRHA research reactor and surface disposal facility) what are called specific guides. For the future there are plans to generalize such specific guides, after they have been through a proper process for issuing regulatory guides. The FANC has also recognized the need to develop a glossary in order to avoid confusion in the terminology used. Currently there are many titles for the regulatory guidance documents, including e.g. guideline, guidance document, concept note, strategic note, advice document, and reflections document.

According to the FANC law, the FANC makes proposals for new legislation or regulation or modification of existing legislation or regulation and submits them to the competent Minister. An inventory of all regulatory initiatives is kept at the FANC. The FANC has a policy document GD010-09 concerning the development of regulations and guides and a procedure PC005-02 concerning the development of regulations. The policy document does not explicitly state that the IAEA safety standards will be systematically taken into account in the development process. During the preparation of the IRRS, the FANC and Bel V identified several opportunities to increase consistency with IAEA safety standards. PC005-02 is being extended to include the development of generic guides (mentioned also as an area for improvement). Possible triggers for developing new or updated regulation are e.g. European directives, new international standards, experience feedback, WENRA harmonization efforts or specific demands from authorities, licensees and other stakeholders). The FANC has recognized that there is no systematic process for evaluating and reviewing regulations and guides (including the assurance of coverage of relevant IAEA standards), and revising as appropriate. In practice the regulations have been updated quite often based on the triggering issues.

Possible stakeholders for consultation (e.g. Bel V, licensee, scientific council) and official advisory bodies are recognized and consulted during the drafting phase. This consultation with licensees includes the

evaluation of the fulfilment of the new binding regulations and whether there is a need for a transition period for some facilities. The process does not include a step where draft regulatory guides are published for public comments. Final binding regulations are available through the FANC website, but so far not all regulatory guides have been published there.

SRNI-2011 was developed based on the WENRA reactor SRLs. Since a comprehensive gap analysis of IAEA safety standards and the Belgian regulations has not been performed, there are some areas missing from the regulations, e.g. siting, construction, commissioning (partially) and safety culture. Also the prime responsibility of the licensee is not explicitly mentioned in the regulations (see Section 1.4).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is not a systematic process for regularly evaluating and reviewing regulations and guides, and revising as appropriate. The policy document does not clearly state that the IAEA safety standards will be systematically taken into account in the development process. One of the primary inputs for FANC in developing draft regulations is the WENRA reference levels which are established after considering, in particular, IAEA safety requirements. However, IAEA safety guides are mostly considered on a case by case basis, given that FANC relies on the fact that its staff drafting regulations have often been involved in drafting IAEA safety standards.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"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."*
(2)	**BASIS: GSR Part 1 Para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides."*
(3)	**BASIS: GSR Part 1 para. 3.2 (c) states that** *"The features of the global safety regime include:* *(c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;*
S17	**Suggestion: The regulatory body should consider enhancing the process for evaluating and reviewing regulations and guides periodically. The process should ensure that the IAEA safety standards are systematically taken into account.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Drafting of process for establishing generic regulatory guides has been initiated. There is also an initiative to extend some specific guides and make them generic. Currently, the development process does not include a step where draft regulatory guides are published for public comments. Also not many finalised regulatory guides are available through the FANC website.*	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."
(2)	**BASIS: GSR Part 1 Para. 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities."*
R23	**Recommendation: The regulatory body should create a systematic structure for regulatory guides, establish a formal process for developing guides and prioritise according to their importance for safety. The regulatory body should extend consultation to include the public when developing the guides.**

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

For the facilities of class I, the regulatory system of the country of origin was adopted, which for NPPs was based essentially on the USNRC regulatory guides. The binding regulations for the operating facilities are contained in chapter 3 of the safety analysis report which is referred to in the license as an official binding document. The safety analysis report is updated when necessary and on occasion of the PSRs, which for all class I facilities were conducted from the beginning of their operating lifetime.

With the promulgation of the SRNI-2011 royal decree the Belgian regulatory body has adopted and implemented in its regulatory framework the WENRA SRLs. SRNI-2011 Chapter 2 includes generic class I safety requirements and Chapter 3 specific safety requirements for power reactors.

A distinction should be made between the effective implementation of the IAEA safety requirements in the Belgian facilities and the implementation of those same requirements within the Belgian legal and regulatory framework. With respect to the former point, because the regulatory body has reviewed the periodic safety reviews of the class I facilities, it could convince itself that the fundamental safety requirements are satisfactorily implemented in the facilities. On the other hand, the adoption of newer IAEA standards in national regulations and guides has sparsely taken place and has been recognizably not followed-up in a systematic manner (see suggestion in chapter 9.1). There are yet some examples of such adoptions, e.g. the Belgian guide issued for PSR based on IAEA NS-G-2.10/SSG-25 to further detail the requirements of Art. 14 SRNI-2011. For new projects currently in the pre-licensing or licensing phase the regulatory body has approached the issue in a more systematic way creating for the specific facilities at hand (e.g. the MYRRHA research reactor) what are called specific guides (e.g. for the seismic hazard evaluation of MYRRHA). For the future there are plans to generalize such specific guides, after they have been through a proper process for issuing regulatory guides.

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Specific requirements for waste disposal facilities and storage of radioactive waste and spent fuel are under development and will be included in an update of SRNI-2011. As part of the pre-licensing process for proposed near surface disposal facility, the FANC developed a number of guides that were intended to

assist the applicant with the development of the required safety case in support of the license application. The suite of guides covered:

- Policy and guidelines for assessing disposal facilities
- Consideration of external events in the design of surface disposal facilities
- Radiation protection criteria during operation of disposal facilities
- Radiation protection criteria for post-operational safety assessment of surface disposal facilities
- Safety objectives and principles for surface disposal facilities
- Treatment of biosphere in safety assessment for disposal facilities
- Risks of human intrusion for surface disposal facilities
- Groundwater consideration for surface disposal facilities
- Earthquakes guidance for surface disposal facilities.

In addition, the FANC developed a set of regulatory evaluation criteria to be used as part of the regulatory review of the individual chapters of the safety case documentation.

The FANC has set generic clearance levels which are included as an annex to GRR-2001, however, it is recognised that additional clearance levels are required for surface contaminated materials.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *As a result of feedback based on the application of the existing clearance levels, a need for clearance levels in terms of surface contamination has been identified.*	
(1)	**BASIS: GSR-PART 3 para 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from further regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of such criteria. By means of this approval the regulatory body shall ensure that sources that have been cleared do not again become subject to the requirements for notification, registration or licensing unless it so specifies."*
(2)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include:* - *Establishing safety and environmental criteria for the decommissioning of facilities, including criteria for clearance of material during decommissioning and conditions on the end state of decommissioning and on the removal of controls;"*
S18	**Suggestion: The regulatory body should consider developing clearance levels for surface contaminated items.**

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES

The guides available to authorization applicants are fairly comprehensive in scope and allow for a detailed evaluation. While security is not addressed in the regulations (see Section 12), security provisions are nonetheless captured in the form of licence conditions, which are binding upon the licensee. The guides clearly outline the process for authorization, and generally appear to be well-written and suitable for their intended purpose. It is felt that compliance with IAEA requirements in this matter is respected.

The royal decree GRR-2001 is written for all types of facilities, and some requirements were previously often misunderstood by industrial radiographers. To address the systemic non-compliances found in this

industry, the FANC has increased regulatory inspections to these licensees, and has reached out to licensees with a series of stakeholders meetings with the industry to seek their input and to clarify regulatory requirements. While not an official policy, the practice of holding stakeholder meetings has been very successful in increasing regulatory compliance within the industry. In general regulatory matters, particularly with industrial radiography, the FANC has also been very proactive in holding outreach stakeholder meetings to seek licensee input.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *To assist licensees understand and comply with existing and new regulatory requirements, FANC held several stakeholder meetings with licensees to seek input, and disseminate information. This outreach has yielded positive results in terms of licensee safety and compliance.*	
(1)	**BASIS: CoC 22 (j) states that** *"Every State should ensure that its regulatory body Authorization by the regulatory body, takes enforcement actions, as appropriate, to ensure compliance with regulatory requirements."*
GP5	**Good Practice: FANC has taken a constructive approach to improve industrial radiography compliance by holding stakeholder meetings to seek industry feedback and explain new regulatory requirements.**

The regulations for medical exposure are based on the current Euratom Directives as well as the relevant IAEA safety standards and reports. Regular consultations and round table discussions are held with relevant professional groups, universities and other regulatory authorities. Through this stakeholder engagement, guidance has been developed for the reduction of patient dose and education and training awareness for certain practices.

Furthermore, good practice guidance for the medical sector has been developed by the Health Protection Section and published by the FANC in the form of user friendly leaflets. Specific examples include guidance on areas such as dental radiography and protection of women of child bearing age undergoing medical exposures. This guidance has been disseminated to all relevant parties. More details on guidance within the medical sector including criteria of acceptability of radiation equipment, incident reporting and clinical audit is given in Section 11.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The current requirements for decommissioning are specified in the GRR-2001, the FANC position paper on decommissioning (2006) and the FANC conceptual note on facility final shutdown and decommissioning (2012). Additionally, the FANC has developed draft regulations on decommissioning based on the WENRA SRLs for decommissioning. These are intended to be published as a royal decree supplementing the SRNI-2011.

The requirements have been developed addressing decommissioning of class I facilities and a subset of class II nuclear facilities. It is not evident what requirements are applicable to other licensed facilities. While requirements exist for collection and retention of records and reports relevant to decommissioning, the FANC has no guidance with regard to the manner in which such records are to be collected and retained.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *It is not evident that all the responsibilities as per WS-R-5 para 3.6 have been discharged by FANC, in particular:* - *while requirements exist for collection and retention of records and reports relevant to decommissioning, FANC has no guide with regard to the manner in which such records are collected and retained in this regard* - *while requirements related to decommissioning of class I and class IIA facilities exist, it is unclear what the decommissioning requirements are for other authorised facilities.*	
(1)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include:* - *Establishing criteria for determining when a facility or part of a facility is permanently shut down, based on termination of the authorized activities;* - *Establishing safety and environmental criteria for the decommissioning of facilities, including criteria for clearance of material during decommissioning and conditions on the end state of decommissioning and on the removal of controls;* - *Establishing requirements for decommissioning planning;* - *Reviewing the initial decommissioning plan and reviewing and approving the final decommissioning plan before allowing decommissioning activities to be commenced;* - *Implementing inspection and review of decommissioning activities and taking enforcement actions in case of non-compliance with safety requirements;* - *Establishing policies and requirements for the collection and retention of records and reports relevant to decommissioning;* - *Evaluating the end state of a decommissioned facility and deciding whether the conditions have been met to allow the termination of the practice and/or release from regulatory controls or whether further activities or controls are needed;* - *Giving interested parties an opportunity to provide comments on the plan before it is approved."*
R24	**Recommendation: The regulatory body should establish clear requirements for decommissioning of authorised facilities including class II, class III and other facilities such as NORM and other work activities.**
S19	**Suggestion: The regulatory body should consider establishing guidance on how records relevant to decommissioning are collected and retained.**

9.6. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

Belgium has established the following legislation pertaining amongst others to the safe transport of radioactive material: Law of 15 April 1994 and the implementation of this law in royal decree of 20 July 2001 (GRR-2001). In the Law of 15 April 1994, Article 18 specifically stipulates the responsibility of the FANC for the transport of radioactive material.

Article 57 of GRR-2001 requires that transport activities shall comply with the provisions laid down in international modal agreements and regulations governing the carriage of dangerous materials and that these may only be performed subject to a preliminary license. Since these modal agreements are transpositions of the IAEA transport regulations for each mode of transport (air, sea, road railway and inland waterways) the conclusion is that all provisions in IAEA TS-R-1 are fully addressed, including the

responsibilities of the Regulatory Authority with respect to training of staff engaged in the transport of radioactive materials as described in articles 311 - 315 of TS-R-1.

The IAEA supporting guides TS-G-1.1 to TS-G-1.5 have not been directly implemented in the national legislation and regulation, but have been referenced where applicable (e.g. a reference to TS-G-1.1 occurs in document PDSR Guide (http://www.fanc.fgov.be/GED/00000000/2600/2632.pdf) published on the FANC website). The safety guide TS-G-1.2 is implemented through the royal decree of 17 October 2003, in which a national nuclear and radiological emergency plan for the Belgian territory was established, including transport accidents.

Training for staff involved in the transport of radioactive material is one of the cornerstones to ensure safety. Consequently, in many IAEA requirements documents it is emphasized that the Regulatory Authority provides for adequate training capacity commensurate with their individual responsibilities. Training courses can be distinguished in courses for ADR drivers of vehicles and courses for the ADR/RID Safety Advisor. The FANC has been appointed by the royal decree of 6 February to provide these training courses for drivers. The FANC offers basic training courses and refresher courses, the latter type for drivers whose certificate comes close to expiration (validity of certificate is 5 years). On the average 3 courses per year are held, both in the French and in the Dutch language. Training courses destined for the ADR/RID Safety Advisor are offered as a joint effort by recognized organizations (DGT and AIB Vinçotte-Controlatom). However, the exams are set up by the FANC as well as the issuing of the certificates after passing the test.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Training courses can be distinguished in courses for ADR drivers of vehicles and courses for the ADR/RID Safety Advisor. Since the carriers of radioactive materials are limited and the number of new drivers requiring training is relatively small, no private organization currently offers these courses. Since training is required by the decree and by the international modal regulations, FANC provided these training courses for ADR drivers. It is noted that training personnel of licensees does not belong to the responsibility of the regulatory authority and may give rise to conflicts of interest. On the other hand, FANC is commended for ensuring continuity of training possibilities on a temporary basis.*	
(1)	**BASIS: GSR Part 1 para. 2.34 states that** *"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."*
(2)	**BASIS: GSR Part 1 para. 2.41 states that** *"…If no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services."*
(3)	**BASIS: TS-R-1 para's 3.11 – 3.15 state that** *"Workers shall receive appropriate training concerning radiation protection, including the precautions to be observed in order to restrict their occupational exposure and the exposure of other persons who might be affected by their actions."*
S20	**Suggestion: The government should consider making provision for parties other than the regulator to provide training courses for ADR drivers of vehicles carrying radioactive materials.**

9.7. SUMMARY

All areas of the FANC's competence are covered by regulations with the exception of some specific cases that are identified in subchapters 9.1-9.6. Still under development are, for example, the specific safety requirements for waste disposal facilities, decommissioning, and storage of radioactive waste and spent fuel. In anticipation of license application for the near surface facility and the MYRRHA research reactor, the regulatory body has developed a suite of guides to be used by the applicant and the regulatory body.

Currently, there is no systematic process for evaluating and reviewing regulations and guides (including the assurance of coverage of relevant IAEA standards) and revising as appropriate. Drafting of a process for establishing generic guides has been initiated. The regulatory body should also consider consulting the public when developing new regulatory guides.

The FANC has taken an informal proactive approach to improve compliance with the regulatory requirements by holding various stakeholder meetings with the licensees. There has also been a FANC initiative to provide training courses for drivers of vehicles including radioactive material packages. The FANC should consider making provision for parties other than the regulator to provide training courses for ADR drivers of vehicles carrying radioactive materials.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL REQUIREMENTS

Basic responsibilities

The legal basis of the roles of the regulatory body in Emergency Preparedness and Response (EPR) are:

- Law of 15 April 1994 concerning the protection of the population and the environment against the dangers of ionising radiation and concerning the Federal Agency for Nuclear control
- Royal decree of 20 July 2001 concerning the basic safety standards for radiation protection of the population, workers and environment
- Royal decree of 16 February 2006 on the emergency and intervention plans
- Royal decree of 31 January 2003 defining the emergency plan for events and crisis situations requiring a coordination or management at the national level
- Royal decree of 17 October 2003 (the Plan) defining the nuclear and radiological emergency plan for the Belgian territory
- FANC Directive of 17/October 2003 on the emergency reference levels for radiological emergency situations
- Royal decree of 30/11/2011 on the safety requirements for the nuclear installations

In its regulatory role, the FANC and Bel V are responsible for making sure its licensees have the necessary capabilities to cope with the on-site consequences of an emergency.

Article 2.6 of the Plan specifies that "… Operation is conducted in compliance with the law and the conditions provided in the license, under the control of the regulatory bodies; as such, via the installation's Physical Inspection department, it is subject to permanent monitoring by a class I recognized inspection organization. The civil liability for the operation is governed by the law of 22 July 1985 regarding civil liability in the field of nuclear energy". The "recognized inspection organization" is Bel V.

Dedicated inspections on EPR (thematic inspections) are performed regularly by Bel V in accordance with the 3-year inspection strategy and the derived yearly inspection programs/plans (see 7.1.1). To support these EPR inspections, checklists covering the various EPR topics have been developed by Bel V. In the inspection reports, no quantitative criteria are defined but a qualitative assessment leads to deriving conclusions and recommendations to be addressed by the licensee.

Licensees at all levels would benefit from more elaborate guidelines to assist them with their emergency preparedness and response programme. The guidelines will also allow for more consistency and better define the expectations as required by the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Royal decrees on emergency preparedness and response are general in nature and are considered as good entry-point documents. However, more detailed requirements should be given to the licensee allowing for greater consistency throughout the regulatory process and to ensure the licensee has an effective emergency management programme in place.*	
(1)	**BASIS: GS-R-2, 3.9 states that** *"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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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. (Ref. [10], para. 3.2.)"
(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. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
R25	**Recommendation: Regulatory body should further develop guidance on emergency preparedness and response for the licensee.**

Assessment of threats

There are some elements of such threat assessment considered at different stages, such as classification of nuclear installations, integration of emergency arrangements for all kinds of situations (see Royal Decree of 16/02/2006) or the specific assessment of the so-called "reflex-phase" (fast kinetic events) and the associated "reflex response area" but it is not fully consistent with GS-R-2. In the framework of Probabilistic Safety Review (PSR), analysis of the site surroundings (evolution of the external hazards and risks) is performed and actualized.

10.2. FUNCTIONAL REQUIREMENTS

Establishing emergency management and operations

The Royal Decree of 16/02/2006 and the Royal Decree of 31/01/2003 define the emergency plan for events and crisis situations requiring the coordination or management at the national level. The Plan describes the arrangements and the structures to be put in place for nuclear and radiological emergencies at the national, provincial and local levels, including the installation for the response to emergencies, the organizations in charge and their responsibilities within the organisation of the response. The on-site emergency response arrangements are given in the IEPs (Internal Emergency Plan) established by the licensee.

The Governmental Coordination and Crisis Centre (CGCCR) is the National Coordinating Authority. The FANC is the regulatory body and the National Competent Authority (NCA) for domestic emergencies. The Plan defines the roles and responsibilities of all the agencies, organizations and stakeholders. The coordination is quite elaborate and detailed, obligations are fulfilled and exercised.

The person in charge for the management of the nuclear/radiological emergency is the Emergency Director of the Authorities (EDA), presiding over the decision making body (Emergency Management Group, COFECO) in the CGCCR. The on-site emergency response is managed by the Emergency Director of the Licensee (EDL).

Identifying, notifying and activating

The emergency classification system is not fully consistent with the classification system described in GS-R-2 (para. 4.19). Article 2.6 of the Plan defines the obligation: "The licensee informs the regulatory bodies, in accordance with the provisions of this plan, under the conditions laid down by law (see articles

#67 and #76 of the Royal Decree of 20/07/2001) and by the authorization decree. In the event of an accident leading to implementation of this plan, the information is given in accordance with this plan. This information takes priority in time over the aforementioned information. The licensee provides information to the evaluation cell CELEVAL (notification level N1, N2, N3 and NR) and to the Governor (notification level NR) about the state of its installation that they need to accomplish their functions. This information is defined in other chapters in this plan". More details on the reporting requirements are given in 4.3.1 and 4.3.2 of the same document.

During past exercises, possible confusion at the communication/media level between the INES levels and the licensee's notification of the classification on the significance of the event has been noticed. This created communications difficulties during an emergency situation. It was mentioned that this was probably an isolated case. The regulatory body may want to further investigate and if this reoccurs they may want to address this matter with its stakeholders.

The IRRS team noted that on a periodic basis, the regulatory body participates in meetings with bordering states to work towards a common approach to improve the coordination of emergency arrangements.

Taking mitigatory actions

Article 2.6 of Royal Decree 17/10/2003 requires that the licensee

- Be in overall charge of on-site response;
- Do everything necessary to regain control over the facility;
- Mitigate consequences on the site;
- Protect personnel and people staying on site.

These actions can be found under the IEP (Internal Emergency Plan). The IEPs are reviewed periodically and approved by the regulatory body.

Taking urgent protective action

FANC/Bel V will use the Plan as its main basis document. It does not feel it needs specific emergency regulations. They prefer the Royal Decree approach as it gives them the ability to be flexible and adapt to the emergency.

Urgent protective actions and intervention levels are listed in Article 8.2, "Direct protective measures for the general public".

FANC/Bel V was involved in defining the emergency planning zones of the Plan which regulates the issues related to the planning zones (Article 5: Planning and intervention zones). They are consistent with the emergency zoning parameters recommended in GS-G-2.1.

It is suggested that the regulatory body take a more active role with organizations during the awareness campaigns to discuss the advantages of having KI pills pre-distributed to households and special centres, especially within the Reflex Zone. The FANC takes part in the awareness campaigns (e.g. related to the distribution of the KI tablets) but they are not directly responsible for instructions to the public in case of an actual emergency. There are mechanisms in place to allow for public alerting, sheltering, KI tablets and communications strategies for instructing the public.

Providing information and issuing instructions

In emergency situation, the FANC does not have the regulatory authority to disseminate information and provide instructions to the public. They may assist other organizations when requested to do so, but generally, it is the CGCCR who will take the lead role.

Protecting emergency workers

FANC/Bel V was involved in the preparation of the Plan that regulates the issues related to protection of emergency workers (Article 8.1: Protection of intervention personnel). The rules are set by the Articles 20.2, 72.3 and 72.4 of the Royal Decree of 20/07/2001 and in the FANC Directive of 17/10/2003.

The regulatory requirements are consistent with the IAEA standards, however, there is a need to provide additional information to ensure all organizations at different levels fully understand these requirements and more importantly what it means for the protection of emergency workers and volunteers whether they are on-site or off-site. Some initiatives have been taken on this regard, among others in the framework of the preparation of the last large-scale exercise (2012). The IRRS team encourages FANC/Bel V to continue actively the implementation of the actions that have been initiated.

Assessing the initial phase

The licensee is responsible to make the initial assessment based on the plant parameters and EALs, in accordance with the IEP. FANC/Bel V participates in CELEVAL (the evaluation cell which assesses the accident progression, radiological conditions and possible consequences) and a representative of Bel V is sent to the affected site to oversee/supervise the emergency response of the licensee. The FANC operates the TELERAD system which provides real-time, on-line radiological measurements and data for the assessment. The above arrangements are regulated by the Plan.

FANC/Bel V stated that they use some of the Operational Intervention Levels (OILs) as described by the IAEA to assist them with the emergency response. They indicated that some of the OILs are appropriate within their current emergency structure while others do not work and delay their overall response efforts.

Keeping the public informed

During an emergency, the FANC is not directly responsible for informing the public as this is coordinated by INFOCEL at the CGCCR. FANC/Bel V will collect information from the accident site and through its measuring capabilities network, TELERAD, and the measurement cell (CELMES). This information will be used as input for public communication.

10.3. REQUIREMENTS FOR INFRASTRUCTURE

Plans and procedures

The regulatory body requires the licensees to have an IEP in place under regulation SRNI 2011. Section V of the SRNI, "Preparation for emergencies" defines the emergency requirements. Article 27 under Chapter 3 addresses emergency operating procedures and severe accident management guidelines.

The regulatory body evaluates and validates the licensee's IEP during the authorization process. They perform inspections (1 per year for each NPP) and evaluate exercises.

To ensure its role during a nuclear emergency is well understood, the regulatory body would benefit by developing its own nuclear emergency response plan. This will allow for greater comprehension and clarity as to what it is expected to do. It will provide information on how some of its responsibilities are shared with Bel V and what it expects from them during the four main phases of emergency management, "prevention, preparedness, response and recovery".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory body lacks the foundation document which is essential to provide an overview of its emergency response role, responsibilities and objectives. It would capture the elements of what it is to do given a radiological or nuclear accident in Belgium or abroad for all possible threat categories and make reference to existing procedural documentation. It would also describe the complete emergency structure by position at its headquarters as well as its involvement at other locations to prepare for a nuclear or radiological emergency*	
Observation: *The regulatory body may undertake a review of its role in their CI2C (the regulatory body's own Crisis Centre) to allow them to perform their technical assessments and calculations regarding the significance of the emergency. Technical staff would work on various assessment products in advance to prepare themselves ahead of time with credible information. This information will eventually be required by the President at the evaluation cell (CELEVAL) at CGCCR. In order to allow for these assessments, FANC should develop specific tools.*	
Observation: *Currently, FANC has enough staff to perform its day to day emergency functions. However, should it be confronted with an emergency of long duration, it would have to rely on additional staff from other directorates/divisions. Although technical in nature, these people are not necessarily emergency management specialists or experts. This is problematic as the regular regulatory business with non-affected licensees must continue, By adding and training additional staff on emergency preparedness and response matters, this will ensure staff is readily available to address the ongoing emergency as well as its regular regulatory duties.*	
(1)	**BASIS: GS-R-2 para. 5.14 states that** *" Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions as specified in Section 4]. This includes situations involving such sources of exposure as sources illegally brought into the country, falling satellites equipped with sources or radioactive materials released in accidents beyond national borders. (Ref. [3], para. 3.10.) Emergency plans shall be prepared which specify how the responsibilities for the management of interventions will be discharged on the site, off the site and across national [borders], as appropriate, in separate but interconnecting plans. (Ref. [3], Appendix V, para. V.2.)"*
(2)	**BASIS: GS-R-2 para. 5.17 states that** *"The appropriate responsible authorities shall ensure that: (a) emergency plans [are] prepared and approved for any practice or source which could give rise to a need for emergency intervention; (b) [response organizations are] involved in the preparation of emergency plans, as appropriate; (c) the content, features and extent of emergency plans take into account the results of any [threat assessment] and any lessons learned from operating experience and from [emergencies] that have occurred with sources of a similar type [(see paras 3.13–3.20)]; (d) emergency plans [are] periodically reviewed and updated."*
R26	**Recommendation: The regulatory body should develop its own nuclear/radiological emergency response plan.**

Training, drills and exercises

Exercising is an important component of the regulatory control function. After an exercise, Bel V will ask participants, at the affected site and at CELEVAL, to do a self-assessment by completing evaluation forms. Bel V will write the results of the exercise in a report based on the information collected. Seeing as Bel V does not have specific evaluation criteria to evaluate the performance of the licensee's staff during an exercise, they would benefit by developing such criteria.

The regulatory body has an exercise programme in place and they perform several exercises annually. As per the suggestion in Module 12.2, "Interface with Nuclear Security", it is envisaged that future exercises will include a nuclear security component.

The regulatory body along with its federal organizations at the CGCCR and the licensee would benefit by having the local and provincial authorities involved early on in the process when considering developing new tools, as it was the case with the block splitting of emergency planning zones. Tools of this type must be well understood and accepted by local and provincial authorities who will eventually have the task of implementing them.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

The main responsibility for the coordination of all emergency preparedness and response, including radiological and nuclear emergencies, rests with the General Directorate Crisis Centre (CGCCR, under the Ministry of Home Affairs). The FANC, together with Bel V have limited responsibilities in the national emergency preparedness and response system. They provide technical support and scientific expertise (response function). The FANC operates the TELERAD environmental radiation network, which constitutes the CELMES environmental radiological data cell in case of an emergency. A FANC representative presides the CELEVAL situation and consequence assessment cell, which is the main decision aiding body for the decision makers (COFECO) in the CGCCR.

Based on the exercise observed by the IRRS team at the Tihange NPP and at the CGCCR, the teams on-site and in the evaluation cell have the competence, equipment and systems in place to effectively carry out their respective emergency management functions. They have qualified people in both areas who are familiar with the tasks that are required to be performed during an emergency. There was good exchange of information between staff at the NPP and also between the plant and the evaluation cell at the CGCCR.

The primary objectives of the exercise were to test the identification, notification and activation procedures from the IEP. Based on the feedback received after the exercise, observations will most likely not require major changes to the regulatory framework but may lead to recommendations regarding the procedures and tools used.

During the Reflex Phase, the Governor will promptly implement the pre-defined countermeasures for the safety of the population living in the Reflex Zone. The countermeasures implemented early on may not be appropriate for the emergency event they are confronted with. This may require attention by the regulatory body and other authorities.

Seeing as numerous emergency preparedness and response functions fall outside the scope of FANC/Bel V, they look to other organizations for fulfilment of these functions. There is a need to take an in-depth look at the organizational relationships and interfaces between all major response organizations. For this reason, it may be of interest for the government to request an EPREV Mission. If agreed, this Mission should take place before the IRRS Follow-up Mission.

10.5. SUMMARY

After reviewing the major components of EPR for the regulatory body, the IRRS team found that in general, there is a good framework in place which ensures that emergency preparedness and response arrangements with licensees are effective.

Below are areas where the regulatory body should focus to improve its emergency preparedness and response programme.

- To properly capture the exact role and precise functions of the regulatory body, a specific nuclear/radiological emergency response plan should be developed.
- Licensees who want to renew their existing licence and new applicants who apply for a new licence would benefit from specific guidelines on how they should develop their emergency programme. The guidance document would address all aspects of emergency preparedness and response.
- Regular dedicated inspections on EPR are performed by Bel V to check and evaluate the on-site emergency arrangements of the licensees. To support these dedicated inspections, Bel V should further develop specific guidance documents which will give inspectors the material needed to perform their work using a consistent methodology.
- With regards to evaluating exercises on-site, Bel V will collect, after the exercise, feedback (self-assessment) from the Bel V participants. Bel V does not have a formal mechanism in place with established criteria to evaluate the performance of the licensee staff during an exercise.
- In the event of an emergency, FANC/Bel V provides technical and radiological advice along with other support functions to the evaluation and measurement cells located at the CGCCR. The regulatory body works closely with many other organizations (subsidiaries) and depends on them for information during an emergency. It may be of value to have the IAEA perform an EPREV Mission as this will allow for a more complete analysis of the overall emergency programme in Belgium and determine if the functions are properly aligned and well-coordinated.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURE

Responsibilities

Medical Exposures are dealt with in the FANC law and GRR-2001. The law designates the FANC as the competent authority responsible for the implementation of GRR-2001. Radiation Protection Regulations apply to the use of ionising radiation for medical applications including radiology, radiotherapy, nuclear medicine, dental and veterinary applications. Several authorities, namely the FANC, FPS Health (Federal Public Service Health, Food Chain Safety and Environment), NIHDI (National Institute for Health and Disability Insurance), and FAMHP (Federal Agency for Medicine and Health Products), have a role in ensuring the safety of patients undergoing medical exposures. There are agreements in place between the FANC and each of these authorities. Please refer to Module 1, Recommendation R8.

All medical practices are authorised through licensing of the facility. In conjunction with this all medical exposures should be performed under the medical responsibility of a licensed practitioner who must be authorized.

A Medical Jury has been established by FANC decrees which outline the composition details and terms of reference for the Jury. The approval of medical radiation physicists, radiation oncology physicians, nuclear medicine physicians, clinical biologists and occupational physicians are given by the FANC following an assessment and advice by the Medical Jury. The FANC performs the authorization of radiologists, veterinary and dental practitioners. The radio pharmacy commission gives an advice for the recognition of radio-pharmacists. While there are mandatory, FANC-approved radiation protection training courses for medical imaging technologists and operators of radiotherapy equipment (auxiliaries), there is no professional approval mechanism for these staff. This should be reviewed to ensure the principles of radiation protection are given high priority and applied consistently by such staff to the extent possible, irrespective of cultural and professional influences on the provision of clinical services.

The Medical Jury is also available to the FANC for advice on relevant issues such as new clinical procedures.

For radiotherapy and PET facilities, minimum staffing levels (medical staff, physics/technical, nursing and administrative) are established under a royal decree under the responsibility of FPS Health. These staffing levels are set by FPS Health following advice from the National Council for Hospital Provisions, Inspector of Finance and the State Council. There is no evidence to indicate these staffing levels are set from a radiological risk perspective while taking account of clinical need and safety aspects. Although GRR Regulations specify some requirements for staffing levels, there appears to be no coherent approach between both sets of legislation. (Please refer to Recommendation R8). The FANC has no role at these facilities in assessing the adequacy of staffing levels from a radiological safety perspective.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Regulations have not established a coherent approach to ensuring appropriate competences of technical staff in radiotherapy, nuclear medicine and radiology facilities sufficient to ensure optimum radiological safety in the treatment of patients or ensuring the staffing requirements are complied with.*	
(1)	**BASIS: GSR Part 1 para. 2.5 (15) states that** *"The government shall promulgate laws and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: *"Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;"*
(2)	**BASIS: GSR Part-3, Requirement 35 states that;** *'The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty'.*
(3)	**BASIS: GSR Part 3, Requirement 30, para 3.127 (e)***; 'Programmes for appropriate training of personnel having functions relevant to protection and safety of members of the public, as well as periodic retraining as required, to ensure the necessary level of competence'.*
S21	**Suggestion: The government should consider incorporating radiological risk among criteria used in establishing the required professional competences of staff in medical facilities and ensure there is co-ordination between FPS Health and FANC in verifying compliance with the regulations.**

Justification

The FANC has documented a procedure for the justification of new practices involving medical radiation exposure before they are licensed for the first time or adopted for general use in the medical sector. The procedure includes an assessment of the clinical justification and technical aspects. The resulting justification report and additional opinions are attached to the licence application and serve as evidence.

With regard to individual medical exposures, the regulations state that all exposures must be justified and both the prescriber and practitioner have a role at their own level in this process. The Belgium Medical Imaging Platform (BELMIP) has developed referral criteria with an indication of the radiation doses, in conjunction with the College of Radiology, for the prescribers of medical exposure.

In 2011-12 the Belgian College of Radiology audited prescriptions for medical exposures at multiple hospitals and published a report that concluded many radiological procedures were not justified. Furthermore, a population dose survey in 2012 indicates that 48% of the population dose in Belgium is attributed to medical exposures. In 2010, FPS Health founded the collaborative BELMIP which includes the FANC and other relevant stakeholders. This platform has several initiatives for promoting patient safety. One such initiative is awareness campaigns targeted at members of the public, prescribers and practitioners promoting the need for clinical indications in the justification of medical exposures. It is recognised these initiatives are at an early stage and it is advised that the momentum for these campaigns continue and include a focus on creating a culture amongst the relevant professions to introduce and apply awareness, appropriateness and audit which are considered as tools to enhance the justification process. This should assist in modifying existing practices which are a symptom of a process which is currently driven by financial aspects.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are concerns over the number of unjustified exposures following a recent audit by the College of Radiology and the results of the population dose survey in 2012.*	
(1)	**BASIS: GSR Part 3 Requirement 10 states that** *"The government or the regulatory body shall ensure that only justified practices are authorized."*
(2)	**BASIS: GSR Part 3, Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified."*
S22	**Suggestion: The government should consider developing a national policy on justification for medical exposures in consultation with all relevant parties, emphasising current collaborations aimed at achieving a coherent, effective and consistent approach to applying regulatory requirements for the justification of all medical exposures.**

Optimisation

The regulations explicitly establish the principle of optimization and include provisions on establishing Diagnostic Reference Levels, Dose Constraints and QA Programmes.

Diagnostic reference levels have been established by the FANC following a survey of patient dosimetry, for diagnostic radiology, computed tomography and interventional radiology, as set out in the FANC decree 2011. Feedback was also provided to the hospitals on their patient dosimetry results in comparison to the diagnostic reference levels set by the FANC.

Regulations state that dose constraints shall be established for individuals knowingly and willingly helping, other than as part of their occupation, in the support and comfort of patients undergoing medical diagnosis or treatment. It further states that this dose constraint shall be set by the doctor who assumes medical responsibility for the exposure, taking into consideration, where applicable, the directives and recommendations issued by the FANC and in consultation with the medical radiation physics expert. These dose constraints have not been established. The regulations also provide for dose constraints of volunteers in biomedical research projects but these also have yet to be established. However, the Medicines Agency (FAMPH) review and approve all clinical trials. The FANC reviews and approves the clinical trials involving ionising radiation. During this approval process justification is addressed. The FANC requests dose estimates from a medical radiation physicist for volunteers in the trials. If required optimisation of doses is sought. FAMPH and the FANC keep each other informed of applications for clinical trials involving ionising radiation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although provided for in Belgian regulations, dose constraints have not yet been established for those individuals who assist in the support and comfort of patients and those who volunteer for biomedical research projects, the regulation is not currently implemented or enforced.*	
(1)	**BASIS: GSR Part 3 para. 3.148 states that** *"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, to enable the requirements of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	paras 3.172 and 3.173 respectively to be fulfilled for: (i) Exposures of carers and comforters (ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research."
(2)	**BASIS: GSR Part 3 para. 3.172 states that** *"Registrants and licensees shall ensure that relevant dose constraints (para. 3.148(a) (i)) are used in the optimization of protection and safety in any procedure in which an individual acts as a carer or comforter."*
R27	**Recommendation: The regulatory body should enforce the legislation applicable to dose constraints for comforters and carers and volunteers in biomedical research.**

QA programmes are required by the regulations to be undertaken for medical radiation equipment. QA programmes must be implemented by the recognised medical radiation physicist (see recommendation below). FANC has compiled criteria of acceptability for equipment in conventional, dental and veterinary radiology. Criteria of acceptability for computed tomography systems, PET cameras, gamma cameras, SPECT cameras and dose calibrators are currently being finalised. Where criteria of acceptability for certain applications are not available, the FANC states the European criteria of acceptability should be used.

Initiatives in optimisation have also been taken in the application of interventional radiology. A round table discussion was held by the FANC with relevant stakeholders in interventional radiology to discuss optimisation aspects such as education and training and techniques to reduce patient doses. The result was a documented 'White Paper' by the FANC which is available on the website and is ready to be discussed with all relevant organisations of practitioners in interventional radiology.

Education and awareness working group sessions have also been held with relevant stakeholders who are involved in the use of ionising radiation outside radiology departments. These resulted in information being circulated on radiation protection for practical use in an operating theatre setting which was based on IAEA guidance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC are proactive in engaging with stakeholders and other interested parties to promote optimisation and radiation safety in the medical sector as is evident in the guidance documentation developed through the collaborative processes of workshops, and roundtables.*	
(1)	**BASIS: GSR Part 1 Requirement 20 states that** *'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".*
GP6	**Good Practice: FANC has an effective policy of stakeholder engagement to promote radiation safety amongst the relevant clinical professions and members of the public. This ensures that guidance documents and initiative programmes are embraced by stakeholders and used accordingly.**

Unintended Medical Exposures

The FANC carried out a review following a major incident involving radiotherapy in 2007 and determined that actions were required in the areas of QA (clinical audit and external dose audit) and incident reporting. As a result, a radiation protection platform was established at the FPS Health group to address these issues. The platform consisted of FPS Health, FANC, the NIHDI and the College of Radiotherapy. The platform submitted a proposal to the National Cancer Plan (NCP) setting out how to address these issues which included establishing incident reporting guidelines for radiotherapy through a collaborative effort with relevant stakeholders. This collaborative effort ensures the guidelines are embraced for use by the relevant parties in radiotherapy. Efforts are also currently being made to encourage incident reporting.

FPS Health has established an initiative of a 'Quality and Patient Safety' contract with hospitals which requires general incident reporting. This is voluntary and internal to the hospital and can include radiation incidents involving patients.

In close collaboration with the FPS Health and the stakeholders, the existing form for "patient related incident" reporting was extended to a form for reporting of all incidents in nuclear medicine and radiology applications. The feasibility of this form is under evaluation by several nuclear medicine departments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulations do not explicitly state that the measuring and monitoring equipment used for QA purposes, health physics, environmental and area monitoring should be calibrated, nor the frequency by which calibration should be carried out.*	
Observation: *Regulations do not require that licensees promptly investigate and report accidental medical exposures.*	
(1)	**BASIS: GSR Part 3 para. 3.170 (e) states that** *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility: Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment".*
(2)	**BASIS: GSR Part 3 para. 3.166 (d) states that** *"In accordance with para. 3.153(d) and (e), the medical physicist shall ensure that: Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
(3)	**BASIS: GSR Part 3 para. 3.179 states that** *"Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures …"*
(4)	**BASIS: GSR Part 3 para. 3.180 states that** *Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.179:* *(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;"
R28	**Recommendation: The regulatory body should establish requirements for licensees to:** - **calibrate all measuring and monitoring equipment at a specified frequency, and traceable to a standards laboratory; and** - **promptly investigate and report unintended or accidental medical exposures.**

Release of patients

The Superior Health Council (SHC), a scientific establishment linked to FPS Health, has established recommendations for patients who have undergone nuclear medicine procedures and radionuclide therapy procedures. The FANC refers to these guidelines on their website. Advice for pregnant and breast feeding women are also included in these recommendations. The SHC carries out research into policy-supporting matters or issues advisory reports.

Review and records

The previously mentioned proposal submitted to the National Cancer Programme (NCP), by the platform, included the development of a clinical audit programme which was established through a collaborative effort with relevant stakeholders. This programme specifies a systematic radiological review of the radiotherapy facilities which is based on the criteria set out in the IAEA QUATRO manual and includes areas such as responsibilities, training and competence, and incidents. The audit programme is a three stage process which includes self-assessment, internal audit and an external audit by a multidisciplinary team of peers set up by the College of Radiotherapy. To date, 10 of the 25 Radiotherapy facilities have gone through this process with the remaining 15 facilities to go through the process in the next two years.

Together with the FPS Health and the stakeholders, a clinical audit programme of nuclear medicine facilities has also been developed based on the IAEA QUANUM Manual. A Belgian version of this manual was elaborated (B-QUANUM), self-assessments and internal clinical audits are ongoing. External clinical audits are scheduled to commence in 2014 by a team established by the College of Medical Imaging.

A programme for clinical audit within radiology applications is currently in the development stage in coordination with BELMIP, a platform initiated by FPS Health. This is being developed using the IAEA QUADRIL manual.

The introduction of clinical audit programmes through the process outlined is another example of the positive action of engagement with stakeholders (Please refer to Good Practice GP6).

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal/regulatory framework

A legislative and regulatory framework has been established to provide for Occupational Radiation Protection through:

- the Law on the Protection of the General Public and the Environment against the Hazards Arising from Ionizing Radiation and on the Federal Agency for Nuclear Control;

- the royal decree laying down the General Regulation for the Protection of the Public, Workers and the Environment against the Hazards of Ionizing Radiation; and
- the Law of Wellbeing of Workers; and
- several royal and FANC decrees on technical issues.

The existing legislation does not use the terminology of exposure situations in terms of 'planned, emergency and existing'. However, the FANC has established a framework for managing doses received in an emergency situation.

Effective and equivalent dose limits for exposed workers, apprentices and students are stated for a period of 12 consecutive months. There is no requirement for the past five years since there is no dose limit (i.e. maximum dose of 50 mSv) that may be received by a worker in one single year. Dose limits are consistent with GSR Part 3, except for the annual equivalent dose limit for the lens of the eye.

There are regulatory requirements to address the cosmic radiation exposure of aircrew. In this case, a reference level of 1 mSv is established for the assessment and recording of doses. Dose records are sent to the FANC by the airline companies. Moreover, there are procedures for the radiation protection of workers against exposure due to radon in workplaces. The reference level for dose assessment is 400 Bq/m^3. The exposure of workers undertaking remedial actions is also controlled according to specified procedures.

The concept of safety culture is not addressed in the legislation. Recognising this, the FANC and Bel V have drafted a road map towards this direction. More specifically, Bel V has developed a guidance document for the nuclear field although first observations suggest safety culture awareness is higher in nuclear facilities than in medical facilities. The FANC is currently assessing the status of the safety culture level in hospitals. The next step is to promote safety culture in these facilities.

According to the legislation, a Health Physics Department (HPD) must be established by the licensee of class I facilities. Amongst its responsibilities is the development and daily management of the radiological protection programme. During the authorization of such facilities, the occupational radiation protection framework of the facility is reviewed and assessed. Class II and III facilities are also obliged to have an HPD; however, operators of such facilities have the option to contract out this service to an external company. The FANC authorises external AIOs to perform periodic controls (trimestral controls for facilities of class II and annual controls for class III). In this situation, the external HPD and the AIO are usually one and the same, but adopting different roles. Thus, this potentially gives rise to a conflict of interest and the allocation of responsibilities is confusing and sometimes not clear even to the licensee (see recommendation R5).

All recommendations concerning compatibility with GSR Part 3 are formulated at the end of the chapter.

General responsibilities of registrants, licensees and employers

According to legislation the responsibilities of licensees, employers and registrants with regard to occupational exposure are limited to medical and dosimetric surveillance and the arrangement of an HPD. Regulations require that occupational protection and safety is optimised and that exposures are kept as low as reasonably achievable. However, the use of dose constraints in the optimization process is not provided for in the legislation. Currently, dose constraints are not used by operators as a tool to keep doses as low as reasonably achievable.

The use of protective equipment is mentioned in the legislation but there is no clear statement about the provision of facilities, services and equipment commensurate with the expected magnitude and likelihood of occupational exposure. Legislation also makes provision for dosimetry services as well as the training and continuous development of ionising radiation workers.

The FANC approves the educational background for medical doctors, occupational physicians and health physics experts in the radiation protection area.

There is provision in the legislation for the notification of pregnancy and the adaptation of working conditions in case of pregnancy.

All recommendations concerning compatibility with GSR Part 3 are formulated at the end of the chapter.

General responsibilities of workers

All workers, as well as outside workers (i.e. workers engaged in work that involves a source that is not under the control of their employer), are required to comply with relevant regulations by following rules and procedures for protection and safety specified by the HPD or AIOs. However, necessary cooperation between workers and licensees with respect to safety and protection is not clearly provided for in the legislation. Moreover, it is not clear that workers have to provide their employer with information on their past and current work with respect to radiation dose/protection. There is currently no national dose register (various separate records are kept by several organisations and by operators). The requirement that past and current exposure data of outside workers should be provided to the operator appears to be met. However, despite the existing provisions, procedures for managing such dose records are not always applied in a harmonised and integrated way such that outside workers can readily provide the necessary information.

Requirements for radiation protection programmes

Licensees are required to designate relevant areas as controlled or supervised and to establish the necessary procedures for controlling exposures. The requirement to have a suitable storage area for personal clothing at the entrances of controlled areas appears to be met. Information and training are provided to occupationally exposed workers by the licensee as it is described in the legislation. The HPD or employer (at their own expense) must ensure the provision of dosimetry monitoring and personal protective equipment.

Occupationally exposed workers must wear dosimeters on their chest. The intake of radioactive substances or committed doses must be assessed for any worker who may be exposed to radioactive contamination. The results of the individual monitoring are reviewed by the HPD and are sent to the medical department. Health surveillance programmes must be based on general principles of occupational health and designed to assess the initial and continuing fitness of workers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *According to legislation exposure records shall be kept. There is an obligation of employers to send hard copy dose records to the Ministry of Employment annually. The establishment and management of a national dose register is currently being transferred to FANC. Since 2009, in parallel to the annual submission of hard copy dose records to the Ministry of Employment, the records are transferred electronically to FANC by HPDs on a voluntary basis. FANC has been developing a dose register but the project is currently on hold. In the interim, a temporary system is being used to manage dose data. Reviewing the dose history of a worker is possible using the temporary system but not in a straightforward way. In addition, given the annual frequency of transfers, the dose records are not up to date. Finally, it is difficult to produce statistics and to proactively detect instance where dose limits are exceeded.*	
(1)	**BASIS: RS-G-1.1 para. 5.78 states that** *"Dose records should be kept up to date and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	procedures should be established to ensure that assessments of dose from any monitoring period reach the individual's dose record promptly."
(2)	**BASIS: RS-G-1.1 para. 5.79 states that** *"The individual occupational exposure record should be uniquely linked to the worker and should enable the appropriate summation of external and internal doses."*
(3)	**BASIS: GSR-Part 3 para 2.35 states that** *"The regulatory body shall make provisions for establishing, maintaining and retrieving adequate records relating to facilities and activities. These records shall include:* - *records of doses from occupational exposure."*
S23	**Suggestion: The regulatory body should consider establishing and maintaining a national dose registry for the doses received by occupationally exposed workers.**

Monitoring programme technical services

Individual dosimetry services must be approved by the FANC. However, the approval criteria described in the FANC decree are only for dosimetry services performing external dosimetry. No criteria exist for internal dosimetry. The relevant project to address this shortcoming is under development by the FANC. No criteria exist for calibration services.

There are no requirements for dose record keeping services. The FANC is considering establishing a national dose register. This project is still under development (see suggestion above)

No workplace monitoring services exist and no relevant procedures for their approval by the competent authority are described in the regulations.

Training and continuous education programmes for auxiliary staff (e.g. nurses, radiographers) are evaluated by the FANC. Programmes for continuous education are announced using the FANC website.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *Effective and equivalent dose limits for exposed workers, for apprentices and students are consistent with GSR Part-3, except for the dose limit of the eye lens, which at 150 mSv exceeds the 20mSv limit established in GSR Part-3.*
Observation: *Though the principle of optimization is described in the legislation the establishment of dose constrains is not addressed at all. The establishment of dose constraints is described as a task of the HPD in the legislation which is currently under revision.*
Observation: *Legislation does not clearly provide for dose assessment where individual monitoring is inappropriate, inadequate or not feasible. In the legislation the HPD shall determine and characterize the radiation field and the possible contamination of workplaces. Workplace monitoring is not a requirement. Legislation thoroughly describes licensees' individual monitoring obligations, whereas workplace monitoring is not described at all.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Schedule III-1 states that** *"For occupational exposure of workers over the age of 18 years, the dose limits are: … (b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year"*
(2)	**BASIS: GSR Part 3 III-2 states that** *"For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:* - *(b) An equivalent dose to the lens of the eye of 20 mSv in a year"*
(3)	**BASIS: GSR Part 3 para. 3.25 states that** *"For occupational exposure and public exposure, registrants and licensees shall ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety for any particular source within a practice"*
(4)	**BASIS: GSR Part 3 para. 3.98 states that** *"Registrants and licensees, in cooperation with employers where appropriate, shall maintain records of the findings of the workplace monitoring programme. The findings of the workplace monitoring programme shall be made available to workers, where appropriate through their representatives."*
R29	**Recommendation: Government should revise the current legal and regulatory framework to bring it in line with the requirements for:** **i. Equivalent dose limit for the lens of the eye.** **ii. Use of dose constraints as part of the optimization process.** **iii. Establishment of workplace monitoring programmes.**

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

Radiological protection of the environment is governed by the Law of 15 April 1994 (FANC Law) and the General Regulations in the decree of 2001 (GRR 2001). Class I facilities and a subcategory of class II facilities are required to provide an environmental impact assessment report. Further, the licences for class I and II facilities may include specific conditions with respect to the protection of the environment, e.g. limits for liquid and gaseous releases, environmental monitoring.

Section IV of Chapter III of the GRR 2001, which deals with radioactive waste, prohibits the release of liquid radioactive waste into surface waters, soil, sewers or underground conduits and prohibits the discharge of radioactive substances into the atmosphere in the form of gas, dust, smoke or vapour, when their radioactivity exceeds generic release limits given in Annex III of the GRR 2001. It also provides for clearance of solid waste; clearance levels as given in Annex IB (taken from EC - RP 122, Part 1).

Radioactivity on the Belgian territory is monitored continuously by the automatic TELERAD network; the results are made available to the public on the website www.telerad.fgov.be. The FANC also conducts national radon monitoring and the results are publicly available via the FANC website.

The FANC undertakes environmental monitoring in the vicinity of authorised sites. The sampling covers soils, rivers, coastal areas, food chain and discharges. The results are published in the annual "Radiological Monitoring in Belgium" summary reports.

Whilst no specifications recommendations are made in this section the reader is referred to the recommendation on calibration of monitoring equipment (Recommendation R28 in module 11.1).

11.4. SUMMARY

The IRRS team considers that the FANC meets the requirements with respect to regulatory control of medical exposures, although some shortcomings were identified. Recommendations are made in the area of dose constraints, incident investigation and calibration requirements of measuring instruments. It is also suggested that a coherent approach to the regulations establishing the appropriate staffing levels in medical facilities to ensure optimal safety be adopted.

The IRRS team concluded, following a policy discussion on justification, that the Government should consider developing a national policy on the justification of individual medical exposures to address the concern over the population dose attributed to medical applications and the documented results of the recent College of Radiology audit.

It is also acknowledged that it is not always possible to separate radiation protection of patients from general patient protection and therefore several authorities will have a role. It is therefore recommended that the responsibilities of all relevant parties is established and captured in the regulations as outlined in Module 1 (See Recommendations R5 and R9).

This module should also be read in conjunction with recommendations made on evaluating resources to ensure the regulatory body can effectively discharge its duties, adopting a graded approach to authorisation of medical practices and on stipulating inspection frequencies for the different medical applications commensurate with the associated risks. (See Recommendations R11, R22, and Suggestion S3). Consideration is given to formalising the process of confirming final authorisation of medical facilities prior to first clinical use following the commissioning process. Due to the extensive number of medical licensees, consideration should be given to determining if efficiencies could be achieved through the use of an appropriate IT solution (Please refer to Suggestion S11).

The legislative framework regarding occupational radiation protection is in place. However, there is a difference in the definition of planned, emergency and existing exposure situations with respect to the requirements of GSR Part 3, in particular for the issues of the equivalent dose of the lens of the eye, use of dose constraints and workplace monitoring programmes. The development of a national dose register will ensure the dose records are kept updated and uniquely linked to workers.

The arrangements for the control of public and environmental exposures are well defined and effective. The environmental surveillance programmes show that the releases from authorised facilities are low and within the established regulatory limits.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

General legislation and regulation

The following legal acts provide the basic legal framework for regulation of nuclear safety and security as well as the accounting for, and control of nuclear material activities:

- the Law of 15 April 1994 on the protection of the population and environment against the hazards of ionizing radiation and on the Federal Agency for Nuclear Control;
- the royal decree of 20 July 2001 laying down the "General Regulations regarding the protection of the public, the workers and the environment against the hazards of ionising radiation (GRR-2001);
- the OOP36 ministerial instruction of 2003 on response to security at class I facilities;
- the royal decree of 30 November 2011 on the Safety Requirements for Nuclear Installations (SRNI-2011);
- four royal decrees of 17 October 2011. They address categorization and protection of documents, physical protection of nuclear materials, nuclear installations and transport, categorization of nuclear materials and definition of security zones in nuclear installations and nuclear transport organizations, security clearances and certificates, and regulating access to security zones, nuclear material or documents in specific circumstances; and
- the legislation and regulation regarding the application of Safeguards in Belgium.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Some elements of a legal framework for oversight and enforcement of security arrangements needed for maintaining safety are in place but the regulatory framework does not provide a comprehensive set of requirements on implementation of safety and security measures in an integrated manner and further efforts to address the safety and security interface are needed.*	
(1)	**BASIS: GSR Part 1 para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;* *(b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;* *(c) Liaison with law enforcement agencies, as appropriate;* *(d) Integration of emergency response arrangements for safety related and nuclear security related incidents."*
R30	**Recommendation: The regulatory body should ensure that its management system takes due account of safety and security interface and that such interface is more explicitly addressed when drafting new or amended regulations.**

Safety and security of radioactive sources

Belgium made a commitment to follow the recommendations of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. However, some provisions of the Code are not yet adequately

reflected in Belgium regulations: GRR-2001 only provides some requirements for security measures against theft, loss and diversion but not sabotage. In addition, Belgium did not commit to use guidance on import and export of radioactive sources. Presently, in addition to licensing the transport of radioactive sources, the FANC has a role in regulating the import of sources into Belgium. Oversight of sources export is currently managed by Belgium's three Regions.

Recognizing this, the FANC has initiated preparation of regulations strengthening the security measures in this regard. The legislation and regulations currently drafted provide for a verification of the security requirements through regular security assessments, verification of compliance and maintenance of records. Draft regulations related to the export of radioactive sources are also under development. For the time being, the FANC includes security requirements in the conditions of the licence for some activities (such as industrial radiography or transport of radioactive material).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *GRR-2001 set provisions to prevent theft or loss of radioactive sources. In the self-assessment performed in preparation of this IRRS mission, FANC recognizes the need for several updates of regulations to better address security of radioactive sources.*	
(1)	**BASIS: GSR Part 1 requirement 12 states that** *"The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material."*
(2)	**BASIS: GSR Part 3 para 2.27 states that** *"The government shall ensure that infrastructural arrangements are in place for the interfaces between safety and the security of radioactive sources."*
(3)	**BASIS: Code of Conduct on the safety and security of radioactive sources, para. 18 (d), states that** *"Every State should have in place legislation and regulations that:* *(d) specify the requirements for the safety and security of radioactive sources and of the devices in which sources are incorporated."*
(4)	**BASIS: Code of Conduct on the safety and security of radioactive sources, para. 19 (g), states that** *" Such legislation and/or regulations should provide for, in particular:* *(g) requirements for security measures to deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources during all stages of management"*
R31	**Recommendation: Government should amend regulations with regard to improving the security of radioactive sources.**

12.2. REGULATORY OVERSIGHT ACTIVITY

Since 2003, the legal competences of the FANC were broadened to include the security of installations where nuclear material is produced, used or stored. Having the FANC responsible both for safety and security oversight is a key infrastructural arrangement within the governmental framework to foster a coherent approach between safety, security and safeguards matters within the Belgian nuclear

installations. This should make it easier to develop appropriate interfaces in regulations, licensing and inspection.

Licensing class I facilities

The current national legislation and regulations for safety do not have provisions for an interface between safety and the security obligations during the licensing process of nuclear installations, although for the new installations (Myrrha, surface repository for radioactive waste) pre-licensing phase, a joint approach is followed in practice resulting in a FANC document stating regulator expectations with regard to safety, security and safeguards.

Within the FANC, safety and security reviews are performed separately. The security review is fractioned into working groups where BelV is usually involved to look at safety and security implications. Before the security review is complete, the security review process foresees a wrap-up meeting where BelV attends to bring in its safety expertise.

In practice, after the safety review is completed and before the Scientific Council opinion is requested, the FANC department in charge of the security review confirms that there is no security issue which would prevent authorization.

Licensing of class II and III facilities

The 2011 royal decrees are not applicable for class II and III facilities and only the GRR 2001 requirements apply.

In practice, the FANC inserts in the licence for industrial radiography and for transport of radioactive materials conditions related to security. These conditions demonstrate that the safety/security interface was considered.

Inspection and reportable events

There are dedicated FANC inspectors responsible for security inspections. Occasionally, joint safety/security inspections may take place:

- KTM inspections at facilities where fissile material is present. 6 inspections of this types were performed in 2012 following a safety event;
- FLITS inspections (fast limited inspection with thematic scope) was performed at Belgoprocess in 2012 with a follow-up in 2013.

The KTM inspection process is described in FANC`s management system documentation (FANC note) and clearly requires a team of inspectors with safety and security expertise. Its purpose is to check whether adequate safety, security and safeguards provisions are in place and, if modifications to the facility are needed, that such modifications will support both safety and security.

FANC guidance on events to be reported by authorized parties addresses both safety and security events.

Emergency preparedness and response

FANC's expectation is that emergency preparedness and response provisions directed at security events have to be encompassed in the emergency plan of the operator. Such expectation was formalized in a guidance document.

Security emergency preparedness exercises are performed as required by OOP36. Safety emergency preparedness exercises are performed as required by the 2003 royal decree setting Belgium nuclear

emergency preparedness and response plan requirements.

Occasionally, exercises having both safety and security implications are performed and have involved the licensee, local authorities and FANC security department.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Joint safety and security emergency preparedness exercises involving both FANC emergency preparedness and security departments, as well as other interested parties as BelV or local law enforcement authorities, have not yet taken place.*	
(1)	**BASIS: GSR Part 1 para 2.39 (d) states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(d) Integration of emergency response arrangements for safety related and nuclear security related incidents."*
(2)	**BASIS: GS-R-2 para 5.16 states that** *"The plans for response to a nuclear or radiological emergency shall be coordinated with any other plans (such as plans for physical security, law enforcement or fire fighting) that may be implemented in an emergency in order to ensure that the simultaneous implementation of the plans would not seriously reduce their effectiveness or cause conflicts"*
S24	**Suggestion: The regulatory body should consider performing safety and security exercises simultaneously to test emergency preparedness and response provisions set in both the 2003 royal decree and OOP36.**

12.3. INTERFACE WITH OTHER AUTHORITIES

On security topics, there are interfaces with other federal public services (FPS). In particular, the FANC has cooperation arrangements or agreements with:

- FPS-Economy/Energy (accounting for and control of nuclear material);
- Federal police services;
- National Crisis Centrum of the Government;
- FPS-Justice(security): OCAD (threat assessment, including nuclear design basis threat), NVO (critical infrastructure, confidential information protection).

12.4. SUMMARY

The legal and regulatory framework provides clear responsibilities in security and safety areas but could be further improved by ensuring that the FANC management system takes better account of safety/security interface and that such interface is more explicitly addressed when drafting new or amended regulations. The IRRS team concluded that FANC initiated steps to better manage the safety/security interface, both at the regulation level and in FANC implementation with regard to licensing, inspection and emergency preparedness exercises. The FANC is encouraged to take proactive steps to continue improving on the safety/security interface.

The FANC initiative to update national regulations to better address security of radioactive sources should be completed.

The IPPAS mission scheduled in 2014 will also be an opportunity to review Belgium nuclear security

regulatory framework.

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

13.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

FANC response to the accident

Since no immediate impact on Belgium was foreseen after the TEPCO Fukushima Dai-ichi accident, Belgian authorities did not see the necessity of initiating a nuclear emergency state following the accident. Yet a crisis unit consisting of about ten FANC experts was called together on March 14 in the FANC Crisis Centre in order to analyse the accident situation and its possible consequences. This FANC crisis unit dealt primarily with the follow-up of measurements of radioactivity, recommendations on import controls and travel constraints and providing answers to the numerous questions from Belgian media, political authorities and the general public.

Information forming the basis of this evaluation originated from various international sources like the IAEA Incident and Emergency Centre, IRSN France, the Embassy of Japan in Brussels and various news agencies.

Experts of the FANC were participants of the meetings organized in the National Crisis Centre that were meant to advice officials of Ministries of Home Affairs, Economic Affairs, Public Health and Foreign Affairs. These meetings were held until the end of August 2011, first with a frequency of 2-3 times a week, later on less frequently.

The primary goal of the work by the FANC crisis unit was the production of synthesis reports that collected facts and evaluations about the amount and isotope distribution of the radioactivity released from the damaged plants, on the projected paths of radioactivity (based on meteorological data obtained from the Royal Institute of Meteorology) and on measured airborne and deposited radioactivity values. The reports also included recommendations on import controls and travel constraints.

In specific, FANC in cooperation with the Federal Agency for the Safety of the Food Chain played a role in the radiation control of food products originating from Japan. Similarly, in conjunction with the Custom Services and harbour authorities, FANC experts took part in the control of radioactivity of five selected shipments arriving to various harbours in Belgium. In none of the above cases was significant radioactive contamination found. Surface contamination of several thousand containers arriving to two Belgian harbours was measured, 17 out of which were found slightly contaminated and had to be decontaminated.

Goods arriving from Japan were inspected with increased intensity by the end of 2011, after that the normal inspection practice was resumed.

The FANC kept providing advice and recommendations to airports and harbours in Belgium as well as to the Belgian representations in the Far East region. Similarly, recommendations were given by FANC to crews of ships and airplanes entering the area affected by the accident. Belgian citizens returning from Japan after the accident were offered to participate in contamination control examinations. No excessive contamination was found in these cases. Citizens remaining in Japan were provided with advice on travels and possible countermeasures.

On March 11, the FANC decided that the radiological monitoring (air sampling) facilities at Doel, Tihange, Mol, Fleurus, Lixhe and Brussels shall be used in an enhanced radioactive monitoring programme to detect any possible consequence on Belgium of the accident. Monitoring of air dust, of air iodine content, of radioactive deposition on soil and of grass samples was ordered. The monitoring programme was continued until early May 2011. The measured results have shown no significant radioactivity present, the radioactivity concentrations observed were in the order of the detection limits.

Accordingly the programme concluded that no specific precautionary steps were needed and no environmental or health risks were expected in Belgium.

An incidental coincidence with the accident was that on March 14, 2011 the Belgian authorities initiated a new campaign for preventive distribution of iodine tablets. The distribution was performed within one month and the inhabitants of Belgian municipalities located within 20 km from major Belgian or near-border nuclear installations (with the exception of the IRE site in Fleurus for which the radius was limited to 10 km) were invited to collect free stable iodine tablets from their local pharmacy.

FANC communication activity

From the day of the accident, the FANC provided information to the general public through its website. This includes both reports and communication from the FANC and answers to questions submitted by readers. The number of questions by website was higher by a factor of about three in March-April 2011 relative to the entire years of 2009 and 2010, thus indicating the increase of interest by the public. Most naturally the most intensive questioning period was in March 2011, when almost 100 questions were registered, yet during the fall period of 2011 the number of questions stayed at around 30. Note that the website was not the only possibility of posing questions to the FANC; questions arrived also by telephone, mail and e-mail.

Citizens were frequently inquiring in connection with their travel arrangements or related to goods originating from Japan.

The FANC website had an extraordinary number of almost 80.000 hits in March 2011 while this number was around 10.000 in the previous months.

The Director General and the spokespersons of the FANC had frequent appearances in the media. Presence of the FANC in the written press increased by a factor of five in March – April 2011 as compared to the respective value in the entire year of 2010. It is worth noting that even the Belgian Parliament dealt with 42 questions directly related to the accident.

Change of Belgian public opinion after the accident

A public opinion research was conducted in May-June 2011 with a representative sample of 1022 persons that was in fact the fourth such research conducted to obtain data on the risk perception and confidence in authorities of the Belgian population. The results show a marked influence of the accident on the public opinion in almost all aspects related to nuclear safety. For example, the fraction of answers expressing very high or high risk perception of nuclear accidents in Belgium increased to 34% in 2011 from 20% in 2009. In the question whether the accident in Japan has relevance to Belgium the respondents were very much divided, yet the overwhelming majority (78%) of the respondents felt that all possible risks from nuclear installations can never be predicted.

The opinion of the public on nuclear energy has also changed after the accident. While in 2009 32% were totally or rather in favour of it, the corresponding number in 2011 was 18%. In line with that the fraction being totally or rather against nuclear energy changed from 24% to 45% from 2009 to 2011.

An interesting part of the poll deals with the trustworthiness and technical competence of the main actors in the nuclear field. These qualities were rated by the responders between 1 and 5 (5 means the highest satisfaction). The results show that in both qualities scientists from universities are rated the highest (competence ~ 4.1, trustworthiness ~3.6), but all IAEA (4.0, 3.3); SCK-CEN (4.0, 3.3); FANC (3.8, 3.1) and Bel V (3.4, 3.1) are in the range above the median values (3.0, 3.0). Related to these results, the values for how much the actors are known among the public have also been measured. Although these values increased somewhat since 2009, in some cases they are still rather low. Thus the ratios of the responders who know of IAEA, the FANC or Bel V were 19%, 15% and 5%, respectively.

The public opinion review was also extended to the acceptance of the iodine tablet distribution campaign. According to the results, a large majority (74%) of the responders thought that the distribution was a good idea and more than 90% would take the tablets if the authorities so advise.

13.2. TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT

Early safety measures – the "Quick Wins"

Probably in conjunction with the early suggestions by WANO, the Belgian nuclear operator initiated an overview aimed at determining measures and actions to be taken at the Belgian NPP sites that may increase safety with regards to and decrease the vulnerability by events similar to what happened in Fukushima. These early measures were called "Quick Wins" referring to fast positive results expected from them. The actions were typically designed in the period of April to June 2011 and implemented between April and July 2011, although some of them needed longer periods of time or are even now in progress.

In order to characterize the nature of such interventions, the IRRS Team was made acquainted with the actions taken at the Tihange site. A large portion of the measures and actions represent countermeasures against potential flooding and station blackout. Some of the actions related to flooding take advantage of the relatively long time between the "pre-alert" phase of the event and the appearance of its effect at the site. The FANC and Bel V representatives also emphasized to the IRRS Team that the implementation of the Quick Win actions and further actions were very efficient by active involvement of shift supervisors of the plant thus ensuring that practical solutions best adapted to the technical possibilities and constraints of the units were selected during implementation.

In the case of Tihange, the maximum expected flow rate of the river Meuse has been reassessed in the framework of a periodic safety review with the result coming in the beginning of 2011, just before the Fukushima accident. The results showed that the flooding issue was much more important than evaluated in the original design basis. As a consequence, a number of quick wins have been designed and realised, while other (long term) actions were studied. Thus a small wall around the water channel besides the plant has been elevated. Simple yet effective solutions were introduced to provide auxiliary and alternative cooling mechanisms of the core, of the steam generator and of the spent fuel pool for the case of loss of power or conventional cooling means. For this purpose inlet pipes that can be mounted relatively fast on valves or into the auxiliary feedwater line have been manufactured and alternative cooling water routes (e.g. using the fire protection lines or flexible temporary connections) were defined. Emergency diesel generators with safe control panels and specific lightings were installed at sites safe from potential destruction. Use of mobile pumps and mobile diesels generators for providing emergency electrical power are also part of these quick solutions

Bel V held an inspection on 7 September 2011 where the status of the Quick Win solutions was reviewed, discussed and inspected. During this inspection Bel V stated that the decision-making process, the implementation of changes and updating procedures as well as the related training appear to have been conducted with rigor and according to the modification process usually followed.

The Stress Test exercise for NPPs

In line with the initiatives by the European Commission and the European Nuclear Safety Regulators Group (ENSREG), Belgium participated in the targeted safety re-evaluation of its nuclear power plants called the "Stress Test". By definition the Stress Test 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. The re-evaluation process included all operating NPP units in Belgium together with their spent fuel pools as well as the dedicated spent fuel storage facilities (also situated at the sites). Beyond the scope defined by ENSREG, the Belgian regulatory body required the completion of stress test exercises for the major non-power plant nuclear facilities in Belgium as well as the extension of the NPP stress tests on man-induced events. The results of these assessments shall be briefly discussed in the next sub-section.

Conclusions given by the Belgian utility in the reports on the stress test exercise were evaluated by the FANC and Bel V based on their knowledge of the installations, available documentation, information exchanged during technical meetings with the utility and comprehensive inspections held in December 2011. Based on the evaluation results the regulatory body determined additional requirements to those proposed by the utility in the stress test reports. The Belgian National Report on the stress test includes all the above results.

The general conclusion of the stress test process as given in the National Report is summarized as below: "*the stress test assessment revealed that the facilities of the Tihange and Doel nuclear power plants are capable of maintaining their essential safety functions… the facilities are robust enough to face extreme conditions* …" The stress test assessments, however, identified a number of possibilities for further enhancing the robustness of the power plants against such unlikely situations that lead to the TEPCO Fukushima Dai-ichi accident. Some of these conclusions shall be quoted below along with the relevant additional requirements set by the regulatory body.

Concerning protection against earthquakes the assessment proved that at a high confidence level, following a few reinforcement actions, all systems, structures and components important for reaching and maintaining a safe shutdown state of the units are robust enough. The regulatory body required a detailed action plan on the reinforcement actions, repetition in more details of already performed seismic-hazard studies and strict application of certain procedures related to activities having potential effect on seismic resistance.

In the flooding analysis the design basis values of both sites were reviewed and revised. Protective measures have been initiated and started, yet it is also understood that any potential flooding process is slow enough to allow sufficient time for the operator to provide the necessary means for putting the units in a safe state. The regulatory body indicated the need for several specific further actions all contributing to the increase of safety margin and enhancing the robustness of the various countermeasures (new peripheral site protection, non-conventional protective means, emergency preparedness, organization, procedures, prevention of consequential internal hazards) against flooding phenomena.

According to the stress test results, extreme weather conditions may not compromise the safety of the Belgian NPPs. The regulatory body requested further investigations related to the resilience against heavy rains and tornados.

In the subject of loss of safety functions (electrical power supply and ultimate heat sink), the stress test identified the existence of several redundant, independent heat sinks at both plants which make cooling of the reactors and spent fuel pools fairly secured, yet further measures are foreseen for additional possibilities for providing cooling water, while the regulatory body requested evaluation, justification and tests in several particular issues related to the enhancement of providing supplementary and non-conventional cooling.

Similarly the number, redundancy and diversity of power supply mechanisms in the plants ensure safe and reliable power input even in extreme circumstances. Nevertheless further emergency power supply devices as well as additional ways of recharging batteries are being implemented at the units. The regulatory body further required a feasibility study on the possibility of physical separation of high

voltage power supply lines, investigations related to the potential risk of steam-generator draining or overfilling as a result of the loss of ultimate compressed air, reinforcement of emergency lighting at sites used by operators during emergency as well as investigation of the possibility of retaining containment isolation during a station blackout.

In the fields of emergency preparedness and response and severe accident management, the stress test report foresees a number of important actions as direct consequences of the lessons learned from the accident. In fact, the Belgian utility and regulatory body have realized that they are not prepared to cope with an emergency situation affecting several NPP units in parallel; they might face problems with handling emergencies extending over several days or longer and also extreme external conditions may adversely affect or may make unavailable certain emergency preparedness facilities. Accordingly the stress test exercise determined a number of actions to perform, including but not limited to: moving the Tihange operation centre to seismically resistant and flooding-proof location; establishing an off-site emergency operating centre for the Doel site; and assessing the possibility of enhancing the capability of the emergency management organization. For severe accident purposes, further investigations and assessments were decided on the feasibility of filtered venting of the containment, on hydrogen production risks and in the corium-concrete interaction research area. The regulatory body determined that the procedural guidance in severe accident management should be enhanced in a number of definite areas. Further particular actions requested by the regulatory body are aimed at enhancement of devices, means and methods to be used during severe accidents and also increasing the consistency between the emergency training programmes in the two sites.

The actions resulting from the stress test exercise have been summarized in a National Action Plan (NAcP) and submitted and evaluated by international (ENSREG) peer review. Details of the action plan are given in the next section.

Assessment of safety of non-NPP facilities and of consequences of man-made events

At the request of the Belgian Parliament the Belgian nuclear safety regulator required the operators of class I nuclear facilities to perform a safety re-assessment of their facilities in line with the stress test requirements set for the nuclear power plants. These facilities are

- L'Institut National des Radioéléments (IRE) at Fleurus, a public utility foundation that produces radioelements used for diagnoses and therapeutics in nuclear medicine, including an interim waste storage.
- Belgoprocess at Mol-Dessel storing and processing low, medium and high level activity radioactive waste originating from the nuclear power plants and all Belgian nuclear and industrial facilities;
- The Belgian Nuclear Research Centre (SCK-CEN) at Mol operating several research and experimental reactors and facilities for processing nuclear fuel and highly radioactive material, radiochemistry laboratory and interim waste storage;
- The Institute for Reference Materials and Measurements (IRMM) at Geel operating several research laboratories and particle accelerators;
- Franco-Belge de Fabrication du Combustible (FBFC) at Dessel that operated MOX fuel fabrication facilities;
- The solid and liquid waste storage and treatment facility (WAB) at the Doel site.

The assessments covered the following topics:

- Fundamental safety functions (control of reactivity, provision of residual heat sink, confinement of radioactivity)
- Earthquakes
- Flooding
- Extreme meteorological conditions
- Forest fire
- Aircraft crash
- Presence of toxic gases
- Gas explosion and shock-waves
- Cyber-attack
- Loss of power supply and loss of cooling
- Severe accident management

Detailed investigation of these topics would fall outside the scope of the IRRS mission; nevertheless it is worth quoting the major conclusions of the stress test exercise. Accordingly, the evaluations performed in the framework of these tests have demonstrated that in the majority of the circumstances investigated the installations that underwent the test are capable to preserve nuclear safety due either to their redundant and diverse safety equipment implemented during their construction or to the mobile devices available at the sites. All participants have formulated proposals on safety enhancement to convert the facility to be even more robust against extreme conditions. The planned actions cover a large area including completion of on-going investigations or implementation of modifications; initiation of novel studies of possible further modifications; organizational changes and updating procedures.

It has to be noted that currently the FANC is conducting the review of the safety case of the near-surface disposal facility. This review will take into account the lessons learned from the TEPCO Fukushima Dai-ichi accident as well as the conclusions of the stress test performed for the non-NPP facilities.

The Belgian NPP stress test programme was extended by the evaluation of possible consequences of man-made events to supplement the exercise required by ENSREG. The evaluation covered the following events:

- Accidental or intentional aircraft crash
- Presence of toxic or explosive gases and shock-waves
- Cyber-attacks

The evaluations were carried out by the utility for the nuclear power plant sites. In case of aircraft crash the licensee's reports state that the newer units are able to withstand the impact of such an event, the containment of the older ones may be damaged but this does not necessarily lead to damage in the primary, circuit. While the regulatory body requested further developments in improvement measures related to mitigative means, further countermeasures are being studied or implemented in the emergency plans and procedures and in preparation of mitigation guidelines.

For the events of toxic, explosive gases and shock-waves, the licensee initiated a number of actions to protect workers while the regulatory body requested further measures to ensure continued habitability of the control and emergency rooms; to perform further analyses of the consequences of such events and to enhance environmental monitoring and detection of gases.

The results of the analysis by the utility of possible consequences of a cyber-attack state that cyber-attacks cannot represent any threat whatsoever on the operation if the NPPs as the IT systems relevant for safety of the plants are either fully isolated from the outside world or as safety systems use analogue techniques.

However, as new IT technologies are increasingly used, the regulatory body requested an external independent IT-security audit to verify the related risk-reduction measures taken by the utility.

The information related to the National Stress Test Reports discussed above is fully available on the website of the FANC.

CONCLUSION [1]

The IRRS Team considers that FANC and Bel V took appropriate actions in order to cope with the implications of the TEPCO Fukushima Dai-ichi accident. FANC and Bel V were effective and efficient in public communication as well as in the management of the stress test process. The Belgian initiative to extend the stress test exercise to class I non-NPP facilities and to man-made effects is to be commended.

13.3. 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 and was issued on 14 December 2012. It contains the licensee's actions resulted from the stress test exercise of the Belgian nuclear power plants. The IRRS Team was informed that this plan is a living document: it is subject to changes resulting from the continuous assessment by the safety authority, the conclusions of the utility's own evaluations and the actual implementation conditions. Currently it contains about 350 actions some of which are interconnected and/or interdependent.

The major actions in the NAcP all relate to the licensee, no action is foreseen for the FANC or Bel V. The actions are grouped into seven groups ("families") including enhancement of

- protection against external hazards;
- power supply;
- water supply;
- operation management;
- emergency management;
- protection against severe accidents and
- non-conventional means of protection.

Many of the actions are relevant for both plants, e.g. alternative power supplies; minimizing diesel consumption; introduction of specific operational procedures; design and implementation of filtered venting; R&D related to corium-concrete interaction. With a few exceptions, all major actions were due to be completed by the end of 2013. The IRRS Team was informed that due to the tight planning schedule during the stress test process not all the conditions and needs of some of the actions could be fully taken into account in planning, therefore targeted completion dates are continuously re-evaluated. Actually a few of the actions are estimated to be delayed by 3 – 5 years. The regulatory body requested the licensee to speed up certain activities or, if this is not possible, to provide justification for the delays, to implement temporary solutions as compensatory measures, and to analyse potential planning risks.

The IRRS Team was informed that the regulatory system in Belgium had undergone a change not long before the TEPCO Fukushima Dai-ichi accident that resulted in an organization and working method which otherwise is implied by the lessons learned from the accident. According to the FANC, this is why they saw no reason to introduce further changes into the nuclear and radiation safety regulatory regime of

Belgium. The FANC will however start a regulatory project to include the new WENRA reference levels related to the Fukushima accident in the Belgian regulatory framework.

The IRRS Team was acquainted with the IT tools applied in following and supervising the implementation of the stress test actions in NAcP. An Excel database maintained by the licensee contains all important details on the action plan and is meant to keep track of the progress of the actions, status, delays and risk analysis of future actions. An Access database is used by Bel V for the management of the project related to the NAcP.

The IRRS Team was also informed that the FANC and Bel V held an inspection in mid-2013 related to the completion of the actions identified by the stress test. Inadequacy and non-effectiveness of the training of operational and control room personnel in using the new procedures to cope with extreme circumstances were identified.

CONCLUSION [2]

The IRRS Team concludes that FANC and Bel V initiated a thorough re-evaluation of the safety of all major nuclear facilities in Belgium. The results of the re-evaluations were systematically assessed and actions that may further enhance the nuclear and radiation safety in the country were determined and scheduled for realization by the licensee in an Action Plan. FANC and Bel V are determined to supervise the actions in the Action Plan.

The IRRS Team considers that delays in actions foreseen by the National Action Plan may suggest to FANC and Bel V to consider a revision of the target dates of completions in the plan in order to obtain a firm and well founded system of target dates.

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. Nevertheless FANC and Bel V should consider developing a plan of actions to be performed by the regulatory body as a response to the lessons learned from the accident.

13.4. 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 Belgium to further address TEPCO Fukushima Dai-ichi issues in the coming years should be included in the scope of the follow-up IRRS mission to be invited by Belgium.***

Module 1: Responsibilities and Functions of the Government

The 2003 royal decree defines Belgium's nuclear emergency plan. This plan includes a description of the duties and responsibilities of the various organizations (ministers, national crisis centre, FANC, Regional, provincial and municipal authorities…) having roles in a nuclear emergency situation. Following the TEPCO Fukushima Dai-ichi accident, the Minister of Home Affairs, responsible for emergency preparedness and response, announced that this plan would be revised.

CONCLUSION [3]

The IRRS Team did not identify any element regarding the responsibilities and function of the government, which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. The need of revision of the Belgian nuclear emergency plan has been recognized.

Module 2: Global Nuclear Safety Regime

Belgium is a contracting party of relevant international treaties and conventions that establish common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and radiation for peaceful purposes and that provide for an effective coordinated international response to a nuclear or radiological emergency, including:

- the Convention on Nuclear Safety;
- the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- the Convention on Early Notification of a Nuclear Accident.

In addition, a bilateral agreement on emergency preparedness and response with each country neighbouring Belgium has been signed (France, Luxembourg, Netherlands) or is under discussion (Germany).

Belgium hosts international peer review missions such IRRS, OSART and WANO. Belgium also provides experts who volunteer to participate in IRRS or OSART missions to other countries.

In the light of the TEPCO Fukushima Dai-ichi accident, the FANC and Bel V participated in the European "Stress tests", including the associated peer review.

The Belgian report for the sixth review meeting of the contracting parties to the CNS includes a section dedicated to the Fukushima-Daiichi accident follow-up.

CONCLUSION [4]
The IRRS Team considers that FANC and Bel V appropriately engaged in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and that appropriate actions have been taken to fulfil the obligations of the government of Belgium under international treaties and conventions.

Module 3: Responsibilites and Functions of the Regulatory Body

The Law of 1994 creating the FANC allows it to take measures to protect worker, public health and environment. Those measures can be related to any form of use, possession or trade of nuclear materials, consequently the regulatory body is able to exercise its authority to intervene in any facility or activity that present significant radiation risks and take timely decisions in case of accident.

In the case of an emergency, the main communications responsibilities are on the Governmental Crisis Centre (CGCCR). The regulatory body is integrated in this organization and leads the evaluation group (CELEVAL), which has direct contact with the meteorological services and the licensee's emergency centre. (For further information see Module 10 Emergency Preparedness and Response).

Engineering and computational means are available in CELEVAL to make some prognosis in case of accident that allow to forecast possible accident evolutions and anticipate radiation risks to the population in order to take adequate protective measures. The conclusions of that prognosis are transferred to the CGCCR decision making group that has to take the appropriate decisions

CONCLUSION [5]
The IRRS Team considers that in relation to the functions and organization of the regulatory body, the TEPCO Fukushima Dai-ichi accident hasn't raised any new concern not otherwise addressed in this report.

Module 4: Management System of the Regulatory Body

Both the FANC and the Bel V have in place processes for continuous assessment of their management systems, and look for opportunities for improvement, e.g. non-conformances, in the context of ISO 9001:2008. Those processes need to be extended to cope with operational and financial aspects and to take into account additional aspects related to GS-R-3, as it is explained in Module 4.

The long-term balanced management commitment to provide sufficient resources and competences is a specific point of attention of the new FANC strategic plan (c.f. Modules 3 and 4). The determination of the needed competences in the future and human resources will be one of the outputs of the FANC strategic plan. Regarding safety culture, the FANC and BelV have recognized that a formalized and structured process for the promotion, assessment and improvement of safety culture needs to be elaborated.

Promotion of transparency and openness, part of the FANC's mission, is described in different royal decrees and is applied, but some improvements are needed (see Module 3). During the Fukushima-Daiichi accident, open communication and exchange framework were implemented. News was published on a regular basis. A report describing the accident and its consequences and providing recommendations was published. An interactive exchange system based on Q&A with the public was developed. Results of scientific analysis were put on line as soon as available. Specific processes were elaborated in order to control goods coming from contaminated regions.

Development and maintenance of open and constructive relations with regulators of neighbouring countries is described in the international relations policy of FANC. Exchanges and communications with other foreign regulatory bodies and more specifically, with those of neighbouring countries, are well developed. For many years bilateral meetings have been organized on a regular basis with the French safety authority (ASN and IRSN) and also with the Dutch safety authority (Ministry of Economic Affairs). Moreover, Belgium is a member state of the European Union and actively participates in the elaboration, revision or updating of European Directives and to EURATOM working groups leading to open and constructive relations with all European Members States, in particular with neighbour countries.

The FANC policy on international relations has been recently reviewed and ensures appropriate participation in international working groups addressing Fukushima issues (e.g. WENRA, HERCA)

CONCLUSION [6]
The IRRS Team considers that the regulatory body had already identifed and planned some of the improvements of its management system as derived from the application of the TEPCO Fukushima Dai-ichi accident lessons learnt. Some further actions are suggested (see Module 3).

Module 5: Authorization

The Belgian system for providing authorization for all facilities and activities is described in the GRR-2001 and, apart from an improvement project aiming at optimizing the licensing process independently

initiated by the regulatory body (see chapter 5), has not been substantially modified as a consequence of the TEPCO Fukushima Dai-ichi accident. Some modifications in scope were nonetheless adopted for the facilities not yet in operation: within the projects which were still in the pre-licensing or licensing phase, the regulatory body required the execution of a review according to the European Stress Tests (EU ST) specifications. This so-called design stress test had the purpose to integrate possible lessons learned from the accident already in the design of these installations.

As a result of the EU ST for the class I facilities in operation, a series of specific back fitting measures aiming at reinforcing provisions in the area of extreme events beyond the current design were identified. The authorization of such modifications will be followed-up by the regulatory body within the established authorization system.

CONCLUSION [7]
The IRRS Team considers that, with respect to the TEPCO Fukushima Dai-ichi accident no particular concern related to the authorization process was raised, the regulatory body participated in a "stress test"–type exercise for installations in the licensing phase and appropriate actions have been taken.

Module 6: Review and Assessment

The main activity in the area of review and assessment, which was performed after the TEPCO Fukushima Dai-ichi accident, has been conducted by the regulatory body in the frame of the European Stress Tests (EU ST). The EU ST was designed as a targeted reassessment of the available safety margins in the light of the accident, with special attention to the identification of possible cliff edge effects as specified in the ENSREG specifications of May 2011. The main topics covered were the seismic and external flooding hazard, as well as other extreme weather phenomena on a site specific base. Furthermore, the cases of total SBO and loss of ultimate heat sink, as well as severe accidents (including organizational and communication preparedness) were analysed. The Belgian regulatory body required the EU ST be performed for all class I facilities (e.g. NPPs, research reactors and fuel management facilities). In addition, an extension of scope was applied for the Belgian facilities to man-made events, namely aircraft crash, toxic and explosive gases and blast waves, and external attacks on computer based controls and systems (for more details c.f. section 13.2).

The EU ST evaluations of the regulatory body were submitted for approval to the Scientific Council. In the end, a series of measures (further detailed analyses on specific aspects and concrete back fitting) aimed at reinforcing provisions in the area of extreme events beyond the design base were identified. For these measures, the licensees provided an ambitious action plan which was officially approved by the regulatory body and is followed-up regularly.

The Belgian 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 EU ST Peer Review Summary Report of April 2012. As soon as the new WENRA SRLs are officially issued they will be incorporated into the Belgian regulatory framework.

CONCLUSION [8]
The IRRS Team considers that the regulatory body participated in the European stress tests, which were applied to all Belgian class I facilities with a slightly enlarged scope with respects to the ENSREG specifications. The necessary further actions have been planned within an

CONCLUSION [8]
ambitious national action plan. For the adoption of the yet to be issued WENRA SRLs, the regulatory body is committed to act as necessary.

Module 7: Inspection

Targeted inspections to review the implications of the accident were integrated into the inspection programme.

All class 1 facilities have an implementation programme that is based on the stress test activities and its authorization by the regulatory body and subsidiary. Class 1 licensees are currently in the implementation phase of the modifications, and the regulatory body is planning inspection activities for this implementation.

Licensees indicated that the regulatory body has applied specific oversight to post-Fukushima improvements in the review of scheduling and deadlines to be achieved, as this constant pressures serves as the enforcement measure.

CONCLUSION [9]
The IRRS Team considers that the regulatory body is committed to perform the inspections related to the implementation of actions foreseen by the "stress test" exercises conducted by the licensee.

Module 8: Enforcement

The regulatory body has an enforcement policy and processes that provide sufficient assurance that the licensees take appropriate actions in a potential event similar to what happened in Fukushima.

The regulatory body is in the position to use its enforcement process should non-compliance by the licensee necessitate it.

CONCLUSION [10]
The IRRS Team considers that some actions arising from of an enforcement procedure may take longer, but the regulatory body is committed to act as necessary.

Module 9: Regulations and Guides

The FANC and Bel V are actively participating in the work of WENRA for the harmonization of the nuclear safety requirements. WENRA is in the process of updating the existing reactor SRLs based on the lessons learnt from the TEPCO Fukushima Dai-ichi NPP accident. The FANC is currently waiting that the updated WENRA RLs are approved. The plan is then to include the lessons learnt from Fukushima in the Belgian regulations. The schedule for this work has not yet been decided.

CONCLUSION [11]
The IRRS Team considers that the necessary actions related to the revision of regulations and guides have been recognised and the regulatory body is committed to act as necessary.

Module 10: Emergency Preparedness and Response

Upon receiving notification regarding the emergency in Fukushima, prompt actions were taken by the regulatory body. The FANC provided advice to the government and the public on the situation and the measures to be implemented. These actions were mostly directed towards:

a) advising the Belgian citizens who remained in Japan and those who decided to return home;
b) monitoring incoming goods, vehicles and aircrafts arriving from the affected region in Japan; and
c) providing periodic technical assessment updates on the accident progression.

Bel V reviewed the Emergency Operating Procedures, including Severe Accident Management Guidelines, at the nuclear power plants and found the licensees to be compliant with the WENRA reference levels.

Both NPPs have revised their Emergency Preparedness and Response (EP&R) organizational structures as a result of Fukushima to address possible multi-units emergencies. These revisions were included in the Stress Test component and reviewed by the regulatory body (FANC and /Bel V).

There are multiple means based on various technologies available for communicating with the population in the event of a severe accident such as the Fukushima accident (landlines, radio/TV broadcasting, SMS, cellular phones, public address system led by the police or civil defence etc.).

The arrangements for the coordination of public information are defined in the Discipline V of the National Emergency Plan at the federal level (CELINFO), provincial and community level. The means, tools and mechanisms used to alert and inform the population are the following:

a) Public alerting via the sirens network (15 km zone surrounding the NPP sites); and
b) Crisis Alert (formal agreement with the national news agency to distribute emergency messages), SMS/telephone, cell phones, broadcasting system, call centres, police or civil defence public announcements.

No immediate review of the regulatory programme on EP&R was triggered by the Fukushima accident. However, issues and lessons learned from the accident will be taken into consideration during the current ongoing revision process, leading to a revised royal decree on nuclear emergency planning. This is expected to be published in 2015.

CONCLUSION [12]

The IRRS Team considers that in general, from the emergency preparedness and response point-of-view, the emergency response efforts carried out by the regulatory body were adequate and appropriate. The regulatory body has the ability to work within its current emergency structure to do its technical assessments and make recommendations which will allow for appropriate actions to be taken to protect the population. The regulatory body was able to demonstrate that with the revisions and new measures implemented as a result of the Fukushima accident, they have the technical expertise and emergency structure in place to address severe accidents. These new measures and revisions which were introduced were tested in exercises performed.

IRRS BELGIUM TEAM

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APPENDIX II – MISSION PROGRAMME

<table>
<tr><th>Time</th><th>30.11.
SAT</th><th>01.12.
SUN</th><th>02.12.
MON</th><th>03.12.
TUE</th><th>04.12.
WED</th><th>05.12.
THU</th><th>06.12.
FRI</th><th>07.12.
SAT</th><th>08.12.
SUN</th></tr>
<tr><td>9:00-10:00</td><td rowspan="10">Arrival of Team Members</td><td rowspan="3">Team building meeting:
• 5 minutes/TM self-intro
• Refresher training</td><td rowspan="3">Entrance Meeting</td><td rowspan="3">Interviews</td><td rowspan="3">Visits</td><td rowspan="3">Interviews</td><td rowspan="3">Visits</td><td rowspan="3">Interviews</td><td rowspan="3">Visits/EPR exerc.</td><td rowspan="3">DTC writes introductory parts</td><td rowspan="3">TM write Report
TL and DTL review introductory part

Draft text to TL</td><td rowspan="3">• Discussing and improving Draft Report
• Cross-Reading
• TL, DTL, TC and DTC read everything</td><td rowspan="10">Free day</td><td rowspan="10">Reading, Cross-reading of the Report</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td rowspan="2">Lunch</td><td rowspan="2">Lunch with Host</td><td colspan="2">Lunch</td><td colspan="2">Lunch</td><td colspan="3">Lunch</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-14:00</td><td rowspan="3">Interviews + in-group discussions</td><td rowspan="3">Visits</td><td rowspan="3">Interviews + in-group discussion</td><td rowspan="3">Visits</td><td rowspan="3">Interviews + in-group discussions</td><td rowspan="3">Visits/EPR Exercise</td><td rowspan="3">DTC writes introductory parts</td><td>Policy Discussions</td><td rowspan="4">Finalisation of the Draft Report</td></tr>
<tr><td>14:00-15:00</td><td rowspan="2">Initial Team Meeting:
• IRRS process
• Main objectives
• Report writing
• Schedule
• First observations
• In-Group discussions</td><td rowspan="2">Interviews</td><td rowspan="2">Secretariat edits the report
Preliminary Draft Report Ready</td><td rowspan="2">Cross-reading by TM</td></tr>
<tr><td>15:00-16:00</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered</td></tr>
<tr><td>17:00-18:00</td><td></td><td>Daily Team Meeting</td><td colspan="2">Daily Team Meeting</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="2">Daily Team Meeting</td><td colspan="2">Daily Team Meeting</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td colspan="2">Dinner</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="2">Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td></td><td>Writing of the report</td><td colspan="2">Writing of the report</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="2">Writing of the report</td><td>TM Read Draft</td><td>Administrative Assistant edits the report</td></tr>
</table>

<table>
<tr><th></th><th>09.12.
MON</th><th>10.12.
TUE</th><th>11.12.
WED</th><th>12.12.
THU</th><th>13.12.
FRI</th><th></th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">Individual discussions of Rs, Ss and GPs with counterparts</td><td rowspan="2">Cross-Reading
TL, DTL, TC and DTC read everything
Finalisation</td><td rowspan="2">Common read through and finalisation by the Team
Submission of the Draft to the Host</td><td rowspan="2">Discussion with Host</td><td>Submission of the Final Draft</td><td>9:00-10:00</td></tr>
<tr><td>10:00-12:00</td><td rowspan="2">Exit Meeting
Press Conference</td><td>10:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>12:00-13:00</td></tr>
<tr><td>13:00-15:00</td><td>Policy Discussions</td><td rowspan="3">Discussion of the report by the team</td><td rowspan="2">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="2">Host reads Draft</td><td rowspan="2">TL finalises Executive Summary and exit presentation</td><td rowspan="2">TC Drafts the Press Release</td><td rowspan="2">Written comments by the Host

Team meeting for finalisation of the Report</td><td rowspan="5">Departure of Team Members</td><td>13:00-15:00</td></tr>
<tr><td>15:00-17:00</td><td>Individual discussions of Rs, Ss and GPs with counterparts</td><td>15:00-17:00</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td colspan="3">Discussion with Host</td><td>Briefing of IAEA sen. Manager
Finalisation of the press release</td><td>17:00-18:00</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="2">Dinner</td><td rowspan="2">Exit Dinner</td><td>18:00-20:00</td></tr>
<tr><td>20:00-21:00</td><td rowspan="2">Administrative Assistant includes changes</td><td colspan="2" rowspan="2">Administrative Assistant finalises text</td><td colspan="2" rowspan="2">Free</td><td>20:00-21:00</td></tr>
<tr><td>21:00-24:00</td><td>Free</td><td>21:00-24:00</td></tr>
</table>

APPENDIX III – SITE VISITS

SITE VISITS	
1.	TIHANGE - NPP
2.	SCK CEN - RESEARCH REACTOR
3.	BELGOPROCESS – WASTE FACILITY
4.	IRE – ISOTOPE PRODUCTION FACILITY
5.	TRANSRAD – RADIOACTIVE MATERIAL TRANSPORT FACILITY

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	FANC/BEL V Lead Counterpart	FANC/BEL V Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	MOORE Scott FERON Fabien BRANDISAUSKAS Dainius	BENS Jan	MICHIELS Jan
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	MOORE Scott FERON Fabien BRANDISAUSKAS Dainius	POULEUR Yvan	-
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	MELLADO Isabel ALM-LYTZ Kirsi VOGELS Marli	POULEUR Yvan	DE BOECK Benoit
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	MELLADO Isabel ALM-LYTZ Kirsi VOGELS Marli	VAN DER DONCKT Patrick (FANC) STANDAERT Vincent (BEL V)	DRESSELAERS Rony
5.	**AUTHORIZATION**		
	SARDELLA Rosa ALMEIDA Claudio COLLIGAN Alexandre SELLING Henk FRANCOIS Patrice	VAN WONTERGHEM Frederik	-

	IRRS EXPERTS	FANC/BEL V Lead Counterpart	FANC/BEL V Support Staff
	PATHER Thiagan		
6.	**REVIEW AND ASSESSMENT**		
	SARDELLA Rosa ALMEIDA Claudio COLLIGAN Alexandre SELLING Henk FRANCOIS Patrice PATHER Thiagan	DE GELDER Pieter	DE SMET Fabienne
7.	**INSPECTION**		
	RINFRET Francois SZABO Zoltan COLLIGAN Alexandre SELLING Henk FRANCOIS Patrice PATHER Thiagan	VAN HAESENDONCK Michel	SCHRAYEN Virginie
8.	**ENFORCEMENT**		
	RINFRET Francois SZABO Zoltan COLLIGAN Alexandre SELLING Henk FRANCOIS Patrice PATHER Thiagan	SCHRAYEN Virginie	-
9.	**REGULATIONS AND GUIDES**		
	MELLADO Isabel ALM-LYTZ Kirsi VOGELS Marli COLLIGAN Alexandre	BLOMMAERT Walter	KLEIN MEULEKAMP Robin

	IRRS EXPERTS	FANC/BEL V Lead Counterpart	FANC/BEL V Support Staff
	SELLING Henk FRANCOIS Patrice PATHER Thiagan		
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	BEAUDIN Bernie ZOMBORI Peter	VANDECASTEELE Christian	DEGUELDRE Didier
11.	**ADDITIONAL AREAS**		
	CARINOU Eleftheria KENNY Tanya SELLING Henk	FREMOUT An LEONARD Sophie LOURTIE Guy CREEMERS Joris	MANNAERTS Koen PEPIN Stephane
12.	**INTERFACE WITH NUCLEAR SECURITY**		
	MOORE Scott FERON Fabien BRANDISAUSKAS Dainius	DE WILDE Katleen	DU PONT Katie
13.	**REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT**		
	LUX Ivan	as required	as required

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	**Recommendation:** Government should formalize a comprehensive national policy and strategy for nuclear and radiation safety. Among others, the policy should include radioactive waste management and spent fuel management.
	R2	**Recommendation:** The Government should provide in consultation with the regulatory body a more expedited, prioritized process to issue or amend regulations for the safety and security of nuclear facilities and activities. If making changes to regulations proposed by the regulatory body or impacting the regulatory body, the Government should consult the regulatory body.
	R3	**Recommendation:** The Government should broaden the authority of the regulatory body to issue binding technical regulations (e.g. FANC decrees) for nuclear facilities and activities.
	R4	**Recommendation:** Government should ensure the regulatory body has legal authority for inspection at designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party or applicant.
	R5	**Recommendation:** Government should update the regulatory framework to: - ensure that the authorized party responsibility for health physics department cannot be provided by FANC or Bel V; - clarify the roles of AIO and their interfaces with the regulatory body and the authorized parties.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R6	**Recommendation: The Government should establish appropriate provisions to ensure a clear separation of authorities responsible for regulating safety from bodies responsible for nuclear energy policy (i.e. the relationship between State Secretary for Energy and the Minister of Home Affairs).**
	R7	**Recommendation: The Government should review the current allocation of roles and responsibilities of ONDRAF/NIRAS and the regulatory body to ensure separation of roles and responsibilities of both organizations so that the regulatory body decisions are not unduly influenced by prior governmental or ONDRAF/NIRAS decisions.**
	R8	**Recommendation: Government should explicitly assign the prime responsibility for safety to the person or organisation responsible for a facility or an activity.**
	R9	**Recommendation: The government should specify in legislation, the respective functions and responsibilities of all authorities involved in the regulatory oversight of medical exposures and patient safety to ensure effective national co-ordination and cooperation in applying regulatory requirements.**
	R10	**Recommendation: For the export of radioactive sources, the regulatory body and regional government offices should jointly develop a formal process, either through regulations or by communication protocols or MoUs, wherever necessary, to harmonize processes and ensure there are no regulatory gaps or overlaps between the different organizations.**
	S1	**Suggestion: The regulatory body should consider :** **- enhancing interfaces with the relevant governmental bodies having responsibilities for oversight of authorized facilities on domains outside of the regulatory body mandate to ensure timely**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		communication on inspection findings and, whenever appropriate, joint inspections; - increasing regulatory body staff awareness on interfaces and, where applicable, existing agreements, with these other governmental bodies.
	S2	**Suggestion:** FANC, with the support of the Scientific Council if needed, should consider identifying its radiation and nuclear safety research needs periodically and notifying relevant parties so that appropriate associated research programmes are developed.
2. GLOBAL NUCLEAR SAFETY REGIME	GP1	**Good Practice:** The creation by FANC of several international working groups to review the issue of flaws in Doel 3 and Tihange 2 pressure vessels represents a major initiative to address a new and significant safety issue.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R11	**Recommendation:** The regulatory body should develop and implement a process for carrying out a systematic review of its organizational structure, competences and resource needs to effectively discharge its current and future reponsibilities.
	R12	**Recommendation:** The regulatory body should give more detailed internal guidance for inspections, review and assessment to improve the consistency in its decision making.
	S3	**Suggestion:** The regulatory body should consider formalizing and systematically documenting the use of graded approach for allocating resource according to risk.
	S4	**Suggestion:** FANC should consider establishing a transparent decision making process, providing to the public and stakeholder the elements that support its regulatory decisions.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S5	**Suggestion:** The regulatory body should consider the establishment of a clearly defined process and criteria for engagement with a broader spectrum of stakeholders and gathering of public input on decommissioning actions and the final end state of the site.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R13	**Recommendation:** FANC should include in its management system, a process that allows FANC to oversee and review the activities of Bel V and all other organizations performing regulatory functions, to ensure coherence and effectiveness of all regulatory functions including those carried out by FANC, and to identify opportunities for improvements.
	R14	**Recommendation:** The regulatory body including Bel V, and all other organizations performing regulatory functions, should develop and implement a common safety culture policy.
	S6	**Suggestion:** FANC should consider continuing the development and implementation of an integrated management system. This should include processes for assessment and continuous improvement.
	S7	**Suggestion:** The FANC should consider gathering information on actual time spent on specific regulatory activities to improve the planning and management of resources.
	S8	**Suggestion:** The regulatory body should consider finalizing and implementing the competence management system that is being developed and establish a formal and sustainable training programme based on it.
	S9	**Suggestion:** The regulatory body should consider including the financial and operational aspects in the Management Review, to ensure that the strategic objectives of the regulatory body are met.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5. AUTHORIZATION	R15	**Recommendation:** The Government should update provisions so that a licence transfer is explicitly approved by the regulatory body after appropriate review.
	R16	**Recommendation:** The government should update provisions so that the regulatory body is formally involved in the review and assessment of the impacts on the nuclear facility due to changes in its surroundings, before these changes are approved by the relevant authorities.
	R17	**Recommendation:** The government should explicitly include the regulatory body and its activities of review and assessment, including specifying the conditions necessary for safety, in the legal framework describing the licensing regime.
	S10	**Suggestion:** The government should consider including the advice of the Scientific Council in the procedure for confirmation of the construction and operating license.
	S11	**Suggestion:** The regulatory body should consider introducing a formal documented process for confirming the authorisation of facilities in the medical sector following the commissioning process.
	GP2	**Good practice:** FANC has been proactive in ensuring those likely to encounter orphan sources are educated and assisted both legally and financially to ensure the safe detection, storage and recovery of orphan sources.
	R18	**Recommendation:** The regulatory body should increase the robustness in the sealed source tracking process and traceability of sources. More specifically, the following points of improvements are recommended: e) Increase reporting requirements to ensure sources cannot get transferred without a notification being made in the sealed source

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		tracking system. f) Harmonize the tracking and reporting requirements to ensure sealed source transfer notifications are generated, both by the sender and recipient, regardless of the destination or purpose of the transfer including shipments for disposal. g) Transfer authorizations should also be internally communicated to those tracking sealed sources. h) Implement additional measures to protect the Sealed Source Tracking Database file and its software back-ups from accidental over-writes, deletions or edits. Creating automated records of any changes made to the database itself would also be very helpful.
	R19	**Recommendation:** The regulatory body should: c) review the safety related aspects of the initial decommissioning plan and its regular updates d) review and approve the safety related aspects of the final decommissioning plan.
	S12	**Suggestion:** The regulatory body should consider the introduction of a system in which a notification procedure for transports of low risk radioactive material would replace the present licensing requirement.
6. REVIEW AND ASSESSMENT	R20	**Recommendation:** The regulatory body should review its guidance to perform review and assessment of "non-important modifications" of class I facilities in order to clearly identify the criteria for a graded approach.
7. INSPECTION	R21	**Recommendation:** The regulatory body should review the scope of its inspection programme to ensure that it is comprehensive and covers all areas relevant to safety and includes appropriate acceptance criteria
	R22	**Recommendation:** The regulatory body should ensure the inspection programme considers radiological risk and specifies the frequency by

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		which facilities are inspected, in accordance with a graded approach for radiation sources and facilities in the medical sector (classes IIb and III).
	GP3	Good practice: The regulatory body has developed a methodology and training for the inspection of class I and class IIa facilities to capture, analyse and report observations of safety culture.
	S13	Suggestion: The government should consider allowing the director general of FANC to authorize nuclear inspectors.
	S14	Suggestion: The FANC should establish procedures to ensure Authorized Inspection Organizations (AIOs) verify the validity of the Category I and II sealed source inventory when conducting on-site controls.
	S15	Suggestion: For inspections relating to final release of sites from regulatory control, the regulatory body should consider formalising its training programmes covering the relevant inspection areas and establishing effective coordination arrangements in cases where expertise is provided from other departments within FANC.
	GP4	Good Practice: The inspection programme for carriers of radioactive materials is graded based on risk and is recognized by other countries as a good practice.
8. ENFORCEMENT	S16	Suggestion: FANC should consider improving its decision making process for enforcement in order to ensure consistency.
9. REGULATIONS AND GUIDES	S17	Suggestion: The regulatory body should consider enhancing the process for evaluating and reviewing regulations and guides periodically. The process should ensure that the IAEA safety standards are systematically taken into account.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R23	**Recommendation:** The regulatory body should create a systematic structure for regulatory guides, establish a formal process for developing guides and prioritise according to their importance for safety. The regulatory body should extend consultation to include the public when developing the guides.
	S18	**Suggestion:** The regulatory body should consider developing clearance levels for surface contaminated items.
	GP5	**Good Practice:** FANC has taken a constructive approach to improve industrial radiography compliance by holding stakeholder meetings to seek industry feedback and explain new regulatory requirements.
	R24	**Recommendation:** The regulatory body should establish clear requirements for decommissioning of authorised facilities including class II, class III and other facilities such as NORM and other work activities.
	S19	**Suggestion:** The regulatory body should consider establishing guidance on how records relevant to decommissioning are collected and retained.
	S20	**Suggestion:** The government should consider making provision for parties other than the regulator to provide training courses for ADR drivers of vehicles carrying radioactive materials.
10. EMERGENCY PREPAREDNESS AND RESPONSE	R25	**Recommendation:** Regulatory body should further develop guidance on emergency preparedness and response for the licensee.
	R26	**Recommendation:** The regulatory body should develop its own nuclear/radiological emergency response plan.
11. ADDITIONAL AREAS	S21	**Suggestion:** The government should consider incorporating radiological risk among criteria used in establishing the required professional competences of staff in medical facilities and ensure there is co-

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		ordination between FPS Health and FANC in verifying compliance with the regulations.
	S22	**Suggestion: The government should consider developing a national policy on justification for medical exposures in consultation with all relevant parties, emphasising current collaborations aimed at achieving a coherent, effective and consistent approach to applying regulatory requirements for the justification of all medical exposures.**
	R27	**Recommendation: The regulatory body should enforce the legislation applicable to dose constraints for comforters and carers and volunteers in biomedical research.**
	GP6	**Good Practice: FANC has an effective policy of stakeholder engagement to promote radiation safety amongst the relevant clinical professions and members of the public. This ensures that guidance documents and initiative programmes are embraced by stakeholders and used accordingly.**
	R28	**Recommendation: The regulatory body should establish requirements for licensees to:** **- calibrate all measuring and monitoring equipment at a specified frequency, and traceable to a standards laboratory; and** **- promptly investigate and report unintended or accidental medical exposures.**
	S23	**Suggestion: The regulatory body should consider establishing and maintaining a national dose registry for the doses received by occupationally exposed workers.**
	R29	**Recommendation: Government should revise the current legal and regulatory framework to bring it in line with the requirements for:**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		i. Equivalent dose limit for the lens of the eye. ii. Use of dose constraints as part of the optimization process. iii. Establishment of workplace monitoring programmes.
12. INTERFACE WITH NUCLEAR SECURITY	R30	**Recommendation:** The regulatory body should ensure that its management system takes due account of safety and security interface and that such interface is more explicitly addressed when drafting new or amended regulations.
	R31	**Recommendation:** Government should amend regulations with regard to improving the security of radioactive sources.
	S24	**Suggestion:** The regulatory body should consider performing safety and security exercises simultaneously to test emergency preparedness and response provisions set in both the 2003 royal decree and OOP36.
13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICI ACCIDENT	-	-

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

AREA	NO.	CONCLUSION
IMMEDIATE ACTION TAKEN BY THE REGULATORY BODY	**C 1**	**The IRRS Team considers that FANC and Bel V took appropriate actions in order to cope with the implications of the TEPCO Fukushima Dai-ichi accident. FANC and Bel V were effective and efficient in public communication as well as in the management of the stress test process. The Belgian initiative to extend the stress test exercise to class I non-NPP facilities and to man-made effects is to be commended.**
PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT	**C 2**	**The IRRS Team concludes that FANC and Bel V initiated a thorough re-evaluation of the safety of all major nuclear facilities in Belgium. The results of the re-evaluations were systematically assessed and actions that may further enhance the nuclear and radiation safety in the country were determined and scheduled for realization by the licensee in an Action Plan. FANC and Bel V are determined to supervise the actions in the Action Plan.** **The IRRS Team considers that delays in actions foreseen by the National Action Plan may suggest to FANC and Bel V to consider a revision of the target dates of completions in the plan in order to obtain a firm and well founded system of target dates.** **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. Nevertheless FANC and Bel V should consider developing a plan of actions to be performed by the regulatory body as a response to the lessons learned from the accident.**
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**C 3**	**The IRRS Team did not identify any element regarding the responsibilities and function of the government, which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. The need of revision of the Belgian nuclear emergency plan has been**

AREA	NO.	CONCLUSION
		recognized.
2. GLOBAL NUCLEAR SAFETY REGIME	**C 4**	**The IRRS Team considers that FANC and Bel V appropriately engaged in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and that appropriate actions have been taken to fulfil the obligations of the government of Belgium under international treaties and conventions.**
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**C 5**	**The IRRS Team considers that in relation to the functions and organization of the regulatory body, the TEPCO Fukushima Dai-ichi accident hasn't raised any new concern not otherwise addressed in this report.**
4. MANAGMENT SYSTEM OF THE REGULATRY BODY	**C 6**	**The IRRS Team considers that the regulatory body had already identifed and planned some of the improvements of its management system as derived from the application of the TEPCO Fukushima Dai-ichi accident lessons learnt. Some further actions are suggested (see Module 3).**
5. AUTHORIZATION	**C 7**	**The IRRS Team considers that, with respect to the TEPCO Fukushima Dai-ichi accident no particular concern related to the authorization process was raised, the regulatory body participated in a "stress test"–type exercise for installations in the licensing phase and appropriate actions have been taken.**
6. REVIEW AND ASSESSMENT	**C 8**	**The IRRS Team considers that the regulatory body participated in the European stress tests, which were applied to all Belgian class I facilities with a slightly enlarged scope with respects to the ENSREG specifications. The necessary further actions have been planned within an ambitious national action plan. For the adoption of the yet to be issued WENRA SRLs, the regulatory body is committed to act as**

AREA	NO.	CONCLUSION
		necessary.
7. INSPECTION	**C 9**	**The IRRS Team considers that the regulatory body is committed to perform the inspections related to the implementation of actions foreseen by the "stress test" exercises conducted by the licensee.**
8. ENFORCEMENT	**C 10**	**The IRRS Team considers that some actions arising from of an enforcement procedure may take longer, but the regulatory body is committed to act as necessary.**
9. REGULATONS AND GUIDES	**C 11**	**The IRRS Team considers that the necessary actions related to the revision of regulations and guides have been recognised and the regulatory body is committed to act as necessary.**
10. EMERGENCY PREPAREDNESS AND RESPONSE	**C 12**	**The IRRS Team considers that in general, from the emergency preparedness and response point-of-view, the emergency response efforts carried out by the regulatory body were adequate and appropriate. The regulatory body has the ability to work within its current emergency structure to do its technical assessments and make recommendations which will allow for appropriate actions to be taken to protect the population. The regulatory body was able to demonstrate that with the revisions and new measures implemented as a result of the Fukushima accident, they have the technical expertise and emergency structure in place to address severe accidents. These new measures and revisions which were introduced were tested in exercises performed.**

APPENDIX VII – FANC REFERENCE MATERIAL USED FOR THE REVIEW

[1] IRRS Questions and Answers:

- *Module 1: Responsibilities and Functions of the Government*
- *Module 2: Global Nuclear Safety Regime*
- *Module 3: Responsibilities and functions of the Regulatory Body*
- *Module 4: Management System of the Regulatory Body*
- *Module 5: Authorization*
- *Module 6: Review and Assessment*
- *Module 7: Inspection*
- *Module 8: Enforcement*
- *Module 9: Regulations and Guides*
- *Module 10: Emergency Preparedness and Response*
- *Module 11a: Control of Medical Exposures*
- *Module 11b: Occupational Radiation Protection*
- *Module 11c: Transport*
- *Module 11d: Decommissioning, Public and Waste*
- *Module 12: Interface with Nuclear Security*
- *Module 13: Regulatory Implications of the Tepco Fukushima Dai-Ichi Accident*

[2] General Items

1. *Annual report 2012-BelV-EN, 'Annual report Bel V 2012'*
2. *Annual Report 2012-FANC-EN, 'Annual report FANC 2012'*
3. *CNS2011-Questions and Answers, 'Q&A CNS 2011'*
4. *CNS2011-report, 'Fifth meeting of the contracting parties to the Convention on Nuclear Safety'*
5. *CNS2012-report, 'Belgian national Report - Fifth review Meeting of the Convention an Nuclear Safety'*
6. *CNS2014-report, 'Sixth meeting of the contracting parties to the Convention on Nuclear Safety'*
7. *FANC-Bel V presentation-Prep Meeting 14.05.2013, 'IRRS Mission in Belgium 2013 - Preparatory Meeting'*
8. *JC2012-National report, 'Fourth meeting of the Contracting Parties to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management'*
9. *JC2012-Questions and Answers, 'Q&A National report JC 2012'*

[3] Module 1

Legislation

1. *LA-REG-FANC_LAW_1994_04_15-EN, 'Law of 15 April 1994 on the protection of the general public and the environment against the hazards arising from ionising radiation and on the FANC'*
2. *LA-REG-Phase out of nuclear energy-EN, 'Law of 31 January 2003 on the gradual phase-out of nuclear energy for industrial electricity production purposes'*
3. *RD-PUN-Emergency response_17_10_2003-EN, 'Royal Decree of 17 October 2003 establishing the nuclear and radiological emergency plan for the Belgian territory'*
4. *RD-REG-GRR-2001-EN, 'Royal Decree of 20 July 2001 laying down general regulations for the protection of the public, workers and the environment against the dangers of ionising radiation'*
5. *RD-REG-GRR-2001-IA-EN, 'Translation Annexe IA, for tables see FR version!'*
6. *RD-REG-GRR-2001-IB-EN, 'Translation Annexe IB, for tables see FR version!'*
7. *RD-REG-GRR-2001-II-EN, 'Translation Annexe II, for tables see FR version!'*

8. *RD-REG-GRR-2001-III-EN, 'Translation Annexe III, for tables see FR version!'*
9. *RD-REG-GRR-2001-VI-EN, 'Translation Annexe VI, for tables see FR version!'*
10. *RD-REG-GRR-2001-VII-EN, 'Translation Annexe VII, for tables see FR version!'*
11. *RD-REG-SRNI2011-EN, 'Royal Decree of 30 November 2011 on the safety requirements for nuclear installations'*
12. *RD-TRM-Import Export Transit RAM_24_03_2009-EN, 'Royal Decree of 24 March 2009 regulating import, transit and export of radioactive substances'*

[4] Module 2

1. *FG-IF-Event reporting and INES to Class II and III industrial facilities-EN, 'Event reporting and extension of the application of the INES to Class I and III industrial facilities '*
2. *FG-IF-INES_convention-Class I facilities-EN, 'Agreement between FANC, the inspection organisations and the licensees of Class I Facilities on the use of INES'*
3. *FG-IF-INES-convention_Class IIA facilities-EN, 'agreement between Fanc, the inspection organisations and the licensees of Class IIA Facilities on the use of INES'*
4. *LA-REG-Assentiment_Conventions-EN, 'Lois ascentiment JC + loi ascentiment CNS'*
5. *OT-IF-Role FANC and Bel V in the case of an event INES-EN, 'The role of FANC and Bel V in the case of an event for which an INES evaluation must be carried out by a Class I licensee'*

[5] Module 3

1. *OT-MGT-Directives FANC to recognised inspection organisations-N-07-216-EN, 'Directives of the FANC to autorized inspection organisations (AIO) concerning inspections of category I, II and III (or similar) facilities '*
2. *OT-MGT-Management Agreement FANC-Bel V-EN, 'Management Agreement between FANC - Bel V'*
3. *OT-MGT-OrganigrammeBelV, 'organigram 01/07/13'*
4. *OT-MGT-Practical organisation of collaboration between FANC and Bel V-N-009-089-EN, 'practical organisation of collaboration between FANC and Bel V'*
5. *OT-REG-Cooperation FANC BelV_Transverse processes_N009-097-EN, 'Cooperation between FANC - Bel V: Transverse procedures '*
6. *PC003-01-rev2-Recruitment HRM-EN, 'procedure aiming to organise the recruitment process so as to ensure that the candidates recruited comply with the Triennial Staff Plan.'*
7. *PC003-02-rev3-Training-EN, 'procedure aiming to provide Agency staff with effective training based on the needs identified by applying Skills Management Procedure (PC 003-06)'*
8. *PC003-06-rev0-Skills management HRM-EN, 'procedure describing the responsibilities and processes to be observed in order to guarantee, in accordance with the requirements of ISO 9001 and the IAEA guidelines, that staff maintain and develop their skills to enable them to fulfil the responsibilities defined in their job description'*
9. *FG-IF-INES_convention_Class I facilities-EN, 'Agreement between FANC, the inspection organisations and the licensees of Class I facilities on the use of the INES'*
10. *FG-IF-INES-convention_Class IIA facilities-EN, 'Agreement between FANC, the inspection organisations and the licensees of Class IIA facilities on the use of the INES'*

[6] Module 4

FANC

1. *003-155 F rev 1 FANC policy on inspection and control-EN, 'General FANC policy concerning inspections and controls aiming to ensure compliance with GRR-2001'*
2. *GD001-01-rev0-Internal Audit Charter-EN, 'Internal Audit Charter'*
3. *GD002-02-rev0-Assessment of conformity, quality and efficiency of the functioning-EN, 'Assessment of*

conformity, quality and efficiency of the functioning of the FANC'

4. *GD010-02-rev1-Inspection policy-EN, 'General policy on inspections conducted by FANC'*
5. *GD010-04-rev0-General policy on processing of applications and management of licences-EN, 'FANC general policy on processing of applications and management of licences'*
6. *GD010-08-rev0-Enforcement and protective measures-EN, 'FANC general policy on applying enforcement measures and protective measures'*
7. *PC001-01-rev5-Procedure for managing documents related to the quality system-EN, 'Procedure for managing documents related to the quality system'*
8. *PC002-01-rev2-Quality assurance-EN, 'Quality assurance'*
9. *PC006-05-rev2-procedure on processing licence applications for Class I facilities-EN, 'Specific procedure for the section Nuclear Industrial Facilities on treating licence applications for class I facilities'*
10. *PC006-17-rev0-Graded approach NBI-EN, 'Procedure relating to the application of the graded approach to planned activities and reactive activities carried out by the Nuclear Industrial Facilities section'*
11. *PC009-06-rev0-Management of risks associated with FANC operations-EN, 'Management of risks associated with the functioning of the FANC operations'*
12. *PC010-05-rev0-licensing and acceptance of class II and III facilities-EN, 'Procedure shared by the "Nuclear Industrial Facilities" and "Health Protection" sections for licensing and acceptance of Class II and III facilities*
13. *SP007-02-rev0-Importation - transport service inspection programme-EN, 'Importation & Transport Service Inspection Programme'*
14. *GD010-09-General policy on regulation and guides-EN, 'General policy concerning the drafting and maintenance of the regulatory framework within the FANC's areas of competence'*

Bel V

1. *Bel V_TRC concept-EN, 'The concept of TRC in Bel V'*
2. *Q010000-01-00-p-org-management-BelV-EN, 'Procedure describing how the Bel V Foundation is managed'*
3. *Q010000-01-01-p-org-A01 process-EN, 'A01 process'*
4. *Q010100-01-00-p-org-framework BelV-EN, 'Defining duties'*
5. *Q010200-01-00-p-org-policy BelV-EN, 'Defining policy'*
6. *Q010300-01-00-p-org-organisation BelV-EN, 'Managing the organisation'*
7. *Q010302-01-00-p-org-definition and validation of BelV processes-EN, 'Defining and validating processes'*
8. *Q010400-01-00-p-org-assessment operations BelV-EN, 'Assessing the operation of Bel V'*
9. *Q020000-01-00-p-org-f, 'A02: Manage the accounts, manage the projects'*
10. *Q060002-01-00-p-org-e, 'Selection and evaluation of external experts'*
11. *Q060100-01-00-p-org-e, 'Initiate internal requests for expert services'*
12. *Q060100-01-02-t-org-e, 'Safety Analysis Document (SAD) template'*
13. *Q060200-01-00-p-org-e, 'Execute and evaluate analyses of nuclear safety and radiation pprotection'*
14. *Q060300-01-00-p-org-e, 'Deliver Documents and Reports related to expert services'*
15. *Q070101-01-00-p-org-f, 'Technical documentation management'*
16. *Q070102-01-00-p-org-f, 'Knowledge management'*
17. *Q070102-01-01-i-org-e, 'Knowledge transfer form'*
18. *Q070300-01-00-p-org-e, 'Managing operating experience feedback (REX)'*
19. *Q080201-01-02-f-org-f, 'Role descriptions'*
20. *Q080201-01-04-f-org-e, 'Tree of Roles and affectation of people'*

21. *Q080201-01-05-t-org-e, 'Personal History'*
22. *Q080401-01-07-t-org-e, 'Follow-up and maintenance of individual expertise'*
23. *Q110300-01-00-p-org-f, 'Document control'*
24. *Q110301-01-07-i-org-e, 'Technical Information Management Support Tools'*
25. *Visio Bel V level 1 - 2013, 'Description of the processes level 1'*
26. *Visio-Q060000-01-01-p-org-e, 'A06 Provide and manage expert services'*
27. *Visio-v1A-Q070300-01-02-p-all-e, 'A07.03: Managing operation Feedback Experience (REX)'*
28. *Visio-v2A-Q080000-01-01-p-org-e, 'A08: Human Resources Management (HRM)'*
29. *Visio-v2-Q020000-01-01-p-org-f, 'A02 Manage the accounts/ manage the projects'*
30. *Visio-v2-Q070000-01-01-p-org-e, 'A07 : Manage expertise and technical quality'*
31. *Visio-v2-Q110000-01-01-p-org-e, 'A11: Manage support'*
32. *Visio-v2-Q120000-01-01-p-org-f, 'A12 Manage the Quality System (QS)'*
33. *Visio-v2-Q120000-01-03-i-org-e, 'A12 Records Overview'*

[7] Module 5

1. *FG-IF-Advice of the Scientific Council as part of the license procedure for Class I facilities-EN, 'Advice of the Scientific Council as part of the license procedure for Class I facilities'*
2. *FG-IF-standard format and content of the DOPF-EN, 'Guidance for the format and content of the Design Options and Provisions File'*
3. *GD010-04-rev0-General policy on processing of applications and management of licences-EN, 'FANC general policy on processing of applications and management of licences'*
4. *OT-QA-KOLIBRI-37192-v4-Q060000-01-01-p-org-EN, 'Description A06 Process'*
5. *OT-QA-Q060000-01-00-p-org-Process A06-EN, 'Deliver expert services in nuclear safety and radiation protection'*
6. *PC006-05-rev2-procedure on processing licence applications for Class I facilities-EN, 'Specific procedure for the Nuclear Industrial Facilities Section on processing licence applications for Class I facilities'*
7. *RD-REG-GRR-2001-EN, 'Royal Decree of 20 July 2001 laying down general regulations for the protection of the public, workers and the environment against the dangers of ionising radiation'*

[8] Module 6

1. *FG-IF-Decennial safety reviews of Belgian Class I nuclear installations-N-010-137-EN, 'Decennial safety reviews of Belgian Class I nuclear installations'*
2. *OT-MGT-BelV_RD_Program_2013-EN, 'Research and Development Programme 2013'*
3. *OT-MGT-BelV_RD_Strategy_2010-2014-EN, 'Research and Development Strategy 2010-2014'*
4. *OT-MGT-Organigramme BelV-EN, 'organigram 01/07/13'*
5. *OT-MGT-Practical organisation of collaboration between FANC and Bel V-N-009-089_EN, 'Practical organisation of collaboration between FANC and Bel V'*
6. *OT-MGT-Q060001-01-00-p-org-Organizing the Technical Responsibility Centres-EN, 'Organizing the Technical Responsibility Centres (TRC)'*
7. *OT-MGT-Q060002-01-00-p-org-Selection and evaluation of external experts-EN, 'Selection and evaluation of external experts'*
8. *OT-MGT-Q070300-01-00-p-org-Managing operating experience feedback_EN, 'Managing operating experience feedback (REX)'*
9. *RD-REG-SRNI-2011-EN, 'Royal Decree of 30 November 2011 on the safety requirements for nuclear installations'*
10. *RD-REG-GRR-2001-EN, 'Royal Decree of 20 July 2001 laying down the General Regulation for the protection of the public, workers and the environment against the hazards of ionizing radiation, as*

amended'

[9] Module 7

1. *003-155 F rév 1 FANC policy on inspection and control-EN, 'General FANC policy concerning inspections and controls aiming to ensure compliance with GRR-2001'*
2. *OT-IF-Integrated Inspection and Control Strategy-EN, 'ICI (Integrated Inspection and Control Strategy) during 2012-2014 for Nuclear Industrial Facilities'*
3. *OT-IF-Role of FANC and Bel V in the event of an incident or accident-EN, 'The role of FANC and Bel V in the event of an incident or accident'*
4. *PC006-03-rev0-Procedure specific to NBI for the management of incidents-EN, 'Procedure specific to the Nuclear Industrial Facilities section for the management of incidents'*
5. *PC006-04-rev1-Procedure NBI concerning the completion of inspections in class I II and III industrial facilities-EN, 'Procedure specific to Nuclear Industrial Facilities section concerning the completion of inspections in class I, II and III industrial facilities'*
6. *Q030000-01-00-p-all-Commissioning installations-EN, 'Commissioning installations'*
7. *Q030200-01-00-p-cl1-Commissioning new Class I installations or altered Class I installations-EN, 'Commissioning procedure of new Class I installations or Class I installations which have undergone substantial alterations'*
8. *Q040000-01-00-p-all-monitoring-EN, 'Monitoring during operation'*
9. *Q040301-01-00-p-cl1-Systematic inspection Class I and class IIA installations-EN, 'Systematic inspection of Class 1 and Class 2A installations'*
10. *Q040302-01-00-p-cl1-Themed inspection Class I and class IIA installations-EN, 'Themed inspection of installations of Class 1 and Class 2A facilities'*

[10] Module 8

1. *GD010-08-rev0-Enforcement and protective measures-EN, 'FANC general policy on applying enforcement measures and protective measures'*
2. *RD-REG-Administrative fines-EN, 'Royal Decree of 20 December 2007 laying down the administrative procedure for paying administrative fines as established by the law of 15 April 1994 on the protection of the general public and the environment against the hazards arising from ionising radiation and on the FANC'*
3. *RD-REG-Administrative fines-simplified procedure-EN, 'Royal Decree of 20 December 2007 setting the details of the simplified administrative procedure for the payment of administrative fines established by the Law of 15 April 1994 on the protection of the population and the environment against the hazards arising from ionising radiation and on the FANC'*
4. *RD-REG-FANC Inspection department-EN, 'Royal Decree of 20 July 2001 on the powers and appointment of members of the inspection section of the Federal Agency for Nuclear Control responsible for overseeing the implementation of the Law of 15 April 1994 on the protection of the population and the environment against the hazards arising from ionising radiation and on the Federal Agency for Nuclear Control'*

[11] Module 9

1. *FG-REG-Regulatory requirements Class I facilities-EN, 'Nuclear safety regulation for nuclear installations of Class I'*
2. *FG-WAS-Biosphere-EN, 'Safety assessment: biosphere'*
3. *FG-WAS-Earthquake-EN, 'Near surface disposal, on Belgian territory, of short-lived low and intermediate level radioactive waste. "Earthquakes" guidance'*
4. *FG-WAS-External events-EN, 'Surface disposal of low and intermediate level waste on Belgian territory.*

Guideline on the consideration of events of external origin at the design phase of the repository'

5. *FG-WAS-Human Intrusion-EN, 'Surface disposal of low and intermediate level short-lived radioactive waste on the Belgian territory. Guide on considering the risk of human intrusion into surface repositories for radioactive waste'*
6. *FG-WAS-Hydrogeologie-EN, 'Surface disposal of low and intermediate level short-lived radioactive waste on the Belgian territory. Technical guide on "Safety analysis: groundwater aspects"'*
7. *FG-WAS-Periodic reporting of release_2010_12_14-EN, 'Periodic reporting to FANC and Bel V on discharges of liquid and airborne radioactive effluents'*
8. *FG-WAS-Radiation_Protection_Criteria_Post-Operational_Safety_Assessment-EN, 'Technical guide Radiation Protection Criteria for Post-operational Safety Assessment for radioactive waste disposal"'*
9. *FG-WAS-Radiological protection operational period-EN, 'Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste'*
10. *FG-WAS-Technical_Guide-02_Surface_repository-EN, 'Surface Disposal of low and intermediate level short-lived waste on Belgian territory'*
11. *OT-REG-Strategic note_assessing licence applications-EN, 'Facilities for final disposal of radioactive waste.*
12. *Policy and guidelines for assessing licence applications'"*
13. *PC005-02-rev1-Procedure for development of regulatory texts-EN, 'Procedure for the development of regulatory texts'*
14. *OT-REG043-Decommissioning-EN, 'Royal Decree supplementing the Royal Decree of 30 November 2011 laying down safety requirements for nuclear installations with regard to decommissioning'*
15. *RD-REG-Interim storage installations for spent nuclear fuel and solid radioactive waste-EN, 'Royal Decree supplementing the Royal Decree of 30 November 2011 laying down safety requirements for nuclear installations with regard to interim storage installations for spent nuclear fuel and solid radioactive waste packages'*
16. *Use of IAEA Safety Standards in Belgium 2012, 'Overview of the use of IAEA Safety Standards in Belgium'*

[12] Module 10

1. *RD-PUN-Emergency response_17_10_2003-EN, 'Royal Decree of 17 October 2003 establishing the nuclear and radiological emergency plan for the Belgian territory'*

[13] Module 11

Medical Exposures

1. *FD-HTH-Patient Dosimetry-EN, 'Decree of the Federal Agency for Nuclear Control concerning patient dosimetry'*
2. *PC010-05-I-01-rev0-licensing and commissioning of class II and III facilities-EN, 'Assigning processing of a licence application for a Class II or III facility to a competent section*
3. *PC010-05-I-02-rev0-Justification for a new practice -EN, 'Instruction to check justification of a new practice liable to lead to exposure to ionising radiation (art. 20.1.1 of GRR-2001)*
4. *PC010-05-I-03-rev0-recording follow-up of applications in the Central Information System-EN, Administrative processing and recording/follow-up of applications in the Central Information*
5. *System as part of the licensing system for Class II and III facilities*
6. *PC010-05-I-04-rev0-Commissioning process for Class II and III installations article 15 of GRR 2001-EN, 'Method for monitoring the commissioning process for Class II and III installations in accordance with article 15 of GRR-2001'*
7. *PC010-05-rev0-licensing and acceptance of class II and III facilities-EN, 'Procedure shared by the "Nuclear Industrial Facilities" and "Health Protection" sections for licensing and acceptance of Class II and III facilities*
8. *SP006-01-rev2-SPOC-EN, 'List of SPOCs of the Nuclear Industrial Facilities section for the organisation of Class I, II and III facilities*
9. *SP010-02-rev0-Derogation from article 7.3 of GRR-2001-EN, 'Generic criteria, which can be used to derogate from article 7.3 of GRR-2001, during the processing of draft amendments for Class II facilities*
10. *SP010-03-rev0-Allocation of a unique combination code in relation to the licence system-EN, Allocation of a unique combination code for application files in relation to the licence system of Class I, II and III facilities*
11. *SP010-04-rev0-Interpretation of article 12 of GRR-2001 for Class II and III facilities-EN, 'Interpretation of article 12 of GRR-2001 for Class II and III facilities'*
12. *SP010-05-rev0-Specification of additional requirements under licensing system class II and III-EN, 'Specification of additional requirements relating to applications under the licensing system for Class II and III facilities'*
13. *SP010-06-rev0-Specification of types of favourable decisions under the licensing system class II and III-EN, 'Specification of types of favourable decisions under the licensing system for Class II and III facilities'*
14. *SP010-07-rev0-Classification of the different types of modifications for class II and III facilities-EN, 'Classification of the different types of modifications for Class II and III facilities'*
15. *FG-HTH-Radiotherapy Events notification-EN, 'FANC directives relative to the arrangements and criteria for informing the FANC of significant events concerning radiation protection in radiotherapy'*

Occupation Radiation Protection

1. *FD-HTH-FANC decree recognition of dosimetry services-EN, 'FANC Decree of 1 July 2008 establishing the conditions and criteria for recognition of dosimetry departments for performing external dosimetry*
2. *LA-REG-Dosimetrie proposal-EN, 'Draft bill amending the law of 15 April 1994 on the protection of the general public and the environment against the hazards arising from ionising radiation and on the Federal Agency for Nuclear Control*
3. *RD-REG-Health monitoring of workers_28_05_2003-EN, 'Royal Decree of 28 May 2003 on the health monitoring of workers*
4. *RD-REG-On the use of personal protective equipment_13_06_2005-EN, 'Royal Decree on the use of personal protective equipment*

5. *RD-REG-the protection of workers against the hazards of ionising radiation-EN, 'ROYAL DECREE on the protection of workers against the hazards of ionising radiation.*
6. *RD-REG-the protection of workers against the hazards of ionising radiation-EN, 'ROYAL DECREE on the protection of workers against the hazards of ionising radiation*

Discharges, Clearance, and Chronic Exposure; Environmental Monitoring

1. *FG-WAS-Periodic release statement_2010_12_14-EN, 'Periodic reporting to FANC and Bel V on discharges of liquid and airborne radioactive effluents*
2. *OT-DECOM-ICEM96305-EN, 'Proceedings of the 15th International Conference on Environmental Remediation and Radioactive Waste Management - ICEM2013'*
3. *OT-REG020-Interventions on sites contaminated by radioactive substances Proposal-EN, 'DRAFT LEGISLATION relating to the performance of interventions on sites contaminated by radioactive substances'*
4. *OT-REG043-Decommissioning-EN, 'Royal Decree supplementing the Royal Decree of 30 November 2011 laying down safety requirements for nuclear installations with regard to decommissioning'*
5. *RD-REG-Interim storage installations for spent nuclear fuel and solid radioactive waste-EN, 'Royal Decree supplementing the Royal Decree of 30 November 2011 laying down safety requirements for nuclear installations with regard to interim storage installations for spent nuclear fuel and solid radioactive waste packages'*

Transport

1. *RD-REG-GRR-2001-EN, 'Royal Decree of 20 July 2001 laying down general regulations for the protection of the public, workers and the environment against the dangers of ionising radiation'*
2. *RD-TRM-Import Export Transit RAM_24_03_2009-EN, 'Royal Decree of 24 March 2009 regulating import, transit and export of radioactive substances'*
3. *SP007-02-rev0-Importation - transport service inspection programme-EN, 'Importation & Transport Service Inspection Programme'*

[14] Interface Safety Security

1. *FD-REG-Guidelines in the event of detection or discovery of an orphan source-EN-NL, ' Decree setting out guidelines to be observed in the event of detection or discovery of an orphan source in orphan source sensitive facilities in the non-nuclear sector'*
2. *RD-REG-Detection of radioactive materials-EN-NL, 'Royal decree concerning the detection of radioactive materials in certain material and waste flows and the management of orphan source sensitive facilities – erratum'*

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2 -** Preparedness and Response for a Nuclear or Radiological Emergency
4.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3 -** The Management System for Facilities and Activities
5.	**IAEA SAFETY STANDARDS SERIES No. NS-R-1 –** Safety of Nuclear Power Plants: Design
6.	**IAEA SAFETY STANDARDS SERIES No. NS-R-2 –** Safety of Nuclear Power Plants: Operation
7.	**IAEA SAFETY STANDARDS SERIES No. NS-R-4 -** Safety of Research Reactors
8.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1 -** Organization and Staffing of the Regulatory Body for Nuclear Facilities
9.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2 -** Review and Assessment of Nuclear Facilities by the Regulatory Body
10.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3 -** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
11.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.4 -** Documentation for Use in Regulatory Nuclear Facilities
12.	**IAEA SAFETY STANDARDS SERIES No. GS-G-2.1 -** Arrangements for Preparedness for a Nuclear or Radiological Emergency
13.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 -** Application of the Management System for Facilities and Activities
14.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 -** The Management System for Technical Services in Radiation Safety
15.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation
16.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 -** Building Competence in Radiation Protection and the Safe Use of Radiation Sources
17.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.8** – Environmental and Source Monitoring for purposes of Radiation Protection

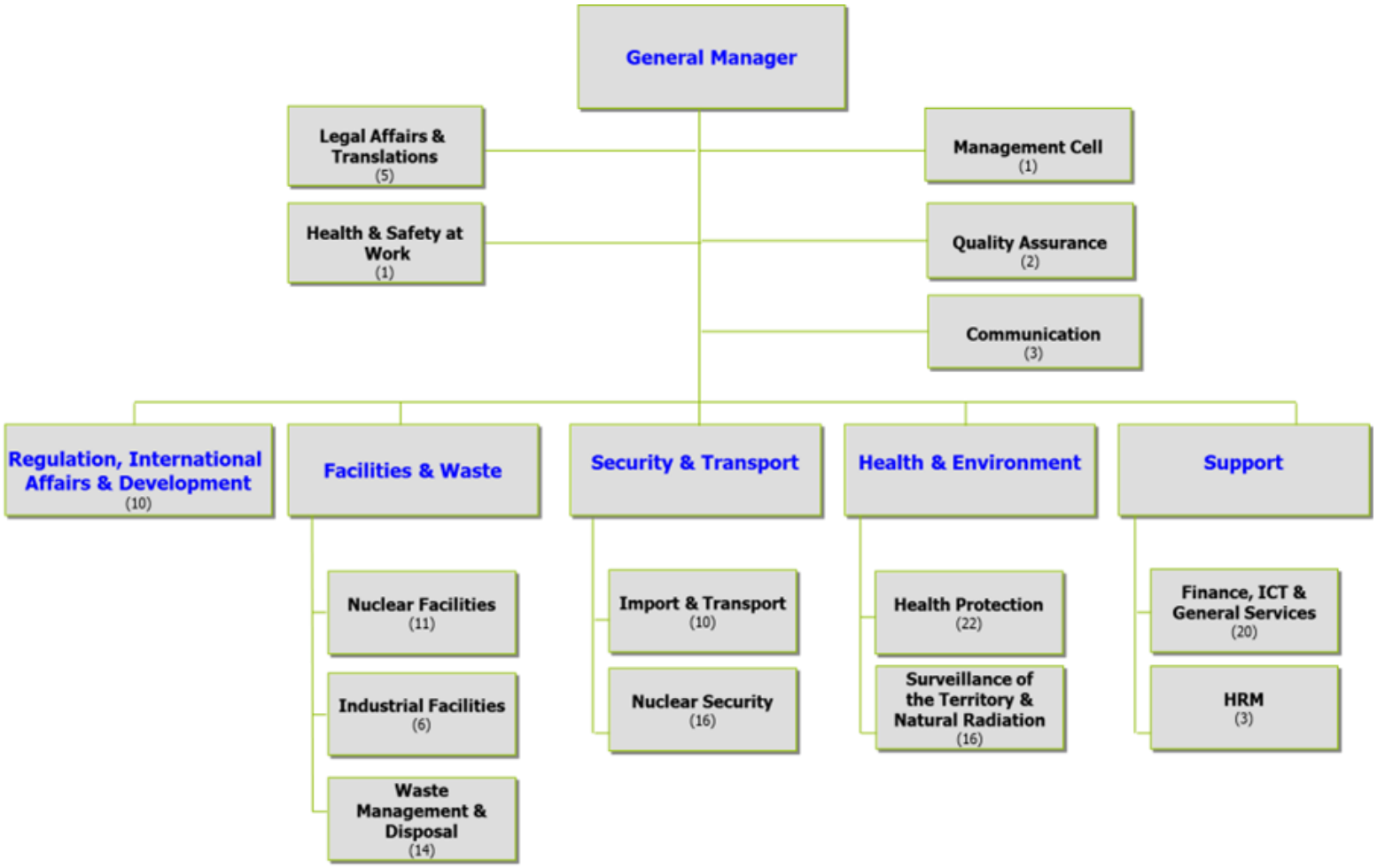
18. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10 -** Periodic Safety Review of Nuclear Power Plants Safety Guide

19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211 -** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide

20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997).

APPENDIX IX – FANC ORGANIZATIONAL CHART



APPENDIX X – BEL V ORGANIZATIONAL CHART