IAEA-NS-IRRS-2017/12
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION

TO

BELGIUM

Brussels, Belgium

27 November to 5 December 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service
IRRS

FANC
federal agency for nuclear control

BEL V

Integrated Regulatory Review Service

IAEA | IRRS

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
FOLLOW-UP MISSION REPORT TO
BELGIUM

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
FOLLOW-UP MISSION REPORT TO
BELGIUM

Mission date:	*27 November to 5 December 2017*
Regulatory body:	*Federal Agency for Nuclear Control (FANC) and Bel V*
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)*

IRRS REVIEW TEAM	
CAMPBELL Robert	Team Leader (United Kingdom)
MOORE Scott	Deputy Team Leader (United States of America)
ALLAIN Olivier	Reviewer (France)
ALM-LYTZ Kirsi	Reviewer (Finland)
BANUS Sander	Observer (Netherlands)
CARINOU Eleftheria	Reviewer (Greece)
COLLIGAN Alexandre	Reviewer (Canada)
JUHASZ Laszlo	Reviewer (Hungary)
TKAVC Marjan	Reviewer (IAEA)
MAGRUDER Stewart	IRRS team Coordinator (IAEA)
MANSOUX Hilaire	IRRS Deputy Team Coordinator (IAEA)
UBANI Martyn O.	IRRS Administrative Assistant (IAEA)

IAEA-2017

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

In December 2013, at the request of the Government of Belgium, the IAEA undertook an IRRS mission to Belgium. The review team comprised eighteen international experts drawn from regulatory bodies in other Member States. The IRRS was a full scope peer review of Belgium's regulatory framework for nuclear and radiation safety. As well as examining the Governmental and legal framework, the IRRS team reviewed relevant activities, mainly being undertaken by the principal organisations with legal authority to regulate nuclear and radiological safety, i.e., the Federal Authority for Nuclear Control (FANC) and its technical arm, Bel V; hereinafter referred to collectively as the Regulatory Body (RB). The IRRS mission made thirty-one Recommendations, and twenty-four Suggestions for the Government and RB to consider, as a means of enhancing the regulation of nuclear and radiation safety in Belgium. The mission also identified six areas of good practice, which IAEA captured to share more widely internationally.

Subsequently in 2016 the Government of Belgium requested a follow-up IRRS mission to review the measures taken to address the original findings made in 2013. A follow-up review mission was conducted in Brussels from 26 November to 5 December 2017. The team comprised seven international regulatory experts; including several who had participated in the original 2013 mission, three technical officers from the IAEA, and an IAEA administrative support officer.

The IRRS team carried out a review of the steps taken to address the findings of the 2013 IRRS mission in the following areas: responsibilities and functions of the Government; responsibilities and functions of the RB; the management system of the RB; activities of the RB related to regulation of the complete range of nuclear facilities and activities, including their authorization, review and assessment, inspection, enforcement as well as development and content of regulations and guides; and emergency preparedness and response. Other areas reviewed included the control of medical exposures, occupational radiation protection, control of discharges, materials clearance, chronic exposure, environmental monitoring for public radiation protection; and the interface with nuclear security. The follow-up review was also used to exchange information and experience between the IRRS team members and the Belgian counterparts in the areas covered by the IRRS mission.

The follow-up mission included interviews and discussions with RB staff, and representatives from other involved organisations. No site visits were necessary for the purposes of concluding the follow-up review. The RB provided the IRRS team with advance reference material and other documentation, to demonstrate progress made in relation to the original findings from 2013.

The IRRS team concluded that the recommendations and suggestions detailed in the 2013 IRRS mission report have been given due consideration by the Belgian counterparts, as evidenced by the documentation provided to the review team and the interviews conducted during the review mission. The follow-up mission team members determined that the majority of findings from the original mission have been adequately addressed and could therefore be considered as closed, some on the basis of progress made and commitments to complete actions in the near-term. This has resulted in clear improvements to the regulatory framework in Belgium to make it more effective and efficient. Notable achievements include:

- New and amended proposals for regulation and other arrangements clarifying roles, responsibilities and authorities within the regulatory framework, including confirmation of the independence of the RB in its reporting lines from those within government responsible for the promotion of nuclear energy and reissuing the transport regulations;
- The amended FANC law has clarified the roles and responsibilities of the RB which has led to closer interaction between FANC and Bel V;

- Replacement in the near term of the Authorized Inspection Organizations (AIOs) with recognized health physics organizations who are accredited by the RB, removing a potential conflict of interest;
- Establishing a project to systematically prepare the RB for the future challenges of regulating an increase in decommissioning activity and radioactive waste safety;
- A new central information system for sealed source inventory and tracking purposes, as well as inspection recording;
- An effective tool developed by Bel V to assist in the review and assessment of safety related modifications through a clearly defined graded approach to safety;
- FANC has taken positive steps to improve patient protection by promoting the justification of medical examinations, estimating diagnostic reference levels and providing relevant information back to the licensee; and
- Establishing a common safety culture policy in the RB and starting safety culture self-assessments.

The RB staff should be commended for the efforts made to address the findings from the 2013 mission.

For the few outstanding findings from 2013, the RB has made reasonable progress but has not fully implemented all the necessary actions to close them, and consequently these findings remain open. The IRRS team believes that it is important that the Government and RB should continue to maintain focus on these remaining areas for improvement and implement the necessary actions. Furthermore, the IRRS team identified a small number of new suggestions as well as some good practices. The RB is encouraged to address these suggestions.

The IRRS team also made the following general observations:

- The RB has undergone some organisational changes since the initial mission and these are now having the desired effect, e.g., improved resource planning. The RB should continue its efforts to further develop its management system to reflect the new organisational model and document all the processes and procedures necessary to implement the recently developed organisational policies. This will take a strong commitment from the RB's entire staff and management. The team believes that this activity needs to receive sustained attention.
- The RB is placing increased emphasis on enhancing its openness and transparency. This is an important aspect of modern regulation as it can enhance public trust and confidence. Several improvements have been made to better communicate regulatory activities aimed at improving public trust. The improvements made to date are commendable.
- FANC has drafted its proposal for the national policy statement regarding nuclear safety, nuclear security, radioactive waste management and radiation protection for the Government.

The RB's preparation for the follow-up mission was thorough, and the administrative and logistical support was excellent. The IRRS team was extended full cooperation by its Belgian counterparts during the technical discussions. The RB counterparts presented clear evidence of the actions they have taken or are still to take to successfully address the IAEA IRRS Mission findings. This work should lead to sustainable improvements to the regulatory and nuclear safety framework within Belgium.

An IAEA press release was issued at the end of the mission and a press conference was held immediately after the exit meeting between the IRRS team and the Belgian counterparts.

I. INTRODUCTION

At the request of the Government of Belgium, an international team of senior safety experts met representatives of FANC and Bel V from 26 November to 5 December 2017 to conduct an IRRS follow-up mission. The purpose of the peer review was to review the Belgian regulatory framework for nuclear and radiation safety. The follow-up mission was formally requested by the Government of Belgium in July 2016. A preparatory meeting was conducted 8 to 9 May 2017 at FANC Headquarters in Brussels to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the regulated facilities and activities in Belgium.

The IRRS team comprised 7 senior regulatory experts from 7 IAEA Member States, 1 observer from an IAEA Member State, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the areas covered by the main mission in 2013.

The RB prepared a follow-up summary report addressing the findings of the initial mission. The results of Belgium's follow-up report and supporting documentation were provided to the team as advance reference material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from FANC, Bel V, the Ministry of Security and Home Affairs, the National Institute for Health and Disability Insurance (NIHDI), ONDRAF/NIRAS and SCK•CEN.

All through the mission the IRRS team received excellent support and cooperation from the Belgian counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the Belgian 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 and activities 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 between FANC, Bel V and IRRS reviewers and through the evaluation of the effectiveness of the Belgian regulatory framework for nuclear and radiation safety and its good practices.

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

- Providing Belgium and its RB with a review of its regulatory programme relating to nuclear and radiation safety, and emergency preparedness in view of the progress made since the initial mission;
- Providing Belgium and its RB with an objective evaluation of its nuclear and radiation safety, as well as 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 RB staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Belgium and its RB with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Belgium, a preparatory meeting for the IRRS follow-up mission was conducted from 8 to 9 May 2017. The preparatory meeting was carried out by the appointed Team Leader Mr Robert Campbell, Deputy Team Leader Mr Scott Moore and the IRRS IAEA team representatives, Mr Stewart Magruder and Mr Teodros Hailu.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of FANC represented by Ms An Wertelaers, Director, Facilities and Waste and Mr Rony Dresselaers, Director, Security and Transport, other senior management and staff from FANC and Bel V. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Nuclear power plants;
- Research reactors;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Transport;
- Patient protection;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal);

Mr Simon Coenen, Liaison Officer for the mission, made presentations on the national context, the current status of FANC and the progress made by FANC since the original mission of 2013.

IAEA staff presented the IRRS principles, process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Belgium in November-December 2017.

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, including meeting and work space; counterparts and the identification of the Liaison Officer; lodging and transport arrangements were also addressed.

FANC provided the IAEA (and the review team) with the advance reference material for the review at the end of September 2017. In preparation for the mission, the IAEA review team members conducted a review of the ARM and provided their initial review comments to the IAEA Team Coordinator prior to the follow-up 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 references for this mission is given in Appendix **VII.**

C) CONDUCT OF THE REVIEW

An initial IRRS review team meeting was conducted on Sunday, 26 November 2017, 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 agree on the methodology for the review and the evaluation among all reviewers. They also presented the schedule for the mission.

The Liaison Officer was present at the initial IRRS review team meeting on Sunday afternoon, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission and a brief summary of the relevant significant changes in Belgium since the initial mission.

The reviewers also reported their first impressions of the ARM and provided the Team Leader with inputs for his slides for a presentation at the entrance meeting.

The IRRS entrance meeting was held on Monday, 27 November 2017, with the participation of RB senior management and staff and a representative from the Ministry of Security and Home Affairs. Opening remarks were made by Mr Jan Bens, Director General of FANC, Mr. Benoît De Boeck, Director General of Bel V, Mr Stewart Magruder, IRRS team Coordinator and Mr Robert Campbell, IRRS Team Leader who made a presentation highlighting the expectations of the mission and initial impressions on the ARM.

Following the entrance meeting, a briefing for the IRRS review team was provided by FANC and Bel V experts on the following topics:

- Overview of Regulatory Framework of Belgium – Role of FANC & Bel V;
- Procedure for drafting regulatory documents – Major regulatory projects in preparation;
- Law of 7 May on Health Physics Arrangements;
- Mission Schedule & Logistics.

During the mission, a review was conducted of all the initial mission review areas with the objective of reviewing the Government and the RB's response to the recommendations and suggestions identified during the original mission. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

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

The IRRS exit meeting was held on Tuesday, 5 December 2017 where the IRRS Team Leader, Mr Robert Campbell presented the results of the follow-up mission highlighting the main findings. This was followed by the statement by Mr Jan Bens in response to the Team Leader's presentation. Closing remarks were made by Mr David Senior, Section Head of the Regulatory Activities Section of the IAEA.

A joint IAEA and FANC press conference took place at the end of the mission during which an IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 1: In order to address this recommendation, a modification to the FANC law of April 1994 was made to establish the process to formalize a comprehensive national policy and strategy for nuclear and radiation safety.

The IRRS team noted that the article 2 ter, added by the law of 7 May 2017, states that: *"The government approves, upon proposal of the FANC, a national policy statement regarding nuclear safety, nuclear security and radiation protection based on, as a minimum, the following points of view:*

- *the justification principle and the priority to nuclear safety and security;*
- *continuous improvement in an international framework;*
- *transparent communication;*
- *safe management of radioactive waste;*
- *the defence in depth approach; and*
- *long term vision.*

The government sends this policy statement to Parliament."

The IRRS team observed that FANC drafted a national policy statement, and sent it to the Minister of Security and Home Affairs in August 2017. In parallel the draft has been submitted for public consultation.

The IRRS team noted that, inter alia, the draft:

- expresses a long term commitment to safety;
- states that the implementation of the policy shall be subject to a graded approach; and
- states the Government's intentions for safe and sustainable radioactive waste management.

The IRRS team noted that the draft does not address spent fuel management.

However, the IRRS team was informed that Belgium complies with the recommendation of the IAEA by combining two documents: the national policy statement regarding nuclear safety, nuclear security and radiation protection, mentioned above, and a national policy for safe management of spent fuel and radioactive waste management formalized in the law of 3 June 2014.

The IRRS team noted that the chapter 7 of the law of 3 June 2014 describes in detail the Belgian national policy on safe management of spent fuel and radioactive waste by transposing the European Council Directive 2011/70 of 19 July 2011.

Status of the finding in the initial mission

Recommendation 1 (R1) is closed on the basis of progress made and confidence in effective completion as a draft of national policy statement regarding nuclear safety, nuclear security and radiation protection has been proposed by FANC to Government and the national policy for safe management of spent fuel and radioactive waste management is formalized in the law of 3 June 2014.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

<table>
<tr><th colspan="2">2013 MISSION RECOMMENDATIONS, SUGGESTIONS</th></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>R2</td><td>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.</td></tr>
<tr><td>R3</td><td>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.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>R4</td><td>Recommendation: Government should ensure the regulatory body has legal authority for inspection at designer, supplier, manufacturer, constructor,</td></tr>
</table>

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
	contractor or operating organization associated with the authorized party or applicant.
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 2: To address this recommendation a modification of the FANC law of April 1994 has been made to streamline the process to issue or amend binding technical regulations. The IRRS team noted that the article 24 bis, added by the law of 7 May 2017, states that: *"The King may determine the cases for which the Agency must issue regulations of a technical and non-political nature for the implementation of the decrees issued pursuant to this law. Those are published in the Belgian Official Gazette."*

Furthermore, new responsibilities have been assigned to the FANC liaison officer in the Ministry of Security and Home Affairs' staff. These responsibilities are described in the FANC procedure PC 005 02 rev 3. The IRRS team noted that the current liaison officer was nominated in 2014 for a non-fixed term by the Minister of Security and Home Affairs.

The IRRS team met with the liaison officer and observed that this individual is a FANC inspector. He is therefore very well known by FANC staff and has regular meetings with the management of FANC. During these meetings, proposed regulatory changes are addressed. The liaison officer is still officially a member of FANC staff.

Recommendation 3: This recommendation is linked with recommendation 2 as the recent modification of the FANC law made to streamline the process to issue or amend binding technical regulations. The IRRS team noted that the article 24 bis, added by the law of 7 May 2017, states that: *"The King may determine the cases for which the Agency must issue regulations of a technical and non-political nature for the implementation of the decrees issued pursuant to this law. Those are published in the Belgian Official Gazette."*

The IRRS team noted that a royal decree was issued in October 2017 to set a series of technical binding regulations on transport. Several drafts of royal decrees are also in preparation.

Recommendation 4: To address this recommendation a modification of the FANC law of April 1994 has been made to extend the legal authority of FANC inspectors for inspection at suppliers

and subcontractors to operators. The IRRS team noted that the law of June 2014 in the article 10 sets that FANC inspectors *" ... shall, at any times and without prior warning have free access to the means of transport, factories, storage facilities, hospitals and, more generally, to all places where equipment or substances capable of emitting ionizing radiation are produced, manufactured, possessed and used, and in all places for which they may have a reasonable ground to presume that the above-mentioned equipment or substances may be found, subject to the provisions of the laws under their supervision , or evidence of the existence of an offense. "*

In a global nuclear supply chain it is sometimes necessary for regulators to carry out inspections in foreign countries. FANC is aware that any inspections abroad are beyond its legal authority, which is only within Belgian territory. Nevertheless, FANC indicated that inspections of designers, suppliers and manufacturers may also be carried out in foreign countries in agreement with and in the presence of the licensee. As an example, the IRRS team noted that an inspection of a supplier of the licensee Electrabel was performed on 3 August 2016. This inspection took place in France at Areva's Le Creusot manufacturing plant.

Recommendation 5: To address this recommendation a modification of the FANC law of 15 April 1994 has been made to clarify the role of recognized legal entities and FANC. The IRRS team noted that specific sections have been added by the law of 7 May 2017 related to health physics.

As a consequence, AIOs will be replaced by recognized organizations of health physics experts who may only assist the licensees (of low-risk facilities/activities) to perform some health physics missions, at the request, under the responsibility of, and paid by the licensees.

Status of the finding in the initial mission

Recommendation 2 (R2) is closed as the Government of Belgium has streamlined the process to issue or amend binding technical regulations and FANC is regularly informed of any changes of regulation by its liaison officer in the Ministry of Security and Home Affairs.

Recommendation 3 (R3) is closed as the authority of FANC to issue binding technical regulations has been broadened.

Recommendation 4 (R4) is closed as FANC inspectors now have legal authority for inspections at designer, supplier, manufacturer, constructor, contractor or operating organizations associated with the authorized party.

Recommendation 5 (R5) is closed as responsibilities of recognized parties for health physics are clarified and the role of the recognized organizations of health physics experts and their interfaces with FANC are more explicitly defined.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS
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*

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.	
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.**

Changes since the initial IRRS mission

Recommendation 6: To address this recommendation, there have been changes within Government. FANC is still a public body which reports to Parliament via the Minister of Security and Home Affairs but this Minister no longer has oversight of the State Secretary of Energy who is responsible for energy policy and for some of the licensees. The function of State Secretary is now assigned to a Minister in charge of Energy, Environment and Sustainable Development without any direct connection with the Minister of Security and Home Affairs. The IRRS team is confident that this independence will be maintained.

Recommendation 7: Significant work has been done by FANC and ONDRAF/NIRAS since the initial IRRS mission. In November 2016 the Government created a Task Force to clarify roles and responsibilities and to identify the interfaces between ONDRAF/NIRAS and FANC.

This task force identified the following topics to work on:

- Acceptance process (of waste);
- Management of steps to radioactive waste transfer;
- National policy for radioactive waste disposal;
- Intervention and site remediation;
- Storage facilities for radium bearing waste;
- Radioactive waste transportation;
- Shut down, decommissioning and dismantling;
- Authorization for nuclear facilities; and
- Inventory of radioactive substances and radioactive waste

At the end of June 2017, the Task Force presented its final report. In July 2017, the Council of Ministers allocated the task of making necessary proposals to the relevant Ministers to address the actions proposed in the report.

FANC and ONDRAF/NIRAS have both prepared several drafts to modify the law and royal decrees. The IRRS team noted that FANC considers that these legal and regulatory activities would be completed within a year.

Status of the finding in the initial mission

Recommendation 6 (R6) is closed as FANC is now a public body which reports to Parliament via the Minister of Security and Home Affairs, who no longer has any direct connection to the Minister responsible for Energy.

Recommendation 7 (R7) is closed on the basis of progress made and confidence in effective completion as roles and responsibilities of ONDRAF/NIRAS and FANC are about to be clarified in order to ensure separation of roles and responsibilities on aspects of radioactive waste management.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
R8	**Recommendation: Government should explicitly assign the prime responsibility for safety to the person or organisation responsible for a facility or an activity.**

Changes since the initial IRRS mission

Recommendation 8: To address this recommendation a modification of the FANC law of April 1994 was made. Article 28 now states that: *"The license holder is responsible, in all circumstances, to ensure the protection of the workers, the population and the environment against the hazards or health disadvantages which could arise from the exercise of its practice. This responsibility cannot be delegated."*

Status of the finding in the initial mission

Recommendation 8 (R8) is closed as the prime responsibility for safety is now explicitly assigned to the person or organisation responsible for a facility or an activity.

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS
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.*

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.**
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.*	
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.**
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).*	
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.**

Changes since the initial IRRS mission

Recommendation 9: To address this recommendation, the Government has issued a policy statement which, inter alia, includes a commitment to ensure patient safety during medical exposures. Two royal decrees of December 2016 are now in place to specify the respective roles and responsibilities of FANC and the Federal Public Service (FPS) Public Health, and FANC and the National Institute for Health and Disability Insurance (NIHDI), in terms of exchanges of information and data. Moreover a collaboration protocol has been signed between FANC and FAMHP for the exchange of data and information in areas of common interest and a respective royal decree will be published soon.

Recommendation 10: Exports of sources are mainly managed by the regional Governments of the 3 Belgian regions; Flanders, Wallonia and Brussels. Each region is responsible for delivering an export licence for radioactive sources. Prior to the delivery of this export licence by the regions, the federal government is responsible for delivering an authorization examining mainly risks of proliferation (for example uranium used in shielding). There are no changes since 2013.

Due to the political situation in Belgium, the constitutional framework which distributes the competences between the federal Government and the regions is complex.

The IRRS team was informed that FANC has decided to wait for the completion of the federal legal framework planned in the near future, to develop the process between all involved stakeholders.

Suggestion 1: In the medical domain, FANC collaborates with the FPS Health (Health, Food Chain Safety and Environment), the NIHDI and the Federal Agency for Medicines and Health Products (FAMHP). Three royal decrees of December 2016 allow the systematic exchange of data and information, which can for instance be used to set up joint inspection campaigns.

Collaboration between FANC and the FPS Employment, Labour and Social Dialogue has been formalized in a protocol. The protocol establishes coordination of actions with respect to the health protection of workers. It includes harmonization of the respective regulations, and a federal approach to the prevention of radiation risks including joint interventions.

Status of the finding in the initial mission

Recommendation 9 (R9) is closed as respective functions and responsibilities of different authorities, in the field of medical exposure, are now clearly specified.

Recommendation 10 (R10) is open as FANC has decided to wait for completion of the federal legal framework in the near term before addressing this recommendation.

Suggestion 1 (S1) is closed as the responsibilities are now clarified and improvement has been made in relation to communication of inspection findings with other relevant administrations.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

There were no findings in this area in the initial IRRS mission.

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

There were no findings in this area in the initial IRRS mission.

1.8. COMPETENCE FOR SAFETY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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 their views on R&D needs for regulatory purposes. Some research programs are nevertheless performed in relation to medical exposures and geological disposal.*	
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.**

Changes since the initial IRRS mission

Suggestion S2: To address this suggestion FANC, with the support of Bel V and research institutes, has strengthened their research programs.

Research activities are led in three different fields:

- Nuclear safety - supported by Bel V;
- Safe management of radioactive waste (geological disposal) - supported by Bel V and FANC;
- Radiation protection - supported by Belgian research institutes and FANC.

The IRRS team observed that the research programs presented by Bel V in relation to safety and geological disposal and by the Belgian Nuclear Research Centre (SCK•CEN) on radiation protection are extensive.

As an example, Bel V invests between 7 to 10 % of its time on research activities. An annual program is established by Bel V and presented to FANC.

For radiation protection research, a convention was signed by the Government and research institutes in spring 2017, with the purpose of attracting and combining resources in radiation protection research available in Belgium.

Status of the finding in the initial mission

Suggestion 2 (S2) is closed as FANC with the support of Bel V and research institutes has strengthened research programs in the field of safety, waste disposal and radiation protection.

1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the initial IRRS mission.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

There were no findings in this area in the initial IRRS mission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

There were no findings in this area in the initial IRRS mission.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 11: The amended FANC law (May 2017) and the associated draft amendment of the royal decree GRR-2001 clarify the role, financing and oversight of Bel V. GRR-2001 describes the tasks that FANC can delegate to Bel V and provides additional legal bases for these activities. These tasks include safety assessments and inspections related to Class I and IIA nuclear facilities. GRR-2001 also describes the oversight by FANC of Bel V. This includes FANC's audits of Bel V and the reporting arrangements of Bel V to FANC. The cooperation between FANC and Bel V is also embedded in the internal governance structure of both organizations. The director general of FANC and four members of the Board of Directors of FANC are also members of the Board of Directors of Bel V. The AIOs will no longer exist after the entry into force of the amended FANC law. FANC and Bel V are refining the management agreement that will be signed after the publication of the amended GRR-2001 (expected mid 2018). This agreement defines, in more detail, the tasks that are delegated to Bel V by FANC.

The Scientific Council acts as an independent advisory body to the management of FANC. The members of the Council are appointed by the Minister of Security and Home Affairs and are nuclear experts. The Council delivers, inter alia, advice for licensing of Class I nuclear installations.

FANC has a three-tiered planning system. The first tier is a long-term strategic plan (9 years) and based on this, the second tier is a mid-term operational plan (POP3) with a duration of three years. The third and final tier is an annual operational plan (POP1) that includes the allocation of resources to each section for specific tasks. Every year, each FANC section develops its own annual plan, in which staffing needs are considered including the resource needs required from other sections. These operational plans are also discussed with Bel V to better coordinate and plan the work.

FANC manages its competence and resources through the "Human Resources Management" policy and the related processes "human resources planning" and "competency management".

The "human resources planning" process ensures that the staffing is commensurate with the organization's strategy. The "competency management" process aims to identify the necessary competencies inside FANC taking into account its legal mission. This process also aims to regularly map the current FANC competencies. Another goal of this process is to identify gaps in competence management and the required corrective actions (recruitment, training). This is discussed in more detail in S8.

Bel V has developed a tool in order to improve the management and assessment of its workload. This tool aims to optimize the allocation of human resources for review and assessment activities and also for work prioritization. This includes the consideration of "work requests" that FANC issues to Bel V and describes in detail what is expected by FANC from Bel V. The workload within Bel V is assessed annually based upon the known activities and historical working hours. The staffing plan for the next year is subsequently produced and allows the planning of the necessary recruitments. A review of the adequacy of Bel V's resources include short (1 year), medium (3 years) and long-term (10 years) planning.

Status of the finding in the initial mission

Recommendation 11 (R11) is closed on the basis of progress made and confidence in the effective completion as the amended FANC law and drafted royal decree will clarify the roles and responsibilities of FANC and Bel V. The resource needs are systematically estimated in short and long-term operational plans. Competence management will be discussed further in S8.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

There were no findings in this area in the initial IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

There were no findings in this area in the initial IRRS mission.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the initial IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

2013 MISSION RECOMMENDATIONS, SUGGESTIONS
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.*

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
R12	**Recommendation: The regulatory body should give more detailed internal guidance for inspections, review and assessment to improve the consistency in its decision making.**
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.*	
S3	**Suggestion: The regulatory body should consider formalizing and systematically documenting the use of graded approach for allocating resource according to risk.**

Changes since the initial IRRS mission

Recommendation 12: Within the FANC management system, the policy on inspections has been defined and published. The underlying processes and specifically the process INS-03 (execution of an inspection) provides more detailed guidance on inspections. For all planned inspections, an inspection guide or scope document will be issued to assist inspectors during inspections.

A "review & assessment" policy has been drafted within the FANC management system. This policy defines basic principles which will enhance the consistency of decision making processes within the regulator body:

- the review basis (regulations, guidelines, international norms) when performing the review and assessment, must be clearly documented;
- the results of the review and assessment must be in writing including justifications;

The IRRS team was informed that additional internal guidance documents (e.g., thematic assessment guides) are not planned to be issued within the scope of review and assessment. Moreover, it was discussed that for certain areas (e.g., security, medical facilities licence applications) internal guidance documents could be useful and FANC will consider that when finalising its revision of the management system.

Bel V has been involved in the development of the policy documents by commenting on them. Bel V has its own management system, including more detailed guidance for review and assessment, and its control activities.

Suggestion 3: For the main operational regulatory functions such as inspection, review and assessment, and authorisation, a graded approach is used, driven by the national regulatory framework that identifies different classes of facilities and associated practices. This graded approach is used in practice by giving more resources and attention to the most safety relevant and complex issues. The graded approach results in a differentiation of the licensing process

according to the type of facility, from the most comprehensive one for a Class I facility, to a simplified and shorter licensing process for a class III installation.

For the authorisation of practices in the medical sector, a graded approach will not be adopted in the regulatory framework. FANC is by law required to license all applications for radioactive or X-ray sources in the medical sector. The same level of regulatory control applies to all practices, such as radiotherapy, nuclear medicine, radiology, dental and veterinary use, by licensing them. However, in practice, more time and resources are allocated for licensing the more complex facilities, for example radiotherapy and nuclear medicine applications. FANC is assessing its processes with the aim of improving its efficiency. This is done by employing different tools like information campaigns, and a risk-oriented prioritization of inspections. At the same time, regulations for the medical sector are under review to introduce a more graded approach in the regulations.

For other regulatory activities such as "Inspection", "Review and Assessment" and "Enforcement", FANC's new management system policies will have high level principles for the use of a graded approach. One of the inspection processes, INS-02 related to the establishment of the annual inspection plan relies on a graded approach.

Bel V has developed a documented and traceable graded approach methodology for the review of "Non-important modifications" (NIM) of NPPs (see R20). Bel V has continued developing this methodology and will extend it to a wider scope of review and assessment activities, for instance in the framework of licensing of new installations and of safety assessment projects concerning existing installations.

The "Enforcement" process also applies the principle of graded approach via the introduction of safety measures and administrative measures (see S16).

Status of the finding in the initial mission

Recommendation 12 (R12) is closed on the basis of progress made and confidence in the effective completion as the management system policies for inspection and review and assessment, and their underlying processes have been developed or are under development. FANC is also developing more detailed inspection-specific guidance. It will also consider developing more detailed guidance for certain areas of review and assessment when finalising the revision of the management system.

Suggestion 3 (S3) is closed on the basis of progress made and confidence in the effective completion as the principle of graded approach used for different classes of nuclear facilities is embedded within the Belgian regulations. The management system policies will include the high level principles of the use of a graded approach within one class of facilities. Bel V has developed a quantitative methodology for the use of a graded approach in the review and assessment of "Non-important modifications" and continues developing the methodology for broader use.

3.7. SAFETY RELATED RECORDS

There were no findings in this area in the initial IRRS mission.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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).*	
S4	**Suggestion: FANC should consider establishing a transparent decision making process, providing to the public and stakeholder the elements that support its regulatory decisions.**
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 4: The main principles of internal and external communications are written in FANC's policy document "Communication". It is currently in draft but will be published within a few months. The updated website of FANC includes a lot of useful and up- to-date information concerning radiation protection and nuclear safety. FANC has decided not to systematically publish regulatory decisions on its website but to respond to requests for information. According to the Belgian transparency laws, anyone can ask for more detailed information related to regulatory decisions. If a request is made, FANC has to provide this information unless the documents are of a confidential nature. The IRRS team was shown two examples of recent requests and the responses of FANC.

FANC typically publishes information related to events at nuclear facilities that are rated as 1 or above on the International Nuclear and Radiological Event Scale (INES), or for events that have a high media impact, and for the most important regulatory decisions related to Class I or IIA installations. An example of a decision that has been published is the issue related to anomalies in the Doel 3 and Tihange 2 reactor pressure vessels. A full set of documents supporting the FANC decisions is available on its website.

In monthly meetings between FANC's operational departments and the communication section, current topics are discussed to determine what might be of public interest and for those topics identified as such, a communication plan is developed.

Suggestion 5: The decommissioning strategy, including the anticipated final end state of the site, has to be documented in the licence application to obtain a dismantling licence in accordance with article 17 of the GRR-2001. This licence application is subject to a "public inquiry" during the licensing process, where the general public is consulted and can provide comments and

remarks on the licence application. The public can be consulted via a request for consultations to the Municipality Executive of all municipalities within a 5km radius. The mayor's office is legally required to inform and consult the local inhabitants.

Since 2013, FANC and Bel V have developed guidance on the regulatory process for release of a nuclear site from regulatory control. The guidance document describes the roles and responsibilities of the different entities within the RB on completion of decommissioning. These include review of final decommissioning report of the licensee; inspections and independent measurements by the RB; advice of other competent bodies; and approval of release from regulatory control by the RB. The guidance document also recommends public consultation where the final end state of the site will be a brownfield. This guidance document will be issued within six months.

Status of the finding in the initial mission

Suggestion 4 (S4) is closed on the basis of progress made and confidence in the effective completion as the communication policy and the related processes and procedures of the FANC management system will define the main principles for public communication.

Suggestion 5 (S5) is closed on the basis of progress made and confidence in the effective completion as the current decommissioning licensing process already includes the aspects of stakeholder involvement and the drafted guidance document on the regulatory process for the release of a nuclear site from regulatory control will cover the topic for the final end state of the site.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**
Observation: *The safety culture within the Regulatory Body itself is not being addressed explicitly.*	
R14	**Recommendation: The regulatory body including Bel V, and all other organizations performing regulatory functions, should develop and implement a common safety culture policy.**

Changes since the initial IRRS mission

Recommendation 13: The amended FANC law (May 2017), the associated draft amendment of the royal decree GRR-2001 and the management agreement between FANC and Bel V have been formalized or are under revision. In this new set of documents, the role, financing and oversight of Bel V in relation to FANC was clarified (see R11). FANC and Bel V have their own management systems. In the current draft of the management agreement between FANC and Bel V the individual management systems or the relationship between the two systems were not mentioned.

FANC is currently doing an overall revision of its management system (see S6). FANC indicated it will integrate its interactions with Bel V and the support provided by Bel V in the processes described in the management system of FANC.

FANC and Bel V use common policy documents. FANC is the owner and author of these policy documents; Bel V has reviewed them and has provided comments to FANC in the drafting process. As an example, the "Inspection" policy was shown to the IRRS team and clearly identifies the oversight by FANC of Bel V. FANC delegates most of the "Review & Assessment" activities of Class I and Class IIA nuclear facilities to Bel V. The scope, objectives and planning of the required review is clearly stated in a "work request" by FANC to Bel V. Before endorsing them, the results of such external reviews by Bel V are reviewed by FANC and discussed if necessary.

Currently, neither FANC nor Bel V can access each other's management system platforms but there are plans to address this.

Twice a year, the management teams of FANC and Bel V meet to:

- coordinate their projects and regulatory activities to promote harmonisation. This means that Bel V can provide input for regulatory initiatives and that the guidance developed by Bel V can be approved by FANC;
- reinforce the coherent and efficient approach within the RB by developing service level agreements e.g., internal mobility, common training and safety culture; and
- ensure that decisions are correctly applied via follow-up meetings and communication.

Recommendation 14: FANC and Bel V have developed a common safety culture policy document. It introduces the following five principles: leadership for safety, promoting individual responsibility, establishing cooperation and open communication, implementing a holistic approach, and ensuring continuous improvement. The references used in the development work were IAEA GSR Part 2 and GS-G-3.5, and OECD/NEA Green Booklet "The safety culture of an effective RB".

Although the aims and references are identical for FANC and Bel V, the approach to implementation is different.

FANC is developing a methodology for event-driven safety culture self-assessment. For this approach FANC selects specific events that fall outside the routine activities. These are reviewed by an "ad hoc" team with respect to safety culture issues. Such an event could be for example an incident/accident which may require substantial resources of the FANC. For such a review, an ad hoc team is gathered, composed of the safety culture officer, some reviewers (that were not actively involved during the event) and some of those who were involved during the event. This team will review the event by evaluating a set of safety culture attributes. The outcome of the review will consist of lessons learned that can be used as input to the management system at the appropriate levels. The anticipated results include some direct lessons and consequent updates for the management system, or for regulations. The results will also be presented to FANC staff. FANC is currently performing their first event investigation using this new approach. A formal procedure for these self-assessments will be produced after this first pilot. They plan to do one review per year per department.

Bel V has chosen a different approach and developed a methodology based on the requirement 14 of GSR Part 2 (assessment and improvement of safety culture). The process of Bel V is described within a procedure integrated within their management system (Q010200-01-01-p-org-e). This model is based on a set of principles and related characteristics to be assessed by the members of an assessment group, with approximately 7 members. This is done in workshops aimed at capturing internal perceptions. For each characteristic, group members select the most suitable assertion, provide facts (findings and arguments) and identify potential actions for improvement. The applied tool is solution oriented and puts emphasis on underlying causes through assessment workshops. The process aims at identifying implicit and shared assumptions and at exploring their influence on safety-related issues. The first self-assessment was carried out at Bel V in 2016. Results of the Safety Culture assessment have been incorporated into Bel V's operational plan.

FANC and Bel V approaches are different; Bel V's is more theoretical giving an overall picture of the maturity level of the safety culture in the RB. FANC's approach is more pragmatic but is limited in certain regulatory activities and does not provide a broader picture about the regulatory safety culture aspects. The approaches seem to complement each other.

Status of the finding in the initial mission

Recommendation 13 (R13) is closed as the amendment of the FANC law and the royal decree GRR-2001, FANC and Bel V management agreement and some of the policies of the FANC management system clarify the role of Bel V for several regulatory activities such as inspections and review and assessment. FANC and Bel V management meet at least twice a year to coordinate their activities and to improve consistency.

Recommendation 14 (R14) is closed as FANC and Bel V have published a common safety culture policy and they have developed methodologies for the self-assessments. Bel V has carried out its first self-assessment in 2016 and FANC is currently doing its first self-assessment.

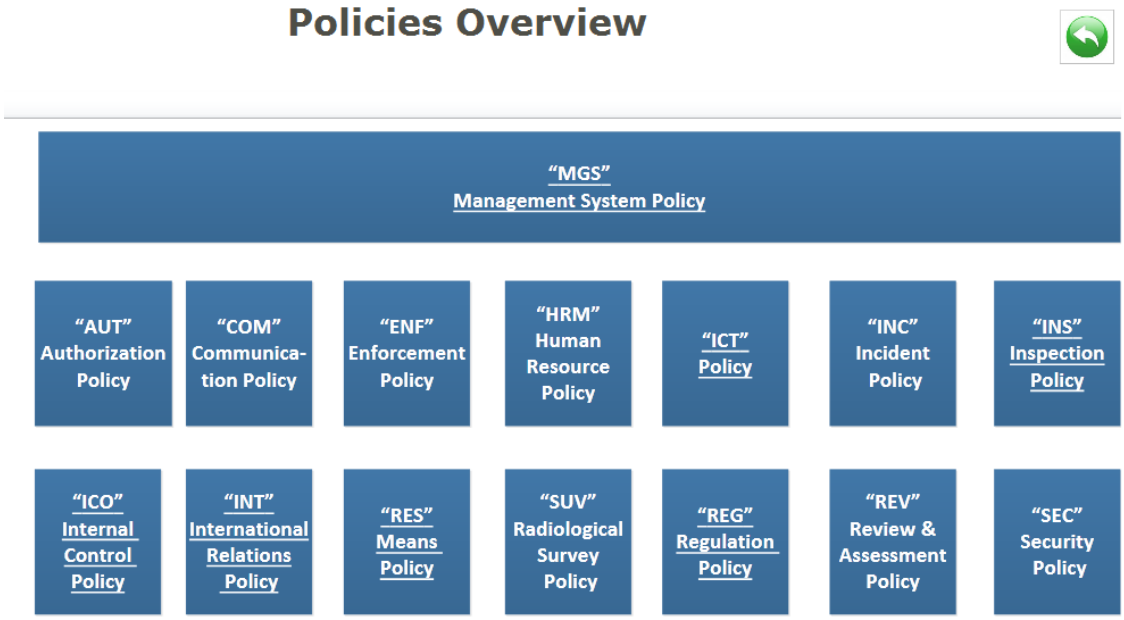
4.2. MANAGEMENT RESPONSIBILITY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
S6	**Suggestion: FANC should consider continuing the development and implementation of an integrated management system. This should include processes for assessment and continuous improvement.**

Changes since the initial IRRS mission

Suggestion 6: After the initial IRRS mission, FANC decided to make an overall revision of its management system and move from a quality management system to an integrated management system in line with the IAEA GS-R-3. FANC concluded that the former ISO 9001:2008 certification is no longer suitable for the purposes of the organization and decided to stop the certification process and to build a new bespoke integrated management system. The new management system relies on fifteen policies (see figure below) that address all of the activities of FANC. For each of the fifteen policies, a responsible policy owner has been designated by FANC management. The group of policy owners is called the College of Policy Owners. This College is responsible for ensuring the coordination, the coherence and the management of the different interfaces between the management system documents. The College plays an important role in the approval process of the management system documents, in the coordination of the continuous improvement process and in the communication of the management system.

Each policy is supported by a set of processes and if needed, procedures can provide instructions for some specifics tasks. Processes are also currently under development. Each process description includes systematically a Responsibility Assignment Matrix (RACI Matrix), a risk analysis and Key Performance Indicators (KPIs). The existing procedures will then be checked to confirm whether they cover all the processes and whether they need some update. A specific dynamic FANC SharePoint site has been developed for the management system documentation.



(Figure 1)

The remodelling of the FANC management system has turned out to be very time-consuming. As a result, the starting phase and the development of the first documents induced a delay into the project. Current expectation is to finalise the overall revision of the management system within one year. The IRRS team encouraged FANC to request a specific mission to evaluate the progress made for the management system in early 2019.

A specific process (MGS-02) related to "Continuous Improvement" has been developed. This "Continuous Improvement" process belongs to the "Management System" policy (MGS). The continuous improvement process includes for example handling of non-conformities and suggestions for continuous improvement, management reviews and audits.

Status of the finding in the initial mission

Suggestion 6 (S6) is closed on the basis of progress made and confidence in effective completion. FANC has decided to completely renew its management system with a different approach to achieve the goal of integrating the management system. Good progress has been made but there is still some work to do to finalise the project. FANC management committed to finalise the management system within the next year.

4.3. RESOURCE MANAGEMENT

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
S7	**Suggestion: The FANC should consider gathering information on actual time spent on specific regulatory activities to improve the planning and management of resources.**

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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 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.*	
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.**

Changes since the initial IRRS mission

Suggestion 7: FANC has not considered recording the actual time spent on specific activities as a priority. The scope for managing human resources (HRM) gives priority to planning of future needs in human resources as well as to skills and competencies. FANC has further developed the allocation of human resources in the annual planning process as well as the follow-up of the status of individual tasks. The approach is now to consider outcomes, not working hours. If some tasks are delayed, the reasons behind this will be discussed, including the proper allocation of resources.

Suggestion 8: With regards to competence management, FANC and Bel V have chosen two different approaches.

In its management system development project, FANC will determine the set of required knowledge and competences for each management system function. This framework will facilitate the management of the staff training program and for drawing up personal development plans. FANC has drafted a new HR policy document and related processes. These documents are still under development. Another process under development describes knowledge transfer. The long-term staffing plan is under discussion at FANC.

FANC has further developed its performance cycle process, where once a year, an evaluation is performed by the section or department head of the employee's performance, to discuss and establish the objectives for the upcoming year as well as the identification of skills and competences that need to be developed. This process is to be used in a systematic way in the future.

The mobility of staff between FANC and Bel V is described in a service level agreement between the two organizations. In addition, some of the training programs are shared by FANC and Bel V.

The project for developing competence management at FANC requires coordination with the labour unions. As a consequence, the project is progressing slower than initially scheduled.

Bel V has developed and implemented a customised version of IAEA's SARCoN as the main tool for assessment of Competence Gap Analysis. The process is described within a set of procedures related to HRM (A08, e.g., Q080202-01-00-p-org-e). After completion of the "Individual Basic Training Programme" (Q080203-01-02-t-org-e), newcomers are expected to carry out a self-evaluation of their competences. Then the middle manager establishes an Individual Specialized Training Programme (Q080203-01-05-t-org-e). Newcomers are expected to apply a SARCoN assessment after approximately 9 months and to reproduce it two years later in order to observe and to evaluate improvements or remaining gaps to be addressed. The IRRS team saw one example of such SARCoN assessments.

Status of the finding in the initial mission

Suggestion 7 (S7) is closed as FANC has further developed its management of human resources with specific attention on a proactive allocation of human resources and follow-up on the results. The original suggestion related to follow-up on the actual working hours is no longer relevant.

Suggestion 8 (S8) is closed as Bel V has implemented a systematic approach for competence management based on IAEA's SARCoN tool. FANC's project related to the function description management and competence management is delayed although there is a good plan for implementation. A new suggestion will be reformulated to refer only to FANC.

New observation from the follow-up mission

In its management system development project, FANC will determine the set of required knowledge and necessary competencies for each management system function. This framework will facilitate the management of the staff training program and development of personal development plans.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation *FANC has drafted a new HR policy and the related processes are under development. FANC's project related to the function description management and competence management is delayed although there is a plan for implementation.*	
(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"*
SF1	**Suggestion: FANC should consider finalizing the competence management system and establishing a systematic training programme based on it.**

4.4. PROCESS IMPLEMENTATION

There were no findings in this area in the initial IRRS mission.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 9: The FANC policy document "Internal Control" describes the organization of the internal control activities according to three control pillars. The first pillar is managed by the department head or the section head (i.e. a hierarchical line). They are responsible for ensuring that activities in the department/section are in line with the policies, processes and procedures. Corrective actions that could improve the department/section activities should be identified and implemented. The governance of the management system belongs to the second pillar. The head of the finance section, the management system cell and the College of Policy Owners are responsible for this second line. Finally, an independent internal audit cell is responsible to ensure that the work performed under the first and the second pillars meets the expectations of FANC.

Four processes are drafted for the implementation of the "Internal Control" policy, these are:

- dash-boarding and reporting;
- description of the second line of defence;
- management review; and
- internal audit.

The inaugural management review will be undertaken in February 2018. This management review will focus on four policies: "HRM", "Resources", "Management System" and "Internal Control". The process for management review means that in a 3 year cycle, all policies will be subject to review at least once. Operational and financial aspects are also included in the management reviews.

Bel V is finalizing a new process for risk reduction and internal control. This process is a new tool to strengthen the management system, ensuring that the decisions taken are actually implemented and will contribute to achieve the strategic objectives. This process will be certified to ISO 9001:2015 in October 2018.

Status of the finding in the initial mission

Suggestion 9 (S9) is closed on the basis of progress made and confidence in effective completion as the management review process of FANC means that all policies, including human and financial resources, as well as the operational and support policies are to be addressed at least once within a cycle of 3 years. The inaugural management review is planned to be carried out in February 2018.

5. AUTHORIZATION

5.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
R15	**Recommendation: The Government should update provisions so that a licence transfer is explicitly approved by the regulatory body after appropriate review.**
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 15: FANC has proposed a royal decree, entitled "royal decree aiming to avoid situations which can give rise to possible liabilities of radioactive waste or of installations to be dismantled". It was submitted for approval to the Minister of Security and Home Affairs'. FANC has confidence that approval will be given in early 2018.

The main elements of the proposed decree include:

- amending the GRR-2001 and, in particular superseding article 5.4 of GRR-2001 dealing with transfer of licences (such as operating licences, clearance licences and dismantling licences for facilities from Class I to Class III); and
- applications to transfer licences between organizations/persons.

In each case, FANC has to assess whether the future licensee is able to meet the licence conditions. FANC may request advice from ONDRAF/NIRAS.

Depending on FANC's conclusions and after a new safety assessment in case of modifications, a new licence is issued, either by the King (for Class I facilities) or by FANC itself (for other facilities and activities). FANC can also propose new/additional conditions (in application of art. 12 of GRR-2001 and in the case of modifications of art. 13 of GRR-2001).

For Class I facilities, the Scientific Council of FANC is also involved in the process.

Recommendation 16: Provisions to ensure that FANC is formally involved in the review and assessment of any impact on nuclear facilities as a result of changes in their surroundings have therefore to be included in regional legal provisions.

The Flanders region is the most significant because the majority of Class I facilities are located here, and the industrial risks are higher. For the Flanders region, a decree of June 2009, modified by the decree of July 2013, identified the governmental entities that should be consulted for advice on any planning application for new facilities.

Since February 2017, this legislation for land use planning has been consolidated. The role of FANC is described in article 35 and 37 and the content of the advice of FANC is described in article 38 of that decree.

FANC performs an assessment of whether the risks of the proposed new (industrial) installation or activity are acceptable. Since the end of 2013, FANC routinely gives opinions as part of (regional) permitting procedures in Flanders. The process, the responsibilities, the hold-points and the workflow have been in cooperated into a FANC internal procedure PC006-22 (FR/NL).

For the Brussels-Capital Region, no nuclear class I facilities are operating and none are planned.

For the Wallonia region, relevant legislation has not yet been established and needs to be further developed. In July 2017 FANC sent an official letter to the authorities in Wallonia, to ensure that FANC is involved in the review and assessment of the impact on nuclear facilities due to changes in their surroundings. The need to resolve recommendation R16 is less pressing as the industrial environment in Wallonia around the two Class I facilities (NPP Tihange and IRE Fleurus) is less developed, and poses relatively low risks to these facilities.

Status of the finding in the initial mission

Recommendation 15 (R15) is closed as FANC has developed a proposed royal decree, addressing licence transfers, that is in the final stage of the regulatory process (approval by the Government).

Recommendation 16 (R16) is closed on the basis of progress made and confidence in effective completion, as FANC is formally involved in the review and assessment of the impact on nuclear facilities due to changes in their surroundings in Flanders, and FANC routinely issues opinions on proposed developments. Work to establish similar arrangements in Wallonia has commenced.

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

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 17: The proposed royal decree regarding the physical control regime is aimed at formally defining the role and responsibilities of Bel V in the regulatory framework, including their review and assessment activities and their interaction with FANC. The publication is anticipated in July 2018.

For Class I and IIA facilities, the proposal includes an amendment of the licensing process described in article 6 and 7 of the GRR-2001. The proposal contains the following provisions:

- when an application for a licence is received at FANC, FANC requests Bel V to perform an independent safety assessment of the application and issue a "Safety Evaluation Report" to FANC; and
- taking into account the Bel V safety assessment, FANC will evaluate the licence application and issue an opinion which will be presented to its Scientific Council.

In addition, FANC is working to update the current licensing process for Class I facilities (specifically drafting a proposal for a complete review of article 6 of GRR-2001). These updates may include the official introduction of a pre-licensing process, explicitly linking the preliminary safety analysis report requirements, as contained in the SRNI-2011, the detailed specification of the contents of the licence, further provisions on the regulatory supervision of the construction and commissioning process and the extension and modernization of the means for a public enquiry. This update of the licensing process is progressing but will not be completed in the near future.

Suggestion 10: For Class I facilities, the Scientific Council of FANC is involved in the licensing process. The licensing procedure of Class I facilities already includes provisions to ask the advice of the Scientific Council in accordance to the GRR-2001.

Status of the finding in the initial mission

Recommendation 17 (R17) is open as the update to regulations regarding review and assessment activities and the licensing procedure for class I facilities is on-going.

Suggestion 10 (S10) is closed, as the role of the Scientific Council in the procedure for confirmation of the construction and operating licence is already clearly formulated in GRR-2001.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**
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.*	
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**

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
	shipments for disposal. **c) Transfer authorizations should also be internally communicated to those tracking sealed sources.** **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.**

Changes since the initial IRRS mission

Suggestion 11: The RB has extensively reworked and streamlined its processes for authorization of the commissioning of facilities. The new process encompassed legislative changes to the royal decree as well as internal procedural changes. The original facility classes, I, II and III, have been slightly modified with the creation of a new sub-class of Class II, known as IIA, which encompasses inter alia, cyclotrons, industrial accelerators, above 1 MeV, and medical facilities used for hadron therapy. Class I and IIA facilities will retain the existing commissioning process requiring the submission and regulatory approval of a detailed commissioning report prior to receiving authorization for routine operation. In contrast, class II (excluding IIA) and III facilities will no longer require the submission of a commissioning report to the regulator prior to commencing routine operation. Instead, the Recognized Health Physics Expert (RPHE), after performing an on-site verification of commissioning tests, will submit a notification to FANC stating that the facility is, from this date, in compliance with all commissioning requirements. FANC will acknowledge receipt and confirm that the facility may commence to routine operations. It should be noted that the on-site RPHE is still expected to complete a commissioning report while on-site and this could be examined during regulatory inspections. Thus, the burdensome task of reviewing commissioning reports for low risk facilities is greatly reduced without compromising safety.

Recommendation 18: FANC has implemented some significant changes to its sealed source tracking system since the initial IRRS mission. It has developed a Central Information System (CIS), a database of all high activity sources, including their use and history of ownership.

Reporting requirements have also been increased. Prior to executing any sealed source transfer, the sender must notify FANC of its intent to transfer a sealed source. This transfer notification is recorded in the CIS thereby unifying source transfer information with sealed source tracking. While the recipient is not required to inform the regulator at the time of transfer, all licensees are required to submit their sealed source inventory to the regulator on a monthly basis as part of the new physical inventory initiative. As such, a sender's notification of source transfer can always be cross-referenced with its recipient's inventory within the timespan of a month or less.

In addition, the resilience of the CIS has been significantly improved from the previous tracking systems as it now resides on internal servers with regular backups and appropriate protections.

Status of the finding in the initial mission

Suggestion 11 (S11) is closed as FANC has developed a procedure (PC010-05) establishing a process for authorization of class II and III facilities, including confirming authorization following commissioning. This has been addressed avoiding a potential administrative burden on the regulator.

Recommendation 18 (R18) is closed as FANC has built an effective sealed source tracking system. New regulations and procedures have been drafted for mandatory inventory reporting and transfer authorizations, creating an effective tracking process for sources.

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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**

Changes since the initial IRRS mission

Recommendation 19: To address Part (a) of this recommendation, FANC has proposed a royal decree entitled "Aiming to avoid situations which may give rise to potential liabilities of radioactive waste or of installations to be dismantled". It will amend the general regulations for the protection of the public and the environment against the dangers of ionising radiation (GRR-2001). This draft decree had been developed in close cooperation with ONDRAF/NIRAS, which is responsible for radioactive waste management on behalf of the Government; the draft decree has followed the FANC process for the development of regulations (PC005-02). It was submitted to relevant stakeholders and advisory bodies in early 2017 for their comments, which were satisfactorily resolved. FANC submitted the draft decree in October 2017 to the Minister of Security and Home Affairs for final approval. It is anticipated to come into effect in early 2018.

The draft decree requires that a "decommissioning file" be created by the responsible Class I and Class IIA licensee. This file is then subject to review and assessment by both the RB and ONDRAF/NIRAS as part of the application for a nuclear site licence. In the "decommissioning file," the licensee must describe the measures it intends to take during the design, construction and operation of an installation to facilitate eventual decommissioning and dismantling. In addition, the licensee is required to estimate the type and quantity of radioactive waste that will be generated through the decommissioning phase of the installation. Moreover, the safety report for an installation must be updated periodically, including refinement of the predictions of any future radioactive waste accumulation, and is subject to approval by the RB.

To address Part (b) of this recommendation, Article 17 of GRR-2001 requires that in order to obtain a licence to commence decommissioning, the licensee must provide adequate documentation to justify the safety of the proposed decommissioning activities. Prior to commencing decommissioning and dismantling, licensees must submit a "Safety Report for Dismantling" to the RB, and a decommissioning plan to ONDRAF/NIRAS. The RB reviews and approves the safety report for dismantling, and ONDRAF/NIRAS reviews and approves the final decommissioning plan.

The format and contents for the safety report for dismantling is outlined in the amended royal decree of 2011, Safety Requirements for Nuclear Installations (SRNI-2011). This amendment implements the Western European Nuclear Regulators Association (WENRA) reference levels for decommissioning into the Belgian regulatory framework.

Separately, ONDRAF/NIRAS has also defined a table of contents for the final decommissioning plan, and although the purpose of the documents is not the same, many of the requirements placed by both documents (i.e., the Safety Report for Dismantling and the decommissioning plan) are identical. This has the benefit of avoiding inconsistent or conflicting regulatory requirements being placed on the licensees. To help ensure consistency of approach a protocol has been documented, agreed and issued jointly by FANC and ONDRAF/NIRAS. This document sets out the arrangements for cooperation between the two organisations to ensure that their respective duties in relation to review and approval of decommissioning safety related documentation are implemented.

Status of the finding in the initial mission

Recommendation 19, parts a) and b) (R19a and R19b) are closed on the basis of progress made and confidence in effective completion as the draft royal decree has been proposed and submitted, and should be approved and come into effect in 2018; FANC has signed a protocol with ONDRAF/NIRAS which clarified the respective roles and responsibilities of both organisations.

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 12: FANC has introduced new legislation for the authorization of transport of radioactive material. The process now allows for the registration of carriers as a form of authorization thereby reducing the regulatory burden of repeatedly licensing routine individual shipments. These changes were legislated for in October 2017 in a new royal decree that will enter into force on 1 January 2018. This new legislation represents a graded approach to authorization based on four different risk categories. Overall, this approach will substantially reduce the administrative effort of transport authorization. Furthermore, it is expected to free-up

resources that can be devoted to field inspections, thereby increasing the regulatory oversight of transport activities. Technical regulations and guidance remain to be published.

Status of the finding in the initial mission

Suggestion 12 (S12) is closed as the royal decree establishing a new system for registering carriers of low risk shipments enters into force 1 January 2018.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

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

6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 20: In the national regulatory framework, "Non-important modifications" (NIM) for Class I and Class IIA facilities are submitted to Bel V for review and approval in accordance to article 23 of the GRR-2001. "Non-important modifications" are modifications that can have an impact on radiological protection or nuclear safety, but do not require changes to the licence. Bel V has developed a methodology that applies a traceable graded approach to reviewing NIM.

This tool uses well-defined criteria in its application. A scoring sheet has been developed, with two broad groups of criteria i.e. importance for safety and the complexity of the NIM.

For each criterion, a score is given. Based on a combination of the scores for the different criteria, the NIM is sub-divided in 3 categories, defining the type of review (category 1: detailed analysis; category 2: some specific aspects will be analysed; category 3: no technical analysis needed).

As part of developing this approach ten NIM were selected for benchmarking and the tool was refined appropriately. The approach is now fully implemented for NIM submitted by the NPPs. For NIM submitted for other nuclear installations, the suitability of this approach is being investigated.

The application of the scoring sheet was demonstrated to the IRRS team.

Status of the finding in the initial mission

Requirement 20 (R20) is closed as the guidance and processes clearly apply a graded approach in the review and assessment of "non-important modifications" of class I facilities.

New observation from the follow-up mission

The IRRS team observed that Bel V not only addressed Recommendation 20, but went further by developing a very effective tool, with well-defined criteria applying a graded approach for reviewing NIM.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the Belgian regulatory framework, "Non-important modifications" (NIM) for Class I and Class IIA facilities are submitted to Bel V for review and approval in accordance with article 23 of the GRR-2001. Bel V developed a methodology on how a documented and traceable graded approach could be introduced in reviewing the NIM. A tool has been established with well-defined criteria to establish a clear graded approach. A scoring sheet has been developed, with two groups of criteria: importance for safety and complexity of the NIM.*	
(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"*
GPF1	**Good Practice: Bel V has developed and implemented an effective tool, with well-defined criteria applying a graded approach for reviewing safety related modifications, termed "non-important modifications."**

6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

6.2.3. BASES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

There were no findings in this area in the initial IRRS mission.

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

There were no findings in this area in the initial IRRS mission.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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**
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.*	
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).**

Changes since the initial IRRS mission

Recommendation 21: The inspection policy, GD010-02 rev. 2, includes the development of inspection programmes which define frequencies that facilities and activities are to be inspected.

The inspection policy includes, respectively for each inspection area: the obligation to define a 6 yearly programme to cover all areas relevant for safety and radiation protection; and an annual inspection plan. FANC and Bel V have established, a common working group to review and then implement a process for an integrated inspection and control programme (IICP) for the Class I facilities.

The implementation of this programme has two main goals: to ensure that all the regulatory provisions applicable to Class I facilities in Belgium for verifying compliance with safety and radiation protection are covered. This is ensured by a systematic verification of the provisions of the IAEA safety standards/guides and by verification of inspection practices in other countries. The second goal is to ensure that the regulatory provisions in force address all the inspected areas.

Two 6-yearly inspection programmes exist: one for the NPPs and one for all other class I facilities. The political and legal context supports the end of the nuclear power generation activities in Belgium. It was decided not to develop an IICP for the construction of new NPPs.

The 6-year cycle of the IICP considers the human resources within FANC and Bel V. Both programmes comprise exhaustive lists of themes for FANC inspections and Bel V controls, specifying if an inspection/control is a thematic one (to verify the consistency of the process) or a systematic one (to verify the implementation of the process in the field).

The frequency by which a specific theme has to be inspected/controlled by the RB is stipulated in the programme, giving guarantees on the fact that the class I facilities are comprehensively and systematically inspected in all the relevant areas every 6 years.

The first IICP was prepared as a draft and will be finalized by the end of 2017. Some operational tools, such as the development of inspection guidelines on each theme and the development of a management tool will be completed by the end of 2017. The inspection guides contain detailed guidance on topics, questions to be asked and issues to be discussed during an inspection.

Recommendation 22: The inspection policy requires the development of inspection programmes with adequate frequencies by which facilities are to be inspected. For industrial class II and III installations, the development of an inspection programme is almost completed. The elements of the inspection programme of Class II and III installations are already translated into the annual inspection plans. Inspection guides are available with the different topics, questions and issues to be discussed during an inspection. Some remaining issues will be finalised by the end of 2017. For medical installations and transport, frequencies of inspections have been determined considering radiological risk using a graded approach. Defined priorities for inspection and 6 risk categories support the inspection planning.

Status of the finding in the initial mission

Requirement 21 (R21) is closed as the new inspection policy and processes applying a graded approach are in use. The inspection programme covers all areas relevant to safety and the development of inspection guidelines is in progress.

Requirement 22 (R22) is closed as the new inspection policy, processes and practices use a graded approach taking account of radiological risk.

7.1.2. INSPECTION PROCESSES AND PRACTICES

There were no findings in this area in the initial IRRS mission.

7.1.3. INSPECTORS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
S13	**Suggestion: The Government should consider allowing the director general of FANC to authorize nuclear inspectors.**

Changes since the initial IRRS mission

Suggestion 13: The existing legal provisions do not allow the Director General of FANC to authorize nuclear inspectors: a nuclear inspector can only be appointed via a royal decree, after an internal process of accreditation. The Director General is involved with this formal approval of the nomination, after the accreditation process, that leads to the written proposition of the nuclear inspector, in a royal decree, for signature and legal publication in the Belgian Official Gazette. The Director General of FANC has been empowered to take the oath of office of the nuclear inspectors. Article 9 of the FANC law ensures that an up-to-date list of nuclear inspectors shall be published at least every two years in the form of a ministerial decree. This decree summarizes the different royal decrees in a single document which gives more transparency to operators, who can directly identify which of FANC staff are nuclear inspectors.

Status of the finding in the initial mission

Suggestion 13 (S13) is closed as an internal process of accreditation is in place in which the Director General is involved, and he is responsible for the implementation of the process. However, the legal provision does not allow the Director General of FANC to authorize nuclear inspectors.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

7.3. INSPECTION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 14: In response to S14, the RB has developed a two-pronged approach: Firstly, they have drafted a new set of technical regulations for mandatory inventory reporting from the

licensees. The second step involved building a database to log and track the radioactive source inventory that is being reported as a result of the new regulations. This software system is known as the Central Information System (CIS).

The draft technical regulations specify the duties of the licensee with respect to complying with the new inventory reporting requirements. The initiative is designed to provide the regulator with current knowledge of each facility's physical radioactive source inventory, thereby increasing oversight of licensees.

As part of this initiative:

- The licensee would now fill its inventory in an Excel template, and submit it to the regulator on a monthly basis. The submission requirements will apply to sealed sources, equipment containing sealed sources and particle accelerators. Open sources, manual brachytherapy seeds and ribbons as well as any fissile material would be excluded;
- The CIS will be able to compare the licensee's submitted inventory with what has been authorized;
- The regulator will always have an up-to-date version of the licensee's inventory in the CIS (current from within the last month);
- A FANC inspector can use this inventory report for physical verification during on-site inspections; and
- The system also tracks inspections that have been performed as well as outstanding non-conformances for each facility.

FANC has taken other legislative initiatives to address the potential conflict of interest stemming from the role of AIOs, that had been noted during the original IRRS mission. Regulatory inspections will soon be performed solely by the FANC inspectors and AIOs will have no role in assisting the regulator. These changes were enacted in the law of 7 May 2017 and will enter into force in 2018. It should be noted that the reference to AIOs in S14 no longer applies, however the general intent of the suggestion, as it pertains to the the Code of Conduct 22(h), remains clear.

The above-mentioned changes meet and exceed the items outlined in Suggestion 14. Substantial progress has been observed and the FANC is well on its way to achieve full completion of its new systems by mid-2018.

Status of the finding in the initial mission

Suggestion 14 (S14) is closed on the basis of progress made and confidence in effective completion of technical regulations for mandatory inventory reporting, providing FANC inspectors with verifiable inventory information when conducting on-site inspections.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS
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*

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
inspections need the support of other departments within FANC. There is currently no process to ensure that this assistance is provided	
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.**

Changes since the initial IRRS mission

Suggestion 15: As mentioned previously in paragraph 7.1.1., since the 2013 Mission, the RB has developed an integrated inspection and control programme (IICP) for all class I facilities. The IICP covers all regulatory activities for a facility within a 6-year period, and its scope includes decommissioning and dismantling activities. Inspection guidance for decommissioning and dismantling activities is still under development and will take cognisance of the technical competences available within the RB.

The RB has initiated a project to better prepare itself for the challenges of regulating the decommissioning and dismantling lifecycle stage of the Belgian nuclear installations. This project has begun to develop principles and guidance in the following topic areas:

- release criteria for site and buildings;
- release criteria for individual items;
- independent measurements to be made by the RB (including in-situ samples); and
- a guide on the process within the RB to enable a licensed nuclear site to be released from regulatory control.

It is anticipated that this guidance will be issued in 2018. When the above activities are completed, the training needs will be analysed and incorporated into training for RB personnel to ensure effective and coordinated implementation of the process and guides for site inspection of these areas.

The issue of successful release from regulatory control is manifesting itself in the near term at two of the existing licensed sites. Some old nuclear fuel production facilities at Dessel are undergoing decommissioning and final site clearance; one site is run by Franco Belge de Fabrication de Combustible (FBFC International) and the other, a shut-down MOX fuel fabrication facility, is run by Belgonucleaire. The activities to decommission and clear these sites are nearing their final stages. Specific programmes are underway for making independent measurements of selected samples from buildings and the ground on both sites. Expertise from other departments within FANC (e.g., Section of Surveillance of the Territory and Natural Radiation) is being employed, where necessary, to support the inspections by Bel V and a nationally accredited environmental laboratory will be contracted by FANC, to assist in defining an adequate programme for sampling.

Status of the finding in the initial mission

Suggestion 15 (S15) is open as the different guidance documents and associated training programs related to the final release of sites from regulatory control are still being developed.

7.8. INSPECTION OF TRANSPORT ACTIVITIES

There were no findings in this area in the initial IRRS mission.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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 /suspension of the license.*	
S16	**Suggestion: FANC should consider improving its decision making process for enforcement in order to ensure consistency.**

Changes since the initial IRRS mission

Suggestion 16: FANC has improved its decision making process for enforcement and has formalized this process with a modification of the FANC law of 1994. FANC has now about 40 nuclear inspectors. FANC has also implemented a graded approach to its enforcement process.

The FANC enforcement process has two types of actions: safety measures and administrative measures. Only administrative measures are used when the non-compliance with the regulations is not associated with a significant hazard.

The use of fines is an effective measure to sanction the licensee when it breaches the law. Enforcement can also include prison sentences according to the law of 1994.

The roles and responsibilities of the nuclear inspector are to prevent or eliminate non-compliances which they observe and which they consider as a hazard. The nuclear inspector may take or impose all appropriate measures, including those of an organizational nature, which he considers necessary for the health and safety of workers and the public and for the protection of the environment. The imposition of those measures is mainly based on the law and the expert judgement of the nuclear inspector. The internal procedure requires the nuclear inspector to consult with his manager, to ensure consistency in decision making.

Safety measures are used to eliminate an immediate danger. The safety measures are written in a FANC decree referring to the law and the different circumstances that lead to those measures. When immediate actions are required, a safety measure may also be immediately and orally imposed on the responsible operator.

The operator is informed in the inspection report of the fact that it has received a warning. The inspection report describes: the findings; the violated article of the regulation; the actions to be taken to stop the violations, as well as the necessary actions to rectify the consequences and to prevent a recurrence. If the deadlines are not respected, further enforcement has to ensue.

Status of the finding in the initial mission

Suggestion 16 (S16) is closed as the update of the decision making process for enforcement has been completed with consideration of a graded approach.

8.2. ENFORCEMENT IMPLEMENTATIONS

There were no findings in this area in the initial IRRS mission.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 17: A new policy document for regulations was recently established (May 2017). Another relevant procedure has been updated (September 2016) and describes the development of regulations (PC005-02, rev. 3). This procedure explicitly anticipates the regular review of the FANC law and the GRR-2001 in order to integrate the various changes and propose them for approval to the relevant authorities. It also states that new/updated regulations need to be coherent with international directives and agreements and also with documents from international organizations. The drafting of new/amended regulations is performed by a working group. The participants of this working group need to have sufficient experience and expertise to ensure coherence with the regulatory framework (European directives, IAEA safety standards, national laws and royal decrees etc.).

The same procedure can be applied for the regulatory guides, although all steps are not necessary (e.g., consultation with the Scientific Council).

Recommendation 23: Bel V has continued to develop its regulatory guides, especially for the new nuclear class I facilities (e.g., safety demonstration, external hazards, radiological consequence analysis, construction and commissioning). There are currently no plans to build

new Class I facilities in Belgium, so there are no specific regulatory requirements on siting. The procedure for developing the regulations (PC005-02) is also applicable for regulatory guides.

An internal document has been developed (2016-06-28-SD-KG-3-3-001) describing the hierarchy of the different regulatory documents. The document also lists the various parties and stakeholders that need to be consulted for each type of regulation. Consultation with the public is not always required: the document lists these cases where consultation with the public is not required (e.g., in case of regulation that has to be issued urgently or in case of laws, where the public consultation is handled via Parliament). For other types of regulatory documents (e.g., guidance documents), FANC can decide whether or not they want to consult the public. The public is not always consulted for draft regulatory guides because of their technical nature. However, the regulatory guides with binding force are published on the FANC website after their finalisation. FANC already publishes binding regulatory guides on its website (http://www.jurion.fanc.fgov.be). FANC also has plans to publish non-binding guides after the updated GRR-2001 has been published.

Status of the finding in the initial mission

Suggestion 17 (S17) is closed as the process for initiating/amending regulations includes a systematic periodic review of regulations, and also foresees that IAEA safety standards are systematically taken into account.

Recommendation 23 (R23) is closed as Bel V has continued developing its regulatory guides and prioritising their development according to their importance to safety. For non-binding regulatory guides, the public is not often consulted but the guides are published on the FANC website.

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

There were no findings in this area in the initial IRRS mission.

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
S18	**Suggestion: The regulatory body should consider developing clearance levels for surface contaminated items.**

Changes since the initial IRRS mission

Suggestion 18: The RB has initiated a project to further enhance its preparedness for the future challenges that decommissioning the Belgian NPPs and other facilities will bring. In the framework of implementing the Euratom Basic Safety Standards Directive 2013/59, the existing regulation GRR-2001 will be amended. A new article will be included in GRR-2001 which will enable FANC to issue a specific technical rule, and it is FANC's intention that clearance levels for specific items will be established, taking into account European recommendations, such as RP113 and RP89 as well as relevant recommendations made in IAEA safety standards. It is

anticipated that the technical rule will be issued in early 2018. Subsequently, clearance levels for items (including clearance levels for surface contaminated items), will be established, also in 2018.

Status of the finding in the initial mission

Suggestion 18 (S18) is closed on the basis of progress made and confidence in effective completion as the Basic Safety Standards Directive 2013/59/Euratom is anticipated to be transposed into Belgian regulations in 2018, which will enable FANC to issue a technical rule, followed by surface clearance levels for specific items, in 2018.

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITES

There were no findings in this area in the initial IRRS mission.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Recommendation 24: A regulation on decommissioning of class I facilities was published in August 2015. In addition, the RB is also developing guidance for decommissioning class I and IIA facilities which is expected to be issued in 2018.

For other class II and class III facilities, FANC has concluded that the need for additional requirements for decommissioning is minimal; only in a few rare circumstances (e.g., linear accelerators for radiotherapy), where the licensee possesses activated materials that cannot be exempted, need to be treated as radioactive waste via ONDRAF/NIRAS arrangements. All other materials that can be exempted should be done via the Health Physics Department of the responsible operator. For facilities with sources, either a certificate of acceptance as radioactive waste by ONDRAF/NIRAS is needed, or a certificate of the supplier of the source declaring that the source has been taken back, or a certificate of the new destination of the source, are sufficient to release the facility from regulatory control and deem it to be effectively decommissioned.

For NORM or other work activities, the decommissioning activities are addressed under Article 9 of GRR-2001. According to this article, facilities need to register with FANC and provide an analysis of their radiological impact. This analysis has to be reviewed whenever significant changes in the activity are proposed or anticipated; decommissioning falls into this category.

The IRRS team discussed this graded approach with FANC, and concluded that FANC can sufficiently establish decommissioning requirements for all licensees and registrants.

Suggestion 19: The regulations for decommissioning class I facilities, referred to above, describe which records need to be collected and retained. Furthermore the aforementioned decommissioning readiness project is producing guidance that will address, among other matters, information and record keeping, such as specifying the contents of Chapter 8 (management of waste accumulations) of the safety assessment report, as well as the information needed in relation to waste in the other chapters; developing the document management process to ensure traceability of waste accumulated; and providing information needed during each phase of the waste management process. FANC expects to issue the guidance in 2018.

Status of the finding in the initial mission

Recommendation 24 (R24) is closed on the basis of progress made and confidence in effective completion as FANC is confident that for less safety-significant facilities (Class II, Class III, NORM), it can sufficiently establish decommissioning requirements for facility clean up and release from regulatory control.

Suggestion 19 (S19) is closed on the basis of progress made and confidence in effective completion as FANC is developing guidance that will address information and records relevant to decommissioning, that it expects to be published in 2018.

9.6. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 20 would require modifying the royal decree of 6 February 2003 to allow the regulator to dispense its training obligations and assign them to a third-party training provider willing to accept the task.

FANC has experienced some difficulties in modifying the royal decree for this purpose, especially in light of higher priority initiatives. FANC has also encountered important challenges in finding a third party interested in providing the training to ADR drivers, as the low volume of trainees involved has not generated any interest from the private sector. It should be noted that there are no apparent deficiencies in the quality of FANC's current training. Despite the above-mentioned issues FANC remains committed to its course of action and will continue to seek progress in the upcoming year.

Status of the finding in the initial mission

Suggestion 20 (S20) is open given the challenging obstacles to overcome and the absence of a planned completion date.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL REQUIREMENTS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
R25	**Recommendation: Regulatory body should further develop guidance on emergency preparedness and response for the licensee.**

Changes since the initial IRRS mission

Recommendation 25: The RB addressed this recommendation through developing its IICP as described in section 7.1.1. A set of "inspection referential" documents for some topical area were produced. These documents contain detailed guidance including objectives and practical arrangements for inspections carried out by the RB.

The relevant document for emergency preparedness and response contains objectives for emergency preparedness and response, and lists licensees to whom the document applies. It provides interface with other process-based "inspection referential" documents. The document gives scope and makes reference to articles of the relevant royal decrees which are regulations on emergency preparedness and response that the licensees must meet. It also lists relevant IAEA Safety Standards and publications as relevant guidance. In addition, there is also an annex, which gives detailed support to the inspection on EP&R. This document is provided to licensees and the annex could be made available too.

While this approach strengthens the inspection process and provides for more consistency among emergency preparedness and response arrangements at licensed sites, there is only limited additional guidance given to the licensees. However, it is noted that in principle the royal decrees themselves provide sufficient means to issue requirements to the licensees (see also the new observation below).

Status of the finding in the initial mission

Recommendation 25 (R25) is closed as the new inspection programme together with the royal decrees on emergency preparedness and response provide sufficient guidance.

New observation from the follow-up mission

The royal decrees in themselves are not completely in-line with the IAEA General Safety Requirements No. GS-R-2. An example of a requirement for licensees not covered by the royal decrees is managing radioactive waste on-site during an emergency.

In addition, GS-R-2 was superseded by GSR Part 7 in 2015, which brought updated and new requirements for emergency preparedness and response. Examples of requirements for licensees not covered by the royal decrees include assessing and determining assistance from off-site at the

preparedness stage and setting conditions, criteria and objectives to be met to terminate the emergency on-site.

It is noted that the revision of the royal decrees is now underway.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The royal decrees on emergency preparedness and response are not in full accordance with GS-R-2, neither do they accord with GSR Part 7, which superseded GS-R-2 in 2015. Since GSR Part 7 updates all the requirements from GS-R-2, updating the decrees to meet GSR Part 7 is suggested.*	
(1)	**BASIS: GS-R-2 Para. 4.86 states that** *"Radioactive waste and contamination shall be appropriately managed"*
(2)	**BASIS: GSR Part7 Para. 5.26 states that** *"The operating organization of a facility or activity in category I, II, III or IV shall assess and determine, at the preparedness stage, when and under what conditions assistance from off-site emergency services may need to be provided on the site, consistent with the hazard assessment and the protection strategy"*
(3)	**BASIS: GSR Part7 Para. 5.100 states that** *"The Government shall ensure that, as part of its emergency preparedness, arrangements are in place for the termination of a nuclear or radiological emergency. ... The planning process shall include ... (d) Conditions, criteria and objectives to be met for enabling the termination of a nuclear or radiological emergency..."*
SF2	**Suggestion: The Government should consider progressing the update of the royal decrees on emergency preparedness and response to meet the requirements of IAEA standard GSR Part 7.**

10.2. FUNCTIONAL REQUIREMENTS

There were no findings in this area in the initial IRRS mission.

New observation from the follow-up mission

Time objectives for critical response functions and tasks to be completed by licensees during the response to an emergency are given only for initial notification and are longer than suggested by the IAEA. In the FANC directive 2010-054 rev 2 (version of 22/10/2014) it is requested to report or notify immediately significant events by successful direct contact with a competent expert (expected to be made within one hour). Confirmation in writingof this initial notification, should be made within 2 more hours as required by the FANC directive 2010-054 rev 2.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The response time objectives for critical response functions and tasks to be completed by the licensees during a response to an emergency are given only for initial notification and are longer than suggested by the IAEA.*	
(1)	**BASIS: GS-G-2.1 Para. 4.26 states that** *"For facilities in threat categories I and II…These arrangements should be established with the goal of meeting the time objectives in Appendix VI."*
(2)	**BASIS: GS-G-2.1 Para. 6.5 states that** *"The arrangements for facilities in threat categories I, II and III should be established with the goal of meeting the time objectives given in Appendix VI."*
SF3	**Suggestion: The RB should consider ensuring that licensees of facilities in Emergency Preparedness Categories I, II and III undertake critical response functions and associated tasks in a timely manner.**

10.3. REQUIREMENTS FOR INFRASTRUCTURE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
R26	**Recommendation: The regulatory body should develop its own**

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
	nuclear/radiological emergency response plan.

Changes since the initial IRRS mission

Recommendation 26: FANC has developed a policy on emergency preparedness and response in the document entitled: 'FANC general policy relating to the management of significant events and crisis management'. This policy document describes the overall response to all types and scales of emergencies, including those that are security related. The response plans contain a graded approach, according to the urgency and the actual or potential consequences of the situation. For example for smaller scale events FANC leads the response, while for large scale events FANC supports the managing authority. This can be at the federal, provincial or municipal level.

While most of the supporting procedures are issued, some of them are still under development and some are planned. Procedures include: operation of the FANC/Bel V internal emergency response centre, operation of the evaluation cell, and operation of the measurement cell.

The policy is described in an overarching document for emergency preparedness and response at the RB. As such it is expected that all emergency related procedures and other internal documents should be listed as references. Currently only non-emergency related procedures are listed as references.

Status of the finding in the initial mission

Recommendation R26 is closed on the basis of progress made and confidence in effective completion as the overarching policy document brings together all emergency related procedures and other related internal documents, which constitute the emergency response plan of the RB.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

There were no findings in this area in the initial IRRS mission.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURE

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**
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.*	
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.**
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.*	
R27	**Recommendation: The regulatory body should enforce the legislation applicable to dose constraints for comforters and carers and volunteers in biomedical research.**
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 21: A royal decree on medical exposure (RD Medical) has been drafted that specifies requirements on basic and continuous training on radiation protection based on radiological risk for medical practitioners and entitled persons (e.g. technologists), previously called auxiliaries. For radiological medical practitioners, their first licence is based on adequate basic training in radiation protection. Furthermore, there is a credit system with FANC attributing credits to activities of continuing education. If radiological medical practitioners have obtained enough credits, they can obtain an extension of their "personal licence" to permit them to continue exercising their tasks using ionizing radiation. For the entitled personnel the list of training courses attended can be checked during the inspections performed by FANC. A close collaboration exists among NIHDI (National Institute for Health and Disability Insurance), FPS Health and FANC to exchange data and information on these aspects that have been formalized by royal decrees.

Suggestion 22: The draft Policy document mentioned in Recommendation 1 addresses the principle of justification, including, in the field of medical exposure. The proposed amendment of the FANC law states that FANC can propose which practices can be adopted for general use or be prohibited. The RD Medical contains the annexes with the practices that have been adopted for general use as well as the prohibited practices. Regarding new practices, the IRRS follow up team was informed that FANC has already documented a procedure for the justification, before the practices are licensed for the first time or adopted for general use in the medical sector. Finally, a protocol agreement has been signed in 2014 by FPS Public Health, NIHDI, FANC and the regions aiming at reducing the number of medical procedures which increase the population dose. In this framework, the referring medical practitioner can use referral criteria available at the website of the FPS Public Health.

Recommendation 27: The RD Medical states that for carers and comforters, the radiological medical practitioner, in cooperation with the medical physics expert, and the radiation physics expert (mentioned as qualified experts in the IAEA GSR part 3) are responsible for keeping the doses of the carers and comforters as low as possible taking into account national and international guidance. Dose constraints for persons under the age of 18 are set at 1 mSv. The same applies for unborn children. Pregnant women cannot be carers or comforters in nuclear medicine practices.

For the establishment of dose constraints in the field of medical or biomedical research there is provision in the RD Medical where it is stated that the dose constraints are set according to the protocol of the research project and based on national and international guidance. In practice, FANC, who authorizes the medical or biomedical research project when ionizing radiation is used, has developed a methodology based on WHO (World Health Organization), ICRP (International Commission on Radiological Protection) and NCS (Dutch Commission for Radiation Dosimetry) guidance using gender and age criteria. If the project does not meet these criteria FANC can ask for a modification.

The IRRS team was informed that both types of dose constraints are being implemented.

Recommendation R28: The RD Medical (articles 42, 43 and 44) sets the requirements for calibration of measuring and monitoring equipment (including the frequency and traceability) as part of the work performed by the medical physics expert. FANC can ask for the calibration certificates during inspections. In relation to unintended or accidental medical exposures the RD Medical (article 48) states that all reasonable measures have to be taken to limit the probability and the scale of such exposures. The licensee is responsible to set up an appropriate system to register and analyse events that led, or could have led, to accidental or unintended exposures.

When such an exposure is clinically significant, the radiological medical practitioner has to inform the referring medical practitioner and the patients or their representatives of this event, the results of the analysis, and, when relevant, the clinical follow-up of the patient. When the exposure is significant according to the criteria set in the draft FANC decree, the event has to be notified to FANC. In cases when, according to FANC, the analysis has not been performed properly then FANC will visit the facility in order to further investigate the event on site. After careful evaluation of the events, FANC can upload a short summary of the event to its website without naming the licensee with the aim of more widely sharing the information.

Status of the finding in the initial mission

Suggestion 21 (S21) is closed on the basis of progress made and confidence in effective completion since the RD Medical where the criteria are described is in the process of being promulgated after the amendment of the FANC law. The coordination with the relevant authorities has been conducted, and FANC has already implemented the relevant process.

Suggestion 22 (S22) is closed on the basis of progress made and confidence in effective completion since the draft Policy document, the amendment of the FANC law and the proposed RD Medical are the legislative documents which show the Government's commitment on the justification of the medical practices. Once promulgated, actions on this suggestion will be complete.

Recommendation 27 (R27) is closed on the basis of progress made and confidence in effective completion since there are the relevant provisions in the proposed RD Medical, which is expected to be promulgated in 2018.

Recommendation 28 (R28) is closed on the basis of progress made and confidence in effective completion since there are the relevant provisions in the RD Medical, which is expected to be promulgated in the near future.

New observation from the follow-up mission

In the Belgian regulatory framework the principle of justification is now clearly addressed. The Belgian Medical Imaging Platform (BELMIP) in cooperation with the College of Radiology has developed referral criteria to help referring medical practitioners justify the examinations on an individual basis. Moreover, since 2013 several awareness campaigns for members of the public, for specific groups (like pregnant women) as well as for referring medical practitioners have been carried out, using mottos, brochures, posters, videos and radio spots to capture people's attention and make them aware of the justification process.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Several awareness campaigns have been carried out in Belgium to make people aware of the justification process in medical exposure.*	
(1)	**BASIS: GSR Part 3 Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified"*
GPF2	**Good Practice: Belgium has been organizing and carrying out several campaigns with regard to justification of medical exposures using methods such as mottos, brochures, posters, videos and radio spots to enhance the**

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	public's and referring medical practitioners' awareness.

11.2. OCCUPATIONAL RADIATION PROTECTION

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
S23	**Suggestion: The regulatory body should consider establishing and maintaining a national dose registry for the doses received by occupationally exposed workers.**
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 23: An amendment of the FANC law of 2014 that entered into force in 2017, gives FANC the authority to establish and maintain a national dose registry. Additionally, the revision of GRR-2001, a new royal decree on the form and content of the registry, and a FANC decree defining the transferring method of the monitoring records to FANC will put in place the relative legislative framework. The registry is now operational; it is populated with data received via a web application on an annual basis. Further improvement on the working categories is needed. The doses of aircrew personnel are included in a separate database which will be integrated in the registry. The web application of the registry was reviewed by the IRRS team.

Recommendation 29: The revision of the GRR-2001, which is expected to be promulgated in 2018, has taken into account:

- the new eye lens dose limit for the occupationally exposed workers and for apprentices and students (article 20). In article 30 there is also a provision on how to monitor the eye lens dose. Some pilot studies on the estimation of the eye lens doses have already been performed in Belgium;
- the use of dose constraints (article 23) which is assigned as the responsibility of the Health Physics Department under the supervision of FANC taking into account national and international guidance; and
- the establishment of workplace monitoring programmes (article 23) as the responsibility of the radiation protection expert. The measurements of the workplace monitoring programme can be used to assess the occupational exposure when the results of individual monitoring are not available.

Status of the finding in the initial mission

Suggestion 23 (S23) is closed, as FANC has an operational dose registry and the relevant regulations have been drafted and are expected to be in place in 2018.

Recommendation 29 (R29) is closed on the basis of progress made and confidence in effective completion as the three parts of this recommendation have been taken into account in the revision of GRR-2001, which is expected to be promulgated in 2018.

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

There were no findings in this area in the initial IRRS mission.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**
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.*	
R31	**Recommendation: Government should amend regulations with regard to improving the security of radioactive sources.**

Changes since the initial IRRS mission

Recommendation 30: To address this recommendation, FANC has modified the procedure PC005-02 "Development of Regulations". The IRRS team noted that the procedure PC005-02 rev 03 encourages the creation of working groups dedicated to specific projects where safety and security experts are represented.

Moreover to facilitate the dissemination of regulatory publications, the FANC legal department sends an email every 3 months to FANC staff titled "Regulatory vigilance" that summarises the regulatory work in progress. The IRRS team observed that such an e-mail was delivered in October 2017.

Recommendation 31: To address this recommendation FANC has prepared a modification of the FANC law to extend the FANC mandate for the security of radioactive materials, including the sealed radioactive sources. These modifications were proposed by FANC in March 2017. The IRRS team noted that this project, has recently been approved in November 2017 by the commission of parliament and is now about to be approved by the parliament itself after a plenary session and then sent to the King for signature.

Status of the finding in the initial mission

Recommendation 30 (R30) is closed as FANC has consolidated its management system to take due account of safety and security interface when drafting new or amending regulations.

Recommendation 31 (R31) is closed on the basis of progress made and confidence in effective completion as the amendment of the FANC law addressing security of radioactive sources is about to be signed by the King.

12.2. REGULATORY OVERSIGHT ACTIVITY

2013 MISSION RECOMMENDATIONS, SUGGESTIONS	
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.*	
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.**

Changes since the initial IRRS mission

Suggestion 24: To address this suggestion, FANC, together with administrations responsible for security aspects (police and army) and the operator performed an exercise on 21 November 2017.

The IRRS team reviewed the exercise scenario and logbook which described an event (leak from a contaminated circuit) which was aggravated by a security incident (taking over the control room by a rogue operator).

The exercise took place in the Doel Nuclear Power Plant and the scenario was played by staff of the operator and security forces in a representative room configured like an NPP control room.

FANC indicates that feed-back from the exercise will be collated and has already planned to program a similar, and more sophisticated, exercise in the near future.

Status of the finding in the initial mission

Suggestion 24 (S24) is closed as an exercise was performed on 21 November 2017 to test emergency preparedness and response to an event combining safety and security elements.

12.3. INTERFACE WITH OTHER AUTHORITIES

There were no findings in this area in the initial IRRS mission.

IRRS FOLLOW-UP MISSION TEAM

APPENDIX I - LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
Mr CAMPBELL Robert	Office for Nuclear Regulation (ONR)	rob.campbell@onr.gov.uk
Mr MOORE Scott	U.S. Nuclear Regulatory Commission (U.S.NRC)	scott.moore@nrc.gov
Mr ALLAIN Olivier	Autorité de Sûreté Nucléaire (ASN)	olivier.allain@asn.fr
Ms ALM-LYTZ Kirsi	Radiation and Nuclear Safety Authority (STUK)	kirsi.alm-lytz@stuk.fi
Ms CARINOU Eleftheria	Greek Atomic Energy Commission (EEAE)	ecarinm@eeae.gr
Mr COLLIGAN Alexandre	Canadian Nuclear Safety Commission (CNSC)	alexandre.colligan@canada.ca
Mr JUHASZ Laszlo	Hungarian Atomic Energy Authority (HAEA)	juhasz@haea.gov.hu
OBSERVER		
Mr BANUS Sander	The Authority for Nuclear Safety and Radiation Protection (ANVS)	sander.banus@anvs.nl
IAEA STAFF		
Mr MAGRUDER Stewart	Division of Nuclear Installation Safety (NSNI)	s.magruder@iaea.org
Mr MANSOUX Hilaire	Division of Radiation Transport and Waste Safety (NSRW)	h.mansoux@iaea.org
Mr TKAVC Marjan	Incident and Emergency Centre (IEC)	m.tkavc@iaea.org
Mr UBANI Martyn O.	Division of Nuclear Installation Safety (NSNI)	m.ubani@iaea.org
FANC LIAISON OFFICER		
Mr COENEN Simon	Federal Agency for Nuclear Control (FANC)	Simon.coenen@fanc.fgov.be

APPENDIX II - MISSION PROGRAMME

	Sunday 26 Nov	Monday 27 Nov	Tuesday 28 Nov	Wednesday 29 Nov	Thursday 30 Nov	Friday 1 Dec	Saturday 2 Dec	Sunday 3 Dec	Monday 4 Dec	Tuesday 5 Dec
8:30-9:00	Arrival of TM			Written Preliminary Findings delivered	Draft text to TL			Written Comments by Host		
9:00-10:00		Entrance Meeting	Interviews (2)	Interviews (4) / TM write Report / Secretariat edits findings	Cross Reading / Secretariat edits Report	Discussion of Executive Summary / Secretariat Finalizes Draft Report	Host reads Draft and submits Written comments*	Free	Discussion with the Host	Exit Meeting
10:00-11:00		Plenary Session				Submission of Draft to Host				Press Conference
11:00-12:00										
12:00-13:00		Lunch	Lunch	Lunch	Lunch	Lunch			Lunch	
13:00-14:00		Interviews (1)	Interviews (3) / TM write findings	Team discusses findings	Cross Reading / Secretariat edits Report	Host reads Draft / TL Finalizes presentation / TC Drafts the Press Release / TM Free		Team Meeting to discuss Comments	Finalisation of the Report	Departure of TM
14:00-15:00										
15:00-16:00				Interviews (5) / TM finalise findings / TM write report	Discussion of the results of cross reading					
16:00-17:00	Initial Team Meeting				TM finalize report / TL/TC write Executive Summary				Presentation of Final Draft of the Report to Host	
17:00-18:00		Daily Team Meeting	Daily Team Meeting	Daily Team Meeting			Free	Free		
18:00:19:00										
19:00-20:00		Dinner	Dinner	Dinner	Dinner				Farewell Diner	
20:00-0:00										

APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	Counterpart	FANC/Bel V Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Olivier ALLAIN	Jan BENS	An WERTELAERS Geert VOLCKAERT An FREMOUT Joris CREEMERS Petra WILLEMS Alexandra JANSSENS Sarah BATOUT (SCK•CEN)
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Olivier ALLAIN	Jan BENS	An WERTELAERS
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Kirsi ALM-LYTZ	Jan BENS	An WERTELAERS Pieter DE GELDER Erik HULSBOSCH

	IRRS Experts	Counterpart	FANC/Bel V Support Staff
			Frederik BERNIER
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Kirsi ALM-LYTZ	Rony DRESSELAERS	Sophie STROOBANT Vincent NYS Benoît BERNARD Simon COENEN
5.	**AUTHORIZATION**		
	Laszlo JUHASZ Alexandre COLLIGAN Robert CAMPBELL Scott MOORE	Frederik VAN WONTERGHEM	Thierry MALDAGUE Alexandra JANSSENS Nadi VAN MECHELEN Martine LIEBENS Ronny SIMENON (ONDRAF/NIRAS)
6.	**REVIEW AND ASSESSMENT**		
	Laszlo JUHASZ Alexandre COLLIGAN Robert CAMPBELL Scott MOORE	Frederik VAN WONTERGHEM	Pieter DE GELDER
7.	**INSPECTION**		

	IRRS Experts	Counterpart	FANC/Bel V Support Staff
	Laszlo JUHASZ Alexandre COLLIGAN Robert CAMPBELL Scott MOORE	Virginie SCHRAYEN	Kamreddine OULDDREN Pierre Barras
8.	**ENFORCEMENT**		
	Laszlo JUHASZ Alexandre COLLIGAN Robert CAMPBELL Scott MOORE	Virginie SCHRAYEN	-
9.	**REGULATIONS AND GUIDES**		
	Kirsi ALM-LYTZ Alexandre COLLIGAN Robert CAMPBELL Scott MOORE	Kristel GEERTS	-
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Marjan TKAVC	Christian VANDECASTEELE	Didier DEGUELDRE
11.	**ADDITIONAL AREAS**		

	IRRS Experts	Counterpart	FANC/Bel V Support Staff
	Eleftheria CARINOU	An FREMOUT	Martine LIEBENS Karen HAEST Marleen VANDECAPPELE Katrien VAN SLAMBROUCK Isabelle DE PAU Thibault VANAUDENHOVE Sylviane CARBONELLE Sophie LEONARD Petra WILLEMS
12.	**INTERFACE WITH NUCLEAR SECURITY**		
	Olivier ALLAIN	Simon VLEUGELS	Pieter VAN NEYGHEM

APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE PREVIOUS IRRS MISSION THAT REMAIN OPEN

Module	Section	R/S	Recommendation/Suggestion
1	1.5	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.**
5	5.2	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.**
7	7.7	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.**
9	9.6	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.**

APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2017 IRRS FOLLOW UP MISSION

Module	Section	RF/SF/GPF	Recommendation, Suggestion or Good Practice
4	4.3	SF1	**Suggestion:** FANC should consider finalizing the competence management system and establishing a systematic training programme based on it.
10	10.1	SF2	**Suggestion:** The Government should consider progressing the update to the royal decrees on emergency preparedness and response to meet the requirements of IAEA standard GSR Part 7.
10	10.2	SF3	**Suggestion:** The RB should consider ensuring that licensees of facilities in Emergency Preparedness Categories I, II and III undertake critical response functions and associated tasks in a timely manner.
6	6.2.1	GPF1	**Good Practice:** Bel V has developed and implemented an effective tool, with well-defined criteria applying a graded approach for reviewing safety related modifications, termed "non-important modifications."
11	11.1	GPF2	**Good Practice:** Belgium has been organizing and carrying out several campaigns with regard to justification of medical exposures using methods such as mottos, brochures, posters, videos and radio spots to enhance the public's and referring medical practitioners' awareness.

APPENDIX VI - REFERENCE MATERIAL PROVIDED BY FANC

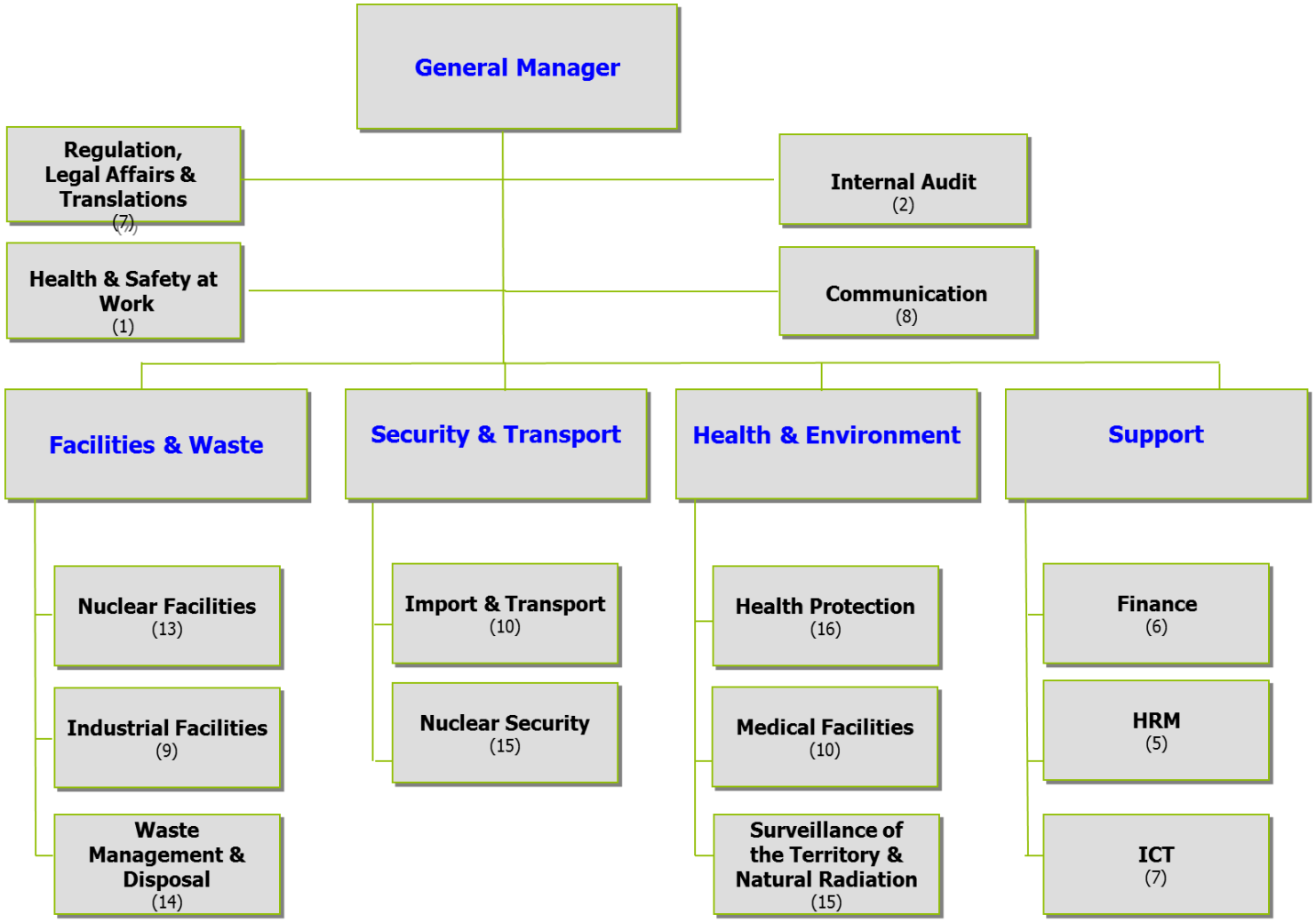
[1]	
	- *IRRS Follow Up – Summary Report*
[2]	
	- *Belgian Report to the 7th Review Meeting of the Contracting Parties to the Convention on Nuclear Safety (CNS)*
[3]	
	- *Draft of the Belgian Report to the 6th Review Meeting of the Contracting Parties to the Joint Convention*

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

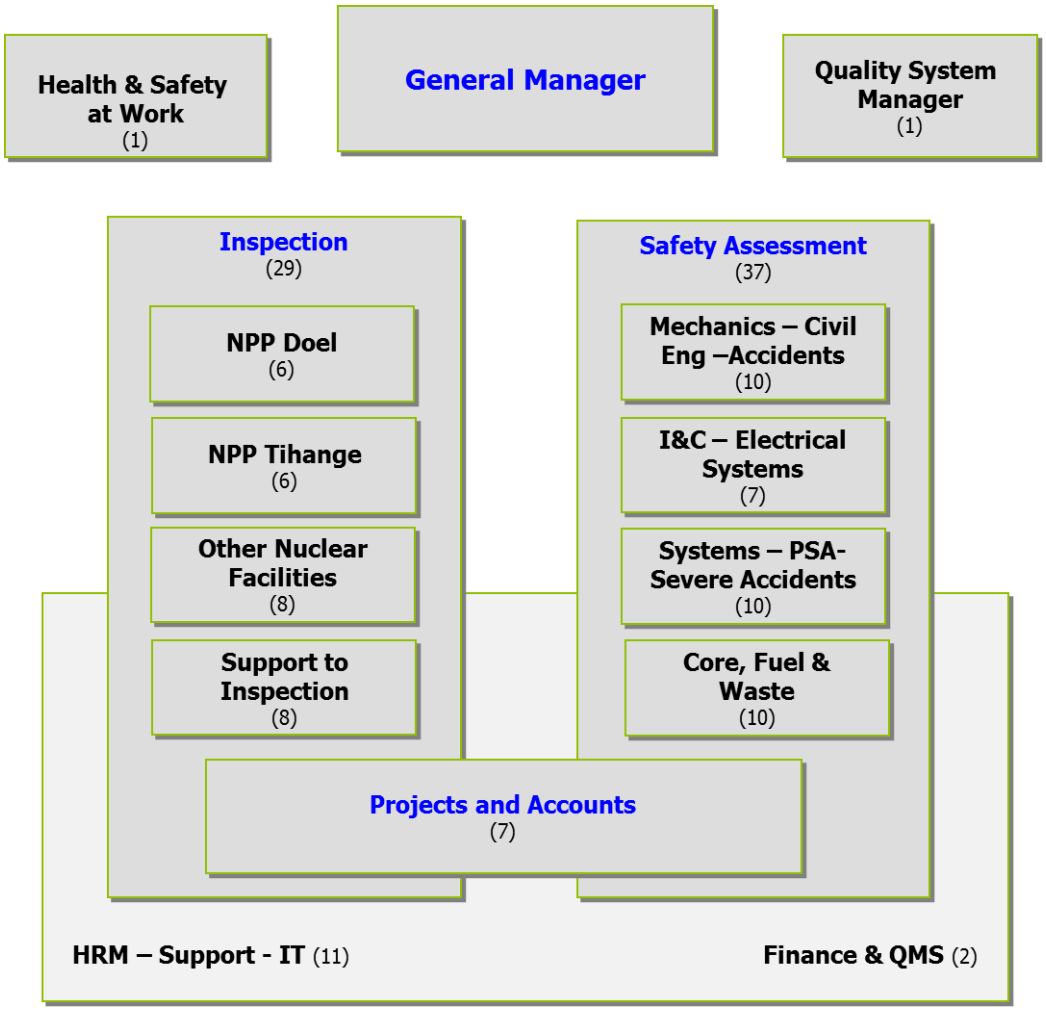
1. **IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2. **IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3. **IAEA SAFETY STANDARDS SERIES No. GSR PART 3** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
4. **IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency
5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
6. **IAEA SAFETY STANDARDS SERIES No. NS-R-1** – Safety of Nuclear Power Plants: Design
7. **IAEA SAFETY STANDARDS SERIES No. NS-R-2** – Safety of Nuclear Power Plants: Operation
8. **IAEA SAFETY STANDARDS SERIES No. NS-R-4** - Safety of Research Reactors
9. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.1-** Organization and Staffing of the Regulatory Body for Nuclear Facilities
10. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
11. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear Facilities
13. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** - Arrangements for Preparedness for a Nuclear or Radiological Emergency
14. **IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** - Application of the Management System for Facilities and Activities
15. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** - The Management System for Technical Services in Radiation Safety
16. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3** - Assessment of Occupational Exposure Due to External Sources of Radiation
17. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4** - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
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).

APPENDIX VIII – ORGANIZATIONAL CHARTS

FANC



BEL V


Health & Safety at Work (1)
General Manager
Quality System Manager (1)
Inspection (29)
NPP Doel (6)
NPP Tihange (6)
Other Nuclear Facilities (8)
Support to Inspection (8)
Safety Assessment (37)
Mechanics – Civil Eng –Accidents (10)
I&C – Electrical Systems (7)
Systems – PSA-Severe Accidents (10)
Core, Fuel & Waste (10)
Projects and Accounts (7)
HRM – Support - IT (11)
Finance & QMS (2)