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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

BELGIUM

Brussels, Belgium

19 to 30 June 2023

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA

Integrated Regulatory Review Service

IRRS

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REPORT OF THE
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Mission dates:	*19 to 30 June 2023*
Regulatory body visited:	*Federal Agency for Nuclear Control (FANC)*
Location:	*Brussels, Belgium*
Regulated facilities, activities, and exposure situations in the mission scope:	*nuclear power plants, radiation sources applications, waste management facilities, emergency preparedness and response, transport, decommissioning, occupational exposure, medical exposure, public exposure, interfaces with nuclear security*
Organized by:	*IAEA*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of the Kingdom of Belgium (hereinafter Belgium), an international team formed by the International Atomic Energy Agency (IAEA) met representatives of the Federal Agency for Nuclear Control (FANC) and Bel V, the regulatory body of Belgium, from 19 to 30 June 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The Minister of the Interior, Institutional Reform and Democratic Renewal welcomed the IRRS team and kicked off the mission. The IRRS team also met with representatives of the Office of the Minister of the Interior, the FANC Board of Directors, the Federal Public Service Health, Food Chain Safety and Environment, the National Agency for Radioactive Waste Management NIRAS/ONDRAF, the National Crisis Centre (NCCN) and the Scientific Council, to review the responsibilities and functions of the Government. The IRRS team consisted of 19 senior regulatory experts from 18 IAEA Member States, two IAEA staff members, one IAEA administrative assistant, and one observer from the European Commission (EC).

The purpose of this mission was to review the Belgium governmental, legal and regulatory framework for nuclear and radiation safety within the competence of FANC and Bel V, against the IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources as international benchmarks for safety. The mission was also used to exchange information and experience between the IRRS team members and their Belgium counterparts in the areas covered by the IRRS, as well as the regulatory implications of the COVID-19 pandemic.

Belgium conducted a self-assessment in preparation for the mission and prepared a preliminary action plan to address areas identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material prior to the mission.

The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes, and development and content of regulations and guides; emergency preparedness and response; nuclear power plants; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; control of medical, occupational and public exposures; and interfaces with nuclear security. The IRRS mission included a policy issue discussion on the challenges on competence management in a changing environment. Therefore, the IRRS Mission to Belgium was a full-scope mission.

The IRRS mission was conducted about six months prior to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission currently scheduled from 3 to 13 December 2023. As such, the IRRS team did not review provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel as they will be covered by the upcoming ARTEMIS mission.

The IRRS team conducted interviews and discussions with the FANC and Bel V staff. Members of the IRRS team also observed regulatory oversight activities at a nuclear power plant, a research reactor, a cyclotron for isotopes production, a radioactive waste management facility, a nuclear medicine department in a hospital and a company for transport of radioactive material. These visits included discussions with management and staff of the facilities.

The IRRS team concluded that Belgium has an effective and consistent regulatory framework for nuclear and radiation safety covering the full range of facilities, activities, and exposure situations. FANC and Bel V form together a competent and independent regulatory body whose staff are committed to deliver the regulatory statutory obligations effectively.

The IRRS team appreciated the outstanding efforts of FANC and Bel V staff regarding their engagement in this extensive international peer review. This active participation enabled the IRRS team to develop a broad understanding of Belgium’s regulatory infrastructure which resulted in the identification of one

good practice and several areas of good performance. Continuing these activities, along with the consideration of several recommendations and suggestions offered by the IRRS team, should further enhance nuclear and radiation safety in the country.

The good practice identified by the IRRS team relates to the oversight approach to regulate the interfaces between safety and security based on their unique use of "confidentiality and the principle of a need-to-know". A particularly noteworthy aspect is the conduct of dedicated annual inspections at all NPPs on this topic.

In addition, the areas of good performance include, amongst others:

- The development and effective use of advanced IT systems for managing the regulatory activities;
- The development and implementation of the assessment of leadership for safety and safety culture within Bel V;
- The position paper of an integrated approach for site release from regulatory control and its implementation for the release of the FBFC fuel fabrication site from regulatory control;
- The regular comprehensive assessment of the licensee's safety performance;
- The implementation of "Fast Limited Inspections with Thematic Scope" (FLITS);
- The way the regulatory body takes into consideration research and development results when preparing regulations and guides for radioactive waste management, including deep geological disposal;
- The interactive tool "Pathway Evaluation Process", which facilitates structured interactions among interested parties on radioactive waste disposal matters;
- The inclusion of the "General Emergency in Reflex Mode" as a fifth emergency class within the Emergency Classification System.

In the spirit of continuous improvement, the IRRS mission report includes recommendations and suggestions intended to improve the Belgium regulatory infrastructure and practices to oversee nuclear and radiation safety.

The IRRS team considered that the main challenge in Belgium is to identify and ensure the necessary competences and adequate financial resources of the regulatory body due to the evolving nuclear energy policy in the country.

Moreover, the IRRS team concluded that the following issues are representative of those which if addressed by the government and the regulatory body, would further enhance the overall effectiveness of the regulatory system:

The Government should:

- ensure that its decisions relating to the nuclear energy policy and the financial resources are made in a timely manner so that FANC fulfils its legal mandate under any circumstances.
- amend regulations to require (a) authorized parties to inform the public on radiation risks; (b) authorized parties to keep the generation of radioactive waste to a minimum and (c) prompt notification of emergencies;
- ensure that national emergency response exercises involving nuclear security events are performed regularly.

The regulatory body should:

- clearly state its strategic organizational objectives;
- update its policy on safety culture and perform self-assessments accordingly;

- maintain necessary competence and skills of its staff;
- complete the regulations in relation to site evaluation for future nuclear facilities;
- revise the regulations relating to specific aspects of: decommissioning; radiation sources facilities and activities; occupational, medical and public exposures; transport of radioactive material; and emergency preparedness and response.

The IRRS team considered the invitation from Belgium of a full scope international peer review as part of the second IRRS cycle to be a sign of openness, transparency and commitment to continuous improvement for safety.

The IRRS team received the full support and cooperation of all parties in the regulatory, technical, and policy issue discussions which were conducted in a very open, transparent and frank manner throughout the mission.

The IAEA issued a press release upon conclusion of the mission.

I. INTRODUCTION

At the request of the Government of the Kingdom of Belgium (hereinafter Belgium), an international team of senior safety experts met representatives of the Federal Agency for Nuclear Control (FANC) and Bel V, the regulatory body of Belgium, from 19 to 30 June 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Belgian governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Belgium in January 2020. A preparatory mission was conducted 16-17 January 2023 at the Headquarters of FANC in Brussels to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Belgium and their related safety aspects and to agree the scope of the IRRS mission.

This mission was organized back-to-back to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled from 3 to 14 December 2023. To avoid unnecessary overlaps between the IRRS and the ARTEMIS missions, the preparation and conduct of the IRRS mission were carried out in a coordinated manner with the ARTEMIS mission. Thus, the provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel, subject of Section 1.7 of this report, are to be reviewed by the upcoming ARTEMIS mission.

The IRRS team consisted of 19 senior regulatory experts from 18 IAEA Member States, two IAEA staff members, one IAEA administrative assistant and one observer from the European Commission (EC). The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes, development and content of regulations and guides; emergency preparedness and response; nuclear power plants; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; occupational radiation protection, control of medical exposure, public exposure control; and interfaces with nuclear security. In addition, a policy issue on competence management in a changing environment was discussed.

The mission was also used to exchange information and experience between the IRRS team members and the Belgian counterparts in the areas covered by the IRRS and the national regulatory implications of the COVID-19 pandemic in Belgium.

FANC and Bel V conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Belgium advance reference material, conduct of interviews with management and staff from FANC and Bel V and direct observation of FANC and Bel V regulatory activities at regulated facilities. Meetings with the Office of the Minister of the Interior, FANC Scientific Council, Board of Directors of the FANC and Federal Public Service Health were also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Belgian radiation and nuclear safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on effectiveness of the regulatory system, and to exchange information and experience in the areas covered by the IRRS, including the regulatory implications of the COVID-19 pandemic in Belgium.

The agreed scope of this IRRS review included all facilities and activities regulated in Belgium by FANC and Bel V. It is expected this IRRS mission will facilitate regulatory improvements in Belgium and other Member States, utilising the knowledge gained and experiences shared between FANC, Bel V and the IRRS team, as well as the evaluation of the Belgian regulatory infrastructure for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing Belgium (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing Belgium (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in Belgium with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing Belgium with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements;

k) providing feedback on the use and application IAEA safety standards;

l) providing feedback on the regulatory implications of pandemic situations.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Belgium, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted on 16 and 17 January 2023. The preparatory meeting was carried out by the appointed Team Leader Mr Ramzi Jammal, Deputy Team Leader Mr Olivier Allain and the IAEA representatives, Mr Jean-René Jubin, IAEA Coordinator, and Ms Vasiliki Kamenopoulou, IAEA Deputy Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of FANC represented by Mr Frank Hardeman, Director General of FANC, other senior management and staff and with the senior management of Bel V, including Mr Michel Van Haesendonck, Director General of Bel V. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Research Reactors;
- Waste management facilities;
- Radiation sources facilities and activities;
- Radioactive waste management facilities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control; and
- Selected policy issues.

Mr Frank Hardeman delivered a presentation on the national context, the current status of FANC and Bel V; Mr Simon Coenen presented the self-assessment process and the overall action plan; and the main counterparts for the different modules presented the results of the self-assessment to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Belgium in June 2023. The proposed composition of the IRRS team was discussed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The FANC Liaison Officers for the IRRS mission were confirmed as Mr Simon Coenen and Mr Cédric van Caloen.

FANC and Bel V provided IAEA with the advance reference material (ARM) for the review on 18 April 2023. In preparation for the mission, the IRRS team members reviewed the Belgian advance reference material and provided their initial impressions to the IAEA Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 18 June 2023 in FANC Headquarter, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officers were present at the initial IRRS Team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 19 June 2023, with the participation of FANC and Bel V senior management and staff. Welcome addresses were delivered by Ms Verlinden, Minister of the Interior, Institutional Reform and Democratic Renewal (hereafter Minister of the Interior) followed by introductory remarks made by Mr Jammal, IRRS Team Leader. FANC Director General Mr Hardeman presented briefly the national regulatory framework and Mr Coenen, IRRS Liaison Officer, presented the self-assessment and action plan prepared as a result of the pre-mission self-assessment. Closing remarks were delivered by Mr Hardeman and Mr Jammal.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Belgium, FANC and Bel V with recommendations and suggestions for improvement and, where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS Team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday 30 June 2023. The opening remarks at the exit meeting were presented by Mr Frank Hardeman and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Ramzi Jammal. Closing remarks were delivered by Ms Anna Bradford, Director, Division of Nuclear Installation Safety, IAEA.

The IAEA issued a press release upon conclusion of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Belgium is a federal state composed of three regions, the Brussels-Capital region, the Walloon region and the Flemish region. The legal framework also reflects this nature having nuclear safety and radiation protection as an issue at the federal level. However, there are interfaces with the regional authorities on certain issues like environmental impact assessment (EIA) and emergency preparedness and response.

Article 23 of the Belgian Constitution mentions "the right to the protection of a healthy environment" as one of the rights that amounts to a dignified life for its citizens. Since having a healthy environment also requires the safety of nuclear facilities operating in Belgium, the law of 15 April 1994 (the FANC law) has been promulgated establishing the infrastructure for the protection of the public and the environment from the potential harmful effects of ionizing radiation and an independent safety authority, the Federal Agency for Nuclear Control (FANC).

The FANC law requires FANC to propose a national policy statement on nuclear safety, nuclear security and radiation protection based on six general principles and the Government to approve and send the statement to the House of Representatives. The Council of Ministers approved the National Statement on Nuclear Safety, Nuclear Security and Radiation Protection on 31 August 2018.

The statement declares the long-term commitment of the Government to nuclear safety, nuclear security and radiation protection, and gives them absolute priority. The government also recognizes its international obligations through conventions and instruments that Belgium is party to, and declares its dedication to participation in international and European organizations on nuclear safety and security, and radiation protection.

The government established its safety policy on seven pillars:

- The principle of continuous improvement;
- The justification principle;
- The principle of defence-in-depth (layered protection);
- The safe and secure management of radioactive waste;
- The coordination of different authorities responsible for safety and security;
- The requirement of maintaining a high level of competence;
- The need for transparent communication.

With these seven pillars, the government also demonstrated that proper attention is given to competence of human resources, leadership for safety and safety culture, etc. However, the statement does not reflect the necessity of, and governmental commitment to provide for, financial provisions and a framework for research and development for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The statement of the Government and its commitment to nuclear safety and security, and radiation protection, does not reflect the need for financial resources and a framework for research and development for safety.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.3 states that** *"National policy and strategy for safety shall express… The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:…* *(d) The need and provision for human and financial resources;* *(e)The provision and framework for research and development; …"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S1	**Suggestion: The Government should consider revising the National Statement on Nuclear Safety, Nuclear Security and Radiation Protection to reflect the importance of the availability of financial resources for the regulatory functions and a framework for research and development for safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Belgian legal infrastructure has several instruments to establish the regulatory requirements on nuclear safety, nuclear security and radiation protection (Figure 1). As a European Member State, Belgium has a legal and regulatory framework implementing the European Directives issued in the framework provided by the EURATOM treaty: the 2009/71/EURATOM Nuclear Safety Directive as amended by the Directive 2014/87/EURATOM, the 2011/70/EURATOM Waste Directive and the 2013/59/EURATOM Basic Safety Standards Directive.

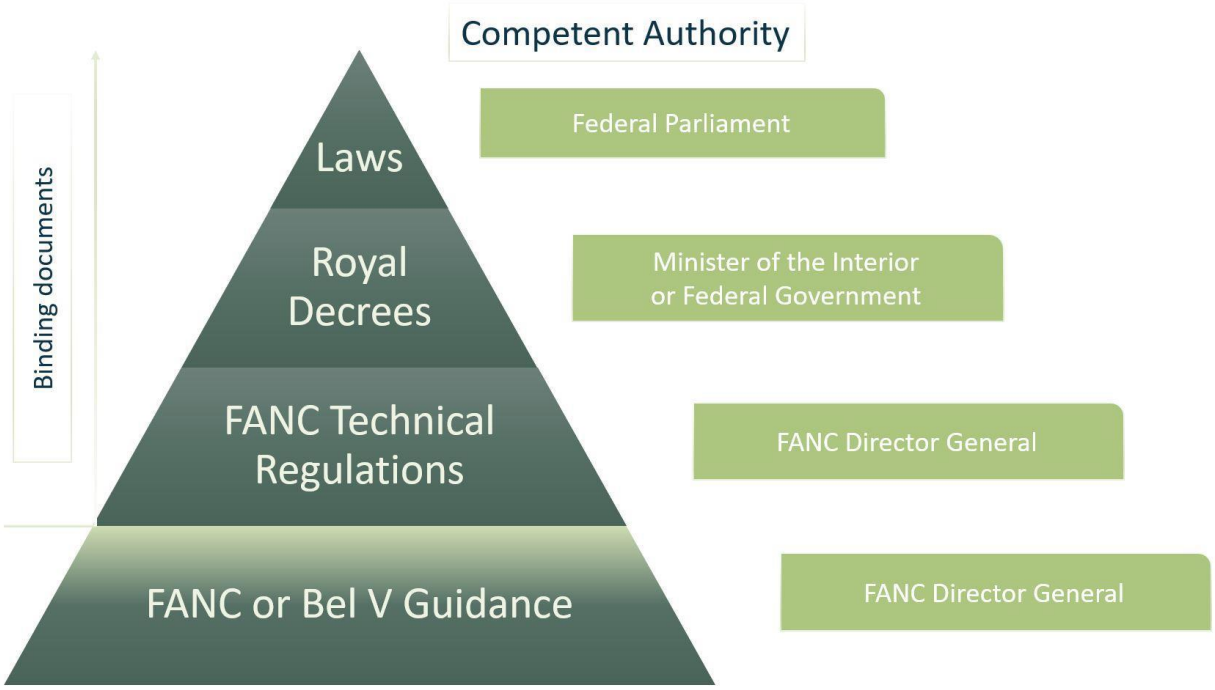

Figure 1 Belgian Regulatory Instruments

The main provisions for radiation protection of workers, the public and the environment against the dangers of ionizing radiation have been addressed by the FANC law, which also established FANC as a new independent safety authority. While the provisions of the FANC law are general, ten royal decrees detail the implementation of the provisions of the FANC law on specific subjects.

Basic safety principles for radiation protection are handled in the royal decree of 20 July 2001 (GRR-2001). Nuclear safety principles were addressed in the royal decree of 30 November 2011 (SRNI-2011) for the safety requirements for nuclear facilities and activities.

The FANC law establishes FANC as the safety authority for nuclear facilities and activities that use ionizing radiation or radioactive materials. FANC issues technical regulations (TR), which are mentioned in the royal decrees. The competent authority for authorization of Class I facilities (classification is provided in GRR-2001) is the King. FANC has been designated as competent authority for authorization of Class II and III facilities and activities by the FANC law. The authorization process for facilities and activities, and appeal mechanisms for authorization decisions are also laid out in GRR-2001.

Industrial safety aspects for ensuring the protection of workers on work premises are the responsibility of the Federal Public Service of Employment, Labour and Social Concertation. These aspects are governed by the law of 4 August 1996 relating to the well-being of workers during the execution of their work and by the code of well-being at work.

National crisis management including radiological and/or nuclear emergencies is carried out by the Federal Public Service Home Affairs, through the National Crisis Centre. FANC and Bel V have active roles in radiological crisis management which are defined in the royal decree of 1 March 2018.

The ownership of the nuclear fuel from import to the declaring of the spent fuel as radioactive waste belongs to a private company, Synatom. However, import and safe transport of the fresh fuel and safe management of nuclear fuel onsite at a nuclear power plant (NPP) are the responsibility of the licensed operator ENGIE. When the spent fuel is declared as radioactive waste, the ownership is transferred to the national waste management agency NIRAS/ONDRAF in accordance with established procedures. NIRAS/ONDRAF is the responsible agency for the management of the radioactive waste resulting from any origin, including the operation and decommissioning of facilities in the nuclear fuel cycle, the use of radioactive materials in industrial and medical applications and the remediation of radioactively contaminated sites.

NIRAS/ONDRAF is also responsible for the financial provisions for the management of radioactive waste generated by other licensees and for the decommissioning of their facilities. FANC has no responsibility for the financial aspects of the management of radioactive waste and spent fuel. However, some interfaces exist in the regulatory framework in GRR-2001, such as the requirement on each operator of a facility to conclude an agreement with NIRAS/ONDRAF, which also provides comments to FANC on waste and decommissioning files submitted in support of a license application for a facility or an activity with waste production. The comments of NIRAS/ONDRAF on these files are part of the licensing procedure for a facility or activity.

Release from regulatory control has not been explicitly defined as a step in the licensing process for facilities in GRR-2001. SRNI-2011 requires the licensee of a Class I facility to submit to FANC a Final Dismantling Report, containing the results of the radiological characterization of the end state; however, this royal decree does not allow a decision after the submission of the report, other than in case of a failure to reach the final state described in the dismantling license. The IRRS team was informed that for Class I facilities, FANC is drafting a royal decree annulling the royal decree on the relevant licence after the review of the Final Dismantling Report. For Class II and III facilities, the FANC expert records the decision on annulment of the relevant authorization. The IRRS team has also been informed that these decisions are approved at different levels within FANC, in accordance with a graded approach, and the process and competent levels for approval are defined in internal documents of FANC.

The Government issued the law of 31 January 2003 on the gradual phase-out of nuclear energy for industrial electricity production which prohibits the construction of new NPPs in Belgium and limits the operational lifetime of the NPPs to 40 years. In application of this law, Doel 3 and Tihange 2 units have been shut down. However, to ensure the electricity supply of Belgium, the Government and the parliament modified this law in 2012 and in 2015, to allow long-term operation (LTO) of Tihange 1, Doel 1 and Doel 2 units for a further 10 years. The phase out programme established by the law of 31 January 2003 and the uncertainties about the future role of nuclear energy in Belgium initiated a drain of competences from FANC and introduced difficulties in human resource management and recruitment of new staff.

In March 2022, the Government agreed to open with the operator a discussion on possible LTO of the two most recent units, Doel 4 and Tihange 3, for an additional 10 years. A mutual agreement on LTO would require a modification of the law of 31 January 2003.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The FANC law establishes FANC as an independent safety authority, reporting to the parliament through the Federal Public Service (FPS) Home Affairs. By 1 September 2001, FANC had become operational and took over the responsibilities of the Office for Technical Safety of Nuclear Installations of the FPS Labour and Employment, the Office for Protection Against Ionizing Radiation of the FPS Public Health and the Environment and the Office for Nuclear Security of the FPS Justice. In 2003, the legal competences of the FANC were extended to include the security of installations where nuclear material is produced, used or stored. In 2017, the FANC law was again amended to include the security of installations where radioactive material is produced, used or stored in the scope of FANC.

A modification of the FANC law allowed FANC to outsource some of its legal tasks to another entity especially created by FANC for this purpose. Exercising this power to ensure realization of its mandate, FANC established a subsidiary organization, Bel V in 2007. Bel V took over the human resources of an authorized inspection body, Association Vinçotte Nuclear (AVN). The delegated tasks include the review and assessment for authorization of Class I and Class IIA facilities, inspections of these facilities and activities, supervision of the HPD of the operator of these facilities and the follow-up of the onsite-emergency measures of the operator. While FANC may issue binding technical regulations and regulatory guides, Bel V may only issue guides. This association of FANC and Bel V constitutes the regulatory body.

The FANC law establishes FANC as a public authority in the category C as defined in the law of 16 March 1954 on the supervision of certain public organisations. According to this law, the budgets of the category C authorities are decided by the management board of said authorities and the relevant Minister only transmits these budgets to the FPS Finance for final approval regarding the political, social and economic status of the state.

The FANC law puts FANC under the remit of the Minister of the Interior, functionally separating it from other entities having responsibilities or interests that could unduly influence their decision-making.

FANC is managed by a board of directors (BoD). The members of the BoD are appointed by royal decree on proposal of the council of ministers, based on their specific scientific or professional qualities, keeping in mind that the members do not compromise the independence of the FANC. To ensure this independence the FANC law lists a number of positions, holders of which are not eligible to be a member of the FANC BoD. The FANC BoD meets approximately six times a year and is responsible for:

- Establishing the long- and short-term global strategy of FANC, with the approval of the mid-term and annual operational plans;
- Establishing the recruitment conditions and employment conditions of personnel, and approving the number of staff of FANC;
- Approving the annual budget of FANC.

The FANC law establishes a Scientific Council with a mandate to advise FANC on its control policy and more specifically to give an opinion on the licence or license renewal applications for nuclear installations before the regulatory decision is made. The opinion of the Scientific Council is not binding but FANC needs to justify its decision if it is against the opinion of the Scientific Council. To ensure the independence of the support of the Scientific Council to the regulatory process, nominees for the Scientific Council are scrutinized to identify any affiliation with parties with a stake in the mandate of FANC and avoid conflicts of interest.

The law of 16 March 1954 also requires the participation of a governmental commissioner in the meetings of the BoD of FANC. The governmental commissioner is appointed by the King and has authority to give their advisory opinion on the decisions of the BoD and to make a suspensive appeal on the decision of the BoD of FANC if they deem that the decision is not compliant with the law or with the statute of the agency, or if it is against the public interest.

According to the law of 16 March 1954, FANC needs to balance its annual budget. Its income is composed of taxes from existing nuclear facilities and activities defined in the FANC law, fees or payments charged for the various services of the FANC, allowances, donations and legacies, and administrative fines. The taxes from existing facilities, particularly NPPs, are the main financial contributors, currently accounts for 75% of its annual income.

In this respect, while the current arrangements for the annual budget cover FANC's potential costs, a considerable decrease in financial sources of FANC is anticipated based on the gradual phase out programme for NPPs. The phase out programme also has a negative impact on FANC's human resource management. The anticipated decrease in FANC's financial resources is not commensurate with its continuing regulatory functions and the need for different and additional competences regarding potential decisions on the future of nuclear energy in Belgium.

The funding scheme for FANC should adequately cover all regulatory functions, including provisions to increase its capabilities for timely and proactive preparation for the changing environment. There is a draft document for potential solutions to this anticipated issue of financial resources, which is up for the discussion at the Minister of the Interior. To ensure the sustainability of the regulatory functions of FANC, the government should develop alternatives for providing sufficient financial resources to FANC.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A challenge for ensuring sufficient financial resources to FANC is anticipated because of the phase out programme for NPPs, particularly considering the challenges the regulator will face in the years to come and the need for additional expertise related to the evolving nuclear environment in the country.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:…* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;…"*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
R1	**Recommendation: The Government should ensure in a timely manner that adequate financial resources will be available for FANC to fulfil its mandate under any circumstances.**

The regulatory decisions of FANC and the decisions on the authorizations of facilities and activities are also subject to appeal. Authorization of Class I facilities can be appealed to the State Council since the decision is made by the King and the authorization is issued by royal decree. The appeal mechanism for the decision is also laid out in the royal decree which issued the license. For Class II and III facilities and activities, the decision is made by FANC, and this decision can be challenged by appeal to the King for the Class II and to the Minister of the Interior for the Class III facilities and activities. Procedures for these appeals are laid out in the GRR-2001. In both cases, the Scientific Council is to provide its opinion on appeal. The IRRS team was informed by the government commissioner that for Class III facilities and activities the final appeal decision is made by the Minister of the Interior based on the procedural fairness of the original decision and on the general public interest.

The appeal mechanisms for a decision of FANC are expected to be carried out in judicial mechanisms instead of by political appointees, to eliminate undue influences in regulatory decision-making.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The FANC law states that "The licence holder shall be responsible, under all circumstances, for ensuring protection of workers, the public, and the environment against health risks or nuisances that could result from his practices. This responsibility may not be delegated." The provision explicitly states that the responsibility cannot be delegated and remains with the licence holder. The provision implicitly states that the licence holder retains the prime responsibility throughout the lifetime of the facility, i.e. under any circumstances. The licence holder is responsible for ensuring safety.

Subsequent paragraphs of the article require the licensee to establish a health physics department (HPD) to discharge this responsibility and explicitly state that the tasks defined to the HPD do not compromise the prime responsibility of the licensee in any way. The roles and responsibilities of the HPD are regulated in detail in GRR 2001 for different facilities and activities. Regarding nuclear facilities and activities, the HPD has responsibilities to oversee nuclear safety during the operation of the facility in addition to its radiation protection tasks. Therefore, the compliance of the HPD with regulations and requirements does not relieve the licensee from its prime responsibility.

The GRR-2001 addresses compliance with regulations holding the licensees responsible for complying with the license conditions according to the GRR-2001. GRR-2001 also holds the licensee responsible for demonstrating compliance with regulation and safety criteria in various articles depending on the class or type of facility and activity. Additionally, compliance with the requirements is also addressed in penal provisions of the FANC law, specifically stating that infringements to this law or its implementation decrees may be subject to either criminal or administrative penalties. Identification of infringements and respective penalties are also regulated separately in the FANC law.

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

FANC is the main body that carries out the regulatory functions in the area of radiation protection, nuclear safety and nuclear security. Certain activities of FANC are delegated to Bel V in accordance with the mechanism provided by the FANC law. Tasks that are delegated to Bel V are defined in the GRR-2001. FANC supervises the activities of Bel V regarding the delegated activities. A Management Agreement has been signed between FANC and Bel V to define practical modalities of the delegation. Other interactions are dealt with in a Collaboration Convention.

NIRAS/ONDRAF has an interface with FANC regarding safe management of waste in the authorization process. These interfaces are identified and regulated in various articles of the GRR-2001 depending on the class of facility and activity. FANC and NIRAS/ONDRAF signed a cooperation agreement to further detail the modalities of cooperation.

Other federal authorities that FANC has signed protocols to address the modalities of cooperation with are the Federal Agency for the Safety of the Food Chain, Federal Agency for Medicines and Health Products, National Institute for Health and Disability Insurance and Federal Public Services for Labour and for Health.

Being a federal state, non-radiological aspects of EIA of the facilities within the scope of FANC such as water management, chemical discharges, etc. belong to the competence of the regional authorities. FANC established a protocol with the environmental authority of the Flanders region to address the modalities of cooperation for EIA of facilities. The IRRS team was informed that a similar protocol is also available for the Walloon region, but the provision is not as clear as the protocol signed with the Flanders region. A similar protocol is also being drafted for the region of Brussels-Capital.

FANC has established formal cooperation with health authorities and professional bodies having responsibilities in the regulatory control of the medical exposure with a common goal to prevent and reduce the risks associated with medical exposure.

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The FANC law authorizes the King to take any measures to protect the people and the environment when an unforeseen event that jeopardises public health occurs, or to avoid risks that could result from the accidental contamination of any places, materials or products by radioactive substances.

Existing and unregulated radiation risks are within the scope of the GRR-2001. GRR-2001 regulates work activities involving natural radiation sources including Radon and cosmic radiation, general provisions on radiation protection, and the roles and responsibilities of the authorities for the management of exposure situations, such as Radon and orphan sources. It establishes the basis of the National Radon Action Plan, which is to be updated every five years. The first national Radon Action Plan 2020-2025 was adopted in January 2020.

FANC can decide which provisions of the GRR-2001 are applicable to unregulated activities, to contamination resulting from past activities or unplanned events, such as orphan sources or emergency situations, and to situations where a long-term exposure risk exists. The identification and assessment of the situation of concern is the responsibility of FANC.

The law of 20 November 2022 regulates the interventions on sites contaminated by radioactive substances from past activities, to impose remediation or restrictions on land use, based on the principles of justification, optimization and dose limits.

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

The provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel are to be reviewed by the upcoming ARTEMIS mission, which is organized back-to-back with this IRRS mission.

1.8. COMPETENCE FOR SAFETY

The Government has enumerated the competence requirements for safety in the FANC law, the decrees and the regulations, addressing the competence of the regulatory body and its technical support organization and licensees.

The FANC law requires each licensee to set up an internal HPD, with specific competence requirements laid out in the GRR-2001 for the training and competence of the health physics experts acting in HPD. FANC examines the application for recognition as an expert in health physics and grants the recognition. As an example of the graded approach, lower class facilities and activities may use an external expert from an external Health Physics Organization, which must also be recognized by FANC. Facilities with medical radiological equipment have to set up a Medical Physics Department to ensure coordination of all tasks attributed to a recognized medical physics expert. The Head of the Medical Physics Department as well as the radiation protection officers, are always members of the licensee's organization.

Royal decrees in specific areas also address the competence requirements for those specific workers, such as operators in nuclear facilities in SRNI-2011 and occupational physicians or practitioners, entitled persons, medical physics experts and medical physics assistants, etc. in the royal decree on medical exposures.

In addition, license applications for construction and operation of facilities shall describe the competence of the operating personnel according to GRR-2001. FANC supervises compliance with the licence conditions by the operator.

The competence requirements laid out in GRR-2001 for HPD staff of the licensee are also applicable to the inspectors of Bel V. FANC has its own internal qualification system for nuclear inspectors, which requires compliance with the same criteria for HPD staff defined in GRR-2001. FANC and Bel V have their own competence management processes, which are further developed in their respective

management systems. According to the FANC law, FANC should provide all necessary international-level training for its personnel, depending on the duties assigned.

SCK CEN, established in the 1950s, is the national research centre in the field of nuclear energy with training as one of its statutory missions. Research and training facilities and research reactors are in this centre. SCK CEN offers specialized services to the nuclear and non-nuclear industry, the medical sector and the public authorities.

To maintain and further develop a high-quality programme in nuclear engineering in Belgium, the Belgian Nuclear Higher Education Network (BNEN) was set up in 2001 by six Belgian universities and SCK CEN. BNEN created an internationally recognized "Master of Science in Nuclear Engineering" programme. Several Belgian universities also organize training programmes in radiological protection at the Master of Science level. Several technical high schools provide training courses in radiological protection and/or nuclear technology. Finally, experts from both the regulatory body and the operators, and technicians can also be trained in foreign countries under a framework of collaboration agreements.

The FANC law requires FANC to receive advice for certain regulatory decisions from the Scientific Council and the Medical Jury, depending on the subject. For some matters FANC also gets advice from other expert councils such as the Superior Health Council, the Superior Council for Prevention and Protection at Work, the Royal Academies for Medicine, etc.

While the Government considers maintaining a high level of competence regarding safety, security and radiation protection as one of the seven pillars of its safety policy, a decision is yet to be made for long-term operation of two NPP units, and there is discussion of the potential for using emerging technologies. The IRRS team was informed that these uncertainties also contributed to the increased pace of the loss of interest of academics, graduates and students in pursuing a career in the nuclear field. This decline in interest has also manifested itself in various areas such as a declining number of recognized experts and the moving of competent staff to other areas of work.

The same circumstances have a strong impact on FANC and Bel V. FANC and Bel V anticipate, in the short and medium terms, regulatory oversight of decommissioning of seven NPP units and possible life extension of two NPP units both of which have different set of competence requirements. This is in addition to the competency need for regulatory control over first of a kind research facility MYRRHA, SMRs, waste geological disposal, etc. To ensure the continuance and adequacy of its regulatory activities, FANC and Bel V would need to develop solutions for securing the competencies that it would need, managing the in-house competence to address emerging tasks, retaining the competent staff and establishing and implementing a strategy for succession planning and knowledge management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Uncertainties over the future of nuclear power in Belgium, especially lack of a Governmental decision on possible long-term operation of some NPPs, hinders the readiness of the regulatory body for emerging tasks.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.3 states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following: …* *(d) The need and provision for human and financial resources;…"*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 1 (Rev. 1) para. 2.34 states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*
R2	**Recommendation: The Government should render its decisions in a timely manner so that the Regulatory Body may have time to ensure its readiness for establishing adequate regulatory control of the emerging activities.**

1.9. PROVISION OF TECHNICAL SERVICES

The FANC law ensures the availability of technical services for environmental monitoring and dosimetry. Based on these legal requirements, FANC established:

- The TELERAD-network for environmental monitoring, completed with environmental sampling and laboratory analysis, for which FANC acquires external support a four-yearly basis, with the main requirements, including requirements for calibration, are listed in technical specifications for the bid;
- A system for dosimetry services, for which FANC is instrumental in recognition of the services including types of dosimeters and readout systems, manages the national dose register and delivers dosimetry passbooks for external workers going on missions abroad.

Additionally, FANC and Bel V established their own emergency preparedness and response arrangements to collaborate with relevant authorities to respond to emergency situations. FANC may acquire technical assistance from various domains, including Bel V, authorized inspection organizations, research and development organizations such as SCK CEN, specialized laboratories at universities, and even from licensed or recognized persons such as health physics or medical physics experts, or health physics organizations.

The FANC law requires FANC to establish a mechanism for and to perform reviews for recognition of dosimetry services. The criteria and procedures for this recognition are contained in GRR-2001 and include an accreditation with respect to relevant international standards, such as ISO/IEC 17025. FANC technical regulations stipulate the criteria and conditions for recognition of dosimetry services for performing external dosimetry, for performing in vivo and in vitro measurements, and for participating in intercomparisons.

While ensuring the calibration of equipment is the responsibility of the recognized experts such as HPD personnel of the licensee as assigned in royal decrees, FANC's regulatory documents have no requirements for calibration of equipment other than being in-line with standards and best practices or a recognition procedure for calibration services. Recommendation R9 in Module 9 addresses this issue.

1.10. SUMMARY

Belgium has an established legal framework for radiation protection and nuclear safety and security. The Government's long-term commitment to safety is articulated in the National Statement. The National Statement on Nuclear Safety, Nuclear Security and Radiation Protection summarizes the commitments of the Government with due consideration given to most elements except the availability of financial resources and a framework for research and development for safety.

FANC and its subsidiary Bel V constitute the independent regulatory body in Belgium. The IRRS team considered that the authorization procedure eliminates undue interference or pressure from governmental authorities. While the appeal mechanisms for regulatory decisions, particularly on the authorization of Class III facilities and activities involves interference from the Government, the basis for decision on an appeal is limited with the administrative powers of the Minister.

The IRRS team considered that the Government needs to clarify, in a timely manner, its view on the future of nuclear power energy in Belgium, so that necessary financial resources can be made available to FANC. This also allows FANC to be prepared to develop solutions and take necessary measures to establish and maintain adequate regulatory control over emerging tasks.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Belgium is a signatory to all relevant international conventions and international agreements for ensuring nuclear safety and security. Belgium made a political commitment to implement the Code of Conduct on the Safety and Security of Radioactive Sources, nominated a Point of Contact for the purpose of facilitating the export and/or import of radioactive sources and made available the responses to the Importing and Exporting states Questionnaire. The IRRS team encouraged Belgium to make its political commitment to implement the IAEA Guidance on the Import and Export of Radioactive Sources and the IAEA Guidance on the Management of Disused Radioactive Sources.

FANC has established and maintains bilateral arrangements with other regulatory bodies and organizations:

- Canadian Nuclear Safety Commission (CNSC);
- French Nuclear Safety Authority (ASN);
- German Federal Ministry for Environment, Nature Conservation and Nuclear Safety (BMUV);
- Dutch Authority for Nuclear Safety and Radiation Protection (ANVS);
- United States Nuclear Regulatory Commission (NRC) and National Nuclear Security Administration (NNSA);
- United Kingdom Office for Nuclear Regulation (ONR).

Under the bilateral arrangements, FANC meets at least once a year with the regulatory bodies that are in the neighbouring countries to exchange information, regulatory experience, conduct trainings, and perform cross-inspections. Although FANC does not have a bilateral arrangement, it organizes periodical meetings with the Swiss Federal Nuclear Safety Inspectorate (ENSI).

Bel V is a founding member of the European Technical Safety Organizations Network (ETSON) and has established cooperation relations with other support organizations through ETSON, TSO Forum IAEA and a cooperation agreement.

The Government supports international activities of the regulatory body and nominates many participants to represent Belgium in various international fora. The IRRS team noted that FANC has a management system policy document (INT) that provides a structure and general guidance for FANC's international activities and participations. This document applies to all FANC's services and departments, including Bel V. FANC and Bel V international participation is addressed in the Collaboration Convention and in another FANC management system document (INT-SP01) that is revised regularly.

FANC policy document (INT) is integrated with its organizational strategic plan of nine years. FANC policy document is reviewed every three years to ensure that its international participations and activities are aligned with FANC's overall strategy.

Belgium is involved in the development and promotion of the IAEA safety standards. Belgium is a member of the IAEA safety standards review committees, namely the Nuclear Safety Standards Committee (NUSSC), Radioactive Waste Safety Standards Committee (WASSC), Radiation Safety Standards Committee (RASSC), Transport Safety Standards Committee (TRANSSC), Emergency Preparedness and Response Standards Committee (EPReSC), and Nuclear Security Guidance Committee (NSGC).

FANC is committed to harmonizing safety practices. Belgium is a founding member of the European Nuclear Safety Regulators Group (ENSREG) and the Western European Nuclear Regulators Association (WENRA). WENRA safety reference levels, which are based on IAEA safety standards

and promote harmonization, are implemented in SRNI-2011. FANC and Bel V are active in various working groups of WENRA.

FANC and Bel V experts participate in the OECD-NEA Steering Committee and are active in CNRA and CSNI and in various working groups and projects of the OECD-NEA.

For radiation safety, FANC is a member of the Heads or European Radiological Protection Competent Authorities (HERCA) and is active in various working groups within HERCA.

Under the FANC law, FANC is to promote and initiate research and development activities with international organizations. The IRRS team considered this requirement as a good performance.

FANC and Bel V are active in various research and development projects. Their participation in these projects depends on regulatory needs and capacity building to support independent regulatory assessment. As part of the Collaboration Convention, FANC and Bel V coordinate their research and development activities, and ensure sharing of results. FANC and Bel V will meet at least once a year to discuss and exchange information on their current and/or planned research and development activities.

Under the European Directive 2009/71, an IRRS mission was conducted in 2013 followed by a follow-up mission in 2017. An IPPAS mission was conducted in 2014, its follow-up mission took place in 2019. Other IAEA peer review missions hosted by Belgium include OSART, SALTO and INSARR. Belgium is planning on hosting an ARTEMIS mission in 2023, and an IPPAS mission by no later than 2027. To date, Belgium has not hosted an EPREV mission. Belgian experts participate in different peer review missions hosted by other member states.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

FANC and Bel V participate in relevant groups and bilateral engagements to share and exchange regulatory and operating experience. FANC is the national coordinator for the International Nuclear Event Scale (INES), while Bel V is the national coordinator for the Incident Reporting System (IRS), the Incident Reporting Systems for Research Reactors (IRSRR) and fuel cycle facilities (FINAS). Both FANC and Bel V participate in the European Clearinghouse on NPP experience feedback.

FANC and Bel V each has established processes for management of sharing of regulatory and operating experience internally and externally. At FANC, management system documents related to the sharing experiences are part of the overall process called INC (Incidents). These documents are INC-00-06-19 (nuclear installations), INC-04-06 (medical exposures) and INC-04-04 (industrial radiation sources). At Bel V, the overall process for managing operating experience feedback is described in procedure document Q040800-01-00-p-org-e. Bel V analyses domestic and international operational experience and the results are presented to FANC twice a year.

2.3. SUMMARY

Belgium fulfils its international obligation in areas of nuclear safety, nuclear security and radiation protection and actively participates in international arrangements (bilateral and multilateral). FANC and Bel V have established and implemented systems and processes to allow sharing of international operating experience and regulatory experience, internally and externally.

The IRRS team acknowledged Belgium’s proactive efforts in fulfilling international obligations and supporting international cooperation, and encouraged Belgium to make its political commitment to implement the IAEA Guidance on the Import and Export of Radioactive Sources and the IAEA Guidance on the Management of Disused Radioactive Sources.

The IRRS team encouraged Belgium to request an EPREV mission to evaluate their level of preparedness for nuclear or radiological emergencies.

The IRRS team considered that having regulations that require FANC to promote and initiate R&D activities with international organizations as a good performance.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

FANC was established as a public authority in the category C as defined in the law of 16 March 1954. FANC has been carrying out its mandate as the regulatory body since 2001 with the sole legal requirement regarding its organizational structure being the separation between regulation development activities and the surveillance and inspection activities. FANC law allows FANC to delegate regulatory activities to its technical support organization, Bel V. This support is mainly for review and assessment (R&A) for Class I nuclear facilities, and the oversight by conducting regulatory controls. Bel V also supports FANC in other activities such as conducting research and development (R&D) and at the international level. Bel V also provides technical assistance to FANC in drafting regulations and guides,

The IRRS team was informed that Bel V has recently signed among others a contract with Netherland's regulatory body, ANVS, to provide technical support. The IRRS team was informed that the top priority of Bel V is always to support FANC. Bel V does not provide any advice or services to Belgian licensees to prevent any potential conflict of interest.

The relations between FANC and Bel V are formalized in a "management agreement" and a "collaboration convention" which were signed in September 2019. FANC and Bel V regularly meet including during technical meetings for the review and assessment of large projects such as Class I facilities. Bel V has its own inspectors however they do not have legal powers for enforcement, and therefore conduct 'controls' and not inspections. The enforcement powers are solely granted to FANC. In cases where the Bel V inspectors find non compliances FANC is informed, and the enforcement action is taken by FANC in accordance with a graded approach.

FANC has its own Board of Directors (BoD) consisting of 14 members. BoD is referred to in the law of 16 March 1954 as the management board. Its responsibility is to approve budget and staffing and to appoint FANC senior executives. Bel V also has its own board of directors, comprising seven members of which five are common with FANC. The Scientific Council is established in accordance with Article 37 of the FANC law. The Scientific Council's mandate is described in GRR-2001. It is composed of 16 members (eight French speaking and eight Dutch speaking), the members are internationally recognized senior-level experts with voting rights. Members of the Scientific Council are appointed by the minister supervising FANC. The Scientific Council convenes at minimum four times a year unless there are licensing processes for major projects which requires it to convene more often. The role of the Scientific Council is to oversee major nuclear events, review an investigation, and assess major projects. Each Scientific Council Member is required to disclose their status with respect to their relations with the nuclear industry to avoid conflict of interest. This requirement is stipulated in Article 11 of the royal decree of 18 December 2002 for the Scientific Council as well as in its internal regulations.

The IRRS team was informed that the Scientific Council does not perform safety evaluation or technical studies, it provides its opinion regarding: proposed FANC regulations, the information submitted by the applicant for licence application, the final assessment and reviews carried out by FANC staff, supported by the Bel V safety review and assessment. The Scientific council may also request the opinion or advice of any external expert (or organization) as it deems appropriate. This was the case during the pressure vessel head hydrogen flaking events. In addition to its regular members, the Scientific Council has honorary members without voting right for added expertise. In general, the Scientific Council follows the national nuclear R&D, the educational development at the universities in Belgium, but does not give statements or advice to the parliament or government on national competence on nuclear and radiation safety

Prior to any Class I licence being issued by the King, the Scientific Council's technical opinion must accompany FANC's proposal to the responsible Minister.

FANC develops its strategic programs. Its latest is of nine years (2023-2032). FANC's plan considers internal factors (e.g., retirement, attrition, and job competence analysis). The plan also considers external factors such as government strategies and its nuclear policies (e.g. decommissioning or licensing of new facilities or long-term operation). FANC also updates its plan on a midterm basis, three years at a time.

FANC is financed by taxes paid directly by the licensees. The tax assessment is based on regulatory activities as planned by FANC including environmental monitoring, emergency preparedness, research and international cooperation. The licensees of Class I facilities are the largest payers of taxes.

Bel V assesses and plans its workload annually. Bel V's cost recovery is based on billing the licensee by the hour for the work performed by its staff. In general, Bel V resources are allocated for oversight activities, R&A, and inspections. The remaining resources are allocated for other supporting activities such as international cooperation and representation, training, as well as R&D. The yearly staffing plan takes into account the information provided by the Technical Responsibility Centres (TRCs) to determine the need for recruitment. Bel V has developed a knowledge assessment methodology to determine the risk of losing its technical specialists. They determine the impact of losing the knowledge of the person and the rarity of the positions. The analysis aims to determine the need for knowledge management development. Bel V has a 10-year strategic plan 2015-2025, this plan was revised in 2019 which allowed Bel V to transfer, consolidate, and continuously develop TSO capabilities. The challenge remains the uncertainty with government policy regarding new build of NPPs and the long-term operations of the existing ones.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The FANC strategic plan 2023-2032, approved by the BoD, states that the FANC functions as an independent safety authority. The BoD oversees FANC administrative functions and verifies FANC fulfils its legal obligation. The members of the BoD are appointed by royal decree and proposed by the Council of Ministers. No special technical expertise in nuclear safety or radiation protection is required to be a BoD member. The BoD meets six times per year and focuses on governing the management on independent regulatory body. A government commissioner attends the BoD meetings.

The BoD approves the annual budget and the staffing of the FANC. The management of the FANC is delegated to a Director General, who is appointed by royal decree for a fixed term of six years. The Director General is responsible for the operation of FANC, management of technical issues and makes regulatory decisions. There is no legal provision to prevent influence of the BoD. Nevertheless, they do not intervene on the safety decision making. FANC staff must respect ethical rules set in labour regulation and provisions for avoiding conflicts of interest of article 10 of the FANC law. Bel V staff must respect provisions of article 38.2 of GRR-2001.

FANC nuclear inspectors have legal enforcement powers. FANC inspectors can take any necessary measure to reduce or eliminate radiation hazards for workers, the public and the environment. In extreme cases and if a practice may result in a specific danger, the nuclear inspector has the power to interrupt an activity.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The 10-year human resource strategy plan developed by FANC provides a roadmap for 2023 to 2025, and a succession planning until 2035 considering the nuclear power programme phase out and LTO of the existing NPPs. Since the beginning of 2023, there is a dedicated position for training and development of "partner talent".

An analysis of the required competences and of the existing workforce started in 2022. It is expected to be completed in July 2023. The analysis covers a scope of 10 years and assesses the required number of staff and matching competences. It considers the national context and governmental decisions regarding nuclear energy phase-out and the possible LTO of existing plants. It also considers the international context related to the new emerging technologies. The analysis will continue with the scope of

developing a human resources (HR) transition plan for the next 10 years. The future HR strategy will cover knowledge management transfer and a new salary model with the goal of attracting, developing and maintaining competence within FANC.

The recruitment process is described in procedure PC003-01, currently under review. Each job description specifies the required core technical competencies. All positions are publicly offered for application and are open to internal candidates. Specific assessments of the applicants are done as appropriate looking not only at technical competencies, but also at behavioural and/or managerial competencies, which are evaluated with the support of an HR consultant. Training needs for newcomers are identified after assessment with respect to the required competencies. A tutorial plan is defined. An annual budget is foreseen for staff training and knowledge management needs. Training of staff consists of multiple and diverse external training courses as well as internal training. Currently this plan is not systematically based on the competence analysis for each position. For foreseeable departures, recruitment is initiated, depending on the importance of the position and on the required experience, up to two years in advance of the actual departure. This approach allows the new staff member to benefit from the competence and experience of the leaving staff member. At Bel V, retired staff can be hired as external consultant for maintaining and transferring the accumulated expertise and knowledge.

Bel V experts involved in the control of activities of nuclear facilities have to be qualified by FANC as experts in health physics, in compliance with the criteria and procedure of Article 73 of GRR-2001. FANC has a process for recognizing experts as FANC nuclear inspectors. Currently, approximately 45 FANC inspectors and 15-20 Bel V inspectors are qualified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC has defined a new strategy on human resource management and started an analysis regarding the required competences in the organization.*	
(1)	**BASIS: GSR Part 2 Requirement 9 states that** *"Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them"*
S2	**Suggestion: FANC should consider completing the analysis on its needed competences and act upon to ensure the availabilities of the necessary competences in the organization.**

Policy Issue: Competence management in a changing environment

Belgium is in a situation where:

- Final shut-down occurred for two NPPs and a final shutdown is scheduled for the five remaining units in 2025, to be followed by a dismantling and decommissioning programme;
- Possibility of a life-time extension of some NPPs;
- New emerging technologies (e.g. new research facility (MYRRHA), medical practices and devices, and Gen IV small modular reactors (SMRs).

These changes in the nuclear environment have created challenges for the regulatory body because they need to maintain competent staff and develop new talents in various areas in order to be able to respond to evolving requirements but at the same time will see a reduction in their financing as a result of the shutdowns.

Belgium expressed its interest in having focused discussions on competence management and to gain insights from IRRS team members' national good practices on issues such as, attracting and retaining competent staff; training program; synergy with other regulatory bodies for expert training; sharing of experts; (re)enforce international high level training initiatives; and optimize the available experts and competences.

The IRRS team members who participated in the discussions shared the same challenges for competence management and capacity building in their regulatory bodies, and in particular: achieving and maintaining sufficient attractiveness for new talents; securing, on the medium and long term, the required competences as nuclear sciences are becoming less popular and hence the number of students is decreasing; and keeping competent staff. They also agreed that the interest towards nuclear sector is decreasing; relevant competence will be needed for the years to come due also to the foreseen radioactive waste management and decommissioning activities.

The policy discussion highlighted the following key items and messages for the regulatory body:

- Approach continuously the ministers for sufficient resources;
- Display flexibility in determining staff salary;
- Develop a competence profile for each position to better prepare and be ready for the future needs;
- Launch fellowship programmes for future staff;
- Conduct outreach activities at universities or high schools, and recruit graduates or young scientists from less relevant specialties. Number of relevant years' experience should not be the decision factors in hiring new talent - more agility and flexibility in hiring profiles is needed.
- Provide training for the new and young staff online and on-the job;
- Encourage seniors and retirees to be involved as mentors as part of the training program;
- Hire multiple junior staff instead of one senior staff when replacing a retired staff (e.g. split the salary, no need for additional funds);
- Consider the society particularities and diversity inclusion when hiring;
- Build and promote better working environment and culture than the industry (e.g. work/life balance, continuous training and the hybrid work option) to attract more talents;
- Establish rotational opportunities or temporary assignments within the organization as part of the staff development and training;
- Allow remote working environment when hiring staff from different regions. This creates opportunities to hire new talents from remote and distant areas.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

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

The Medical Jury has been established to consult on individual authorization of practitioners and recognition of occupational physicians and experts in medical physics. The Medical Jury can also give advice for all questions related to radiation protection in the medical or occupational field upon request of FANC. When needed the Superior Health Council can be consulted.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Many liaison mechanisms are in place with the authorized parties: reporting, control, and approval of some decisions of the HPD, inspection reports, meetings, etc. There are also informal communication and meetings. Meetings can be organized at the request of authorized or applicant parties or at the FANC or Bel V's initiative.

Meetings are planned regularly between authorized parties, FANC and Bel V. The IRRS team was informed that the relationship between the regulatory body and the authorized parties is professional and constructive. This results in a proper definition and closure of actions. In accordance with a graded

approach, controls at Class I facilities are followed by structured and detailed discussions between the regulatory body and the licensees. The IRRS team was informed because of the good relationships between FANC, Bel V and the Class I licensees, there has not been a need to apply hard enforcement measures. However, there are methods and regulatory instruments available if needed for enforcement.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

As described in FANC's management system, regulatory decisions and regulatory recommendations are drafted, reviewed and approved by members of the staff at different organizational levels and approved by the process owner, ranging from the head of the section/department up to the FANC general manager for high-risk facilities.

Bel V has different mechanisms in place to ensure consistency between their decisions. There are TRCs where the TRC coordinator ensures the consistency of the positions that are taken within the concerned technical area. Senior project managers ensure the coherency of Bel V safety evaluations between different projects. The earlier internal body Safety Issue Committee (SIC) comprising of seven high level experts has been replaced by an internal process managed by Bel V high level experts.

There is a FANC procedure relating to the application of a graded approach to some planned and reactive activities. It gives a framework for prioritizing different regulatory activities and could be used as an example for all activities in both organizations.

Facilities and activities are classified in Class I, Class II or III. Medical practices such as radiotherapy and nuclear medicine belong to Class II while radiology, dental and veterinary practices usually belong to Class III. All practices within the medical sector have to be licensed. The regulatory body allocates more time and resources for licensing the more complex facilities, such as radiotherapy and nuclear medicine applications, belonging to Class II. The IRRS team was informed that FANC is looking into improving the effectiveness of the regulatory body by employing different instruments like information campaigns to licensees or a risk-oriented prioritization of inspections.

FANC can also ask advice from the Scientific Council concerning other issues related to Class I facilities, authorization of Class II and III facilities or regulations.

3.7. SAFETY RELATED RECORDS

Records of the results of inspections, enforcement, licensing activities, safety review and assessments are kept within the regulatory body. FANC uses a Central Information System (CIS) and SharePoint for storing the documents in electronic format. SharePoint system was established about 10 years ago. CIS stores all FANC documents related to authorization processing and their final decisions. CIS IT tool was tailor-made to support the FANC regulatory processes for all regulated facilities and activities classes.

Bel V does not have access to the FANC document management system. It has its own document management process and supporting system "KOLIBRI" and IT-system Access based tool for creating the document templates with needed META-data. Bel V has embedded OPEN TEXT search engine on top of KOLIBRI to enhance the usability of collected data. Bel V has also developed its own document workflow system DOCFLOW. Bel V document management system stores all inspection reports, assessment reports, meeting reports, some technical documents, and comprises a database for actions to be taken by the licensees and identified non-conformities (see section 8.1).

FANC prepares decisions taking into account deliverables from Bel V or other advisory bodies. FANC and Bel V have developed state of art document and workflow processes with advanced IT tools to support regulatory review and assessment and inspection functions. The IRRS team considered the effective use of advanced IT systems for managing their activities as a good performance.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

FANC has a communication policy and process as well as supporting procedures to establish guidance on how to communicate and inform its different licensees, other interested parties, including the public.

FANC bi-lingual website is user friendly and contains abundant information on events and relevant issues as well as background information on general matters and about the radiation risks of different facilities and activities. The FANC website comprises also a limited section in German language. A specific space is dedicated to laws and regulations. The web page allows for contacting FANC to ask questions, providing comments and statements. The results of the radiation online measurements performed by the TELERAD network are also available on the FANC web site which also includes the radon map of Belgium.

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

The public is consulted ("public inquiry") in the frame of the licensing process of high-risk facilities (Class I and some Class II), with the possibility to attend information meetings organized by FANC. In specific cases, international consultations are organized (e.g. EU neighbouring countries) according to the EU Directives, EURATOM treaty and the ESPOO convention. Advice and concerns are considered in the licensing process. Bel V provides technical support to FANC communication to the public. FANC may invite Bel V to participate in public meetings and interested parties' engagements. A variety of forums are established to communicate and interact with licensees, adapted to the specific needs of each industrial or medical sector. Near nuclear facilities, operating organisations and local communities organize regular meetings to which they also invite the regulatory body.

Communication of events related to radiation or nuclear safety with the INES scale is systematically and in a structured manner used in Belgium. FANC has written guidance and directives which are applicable to all the industrial Class I, II and III facilities. These guidance and directives identify the type of events which required notification to FANC, Bel V or other institutions. The guides and directives establish the timeliness of the reporting of events to include the applicability of INES for the event. In parallel, FANC has set up specific conventions with the Class I facility licensees and the highest risk Class II facility licensees to use INES as a communication tool to the public. This convention is on a voluntary basis, but all the concerned licensees participate in it. Events that are classified at level 1 or higher on the INES scale, or level 0 which have media interest, are published on the website of FANC. The IRRS team was informed that there is no obligation in the regulations nor in the licenses for the authorized parties to directly inform the public on radiation risks associated with the operation of a facility or the conduct of an activity, even though all licensees of major facilities have put in place public information tools (web sites, magazines, etc.).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no legal obligation for the authorized parties to directly inform the public about radiation risks associated with the operation of a facility or the conduct of an activity.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.68 states that** *"The authorized party shall inform the public about the possible radiation risks (arising from operational states and accidents, including events with a very low probability of occurrence) associated with the operation of a facility or the conduct of an activity. This obligation shall be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means."*
R3	**Recommendation: The Government should establish regulations or other legal means to require the authorized parties to inform the public about the possible radiation risks associated with the operation of a facility or the conduct of an activity.**

3.9. SUMMARY

In Belgium, the regulatory functions and responsibilities are assigned to FANC with the support of Bel V. There are historical and practical reasons for FANC to get support from Bel V in several areas, such as inspections, safety R&A and international co-operation. There is consistency and stability of regulatory control, although regulatory consistency was challenged during the COVID-19 pandemic.

FANC conducts its regulatory function in accordance with a graded approach.

In the context of ongoing discussions on NPP long-term operation and the possible projects to use new technologies such as SMR, there is a concern in relation to the resources and competences needed to discharge the regulatory duties to effectively regulate those future level of activities in Belgium and to maintain the high level of radiation and nuclear safety competence. The IRRS team concluded there is room to improve FANC competence management methodology and proceed to answer the challenges to maintain high competence within the regulatory body.

The IRRS team considered the effective use of advanced IT systems for managing FANC's and Bel V's activities as a good performance.

FANC and Bel V have well established processes to communicate and liaise with licensees and interested parties, including the public. However, the obligation for licensees to inform the public about the possible radiation risks is not binding.

4. MANAGEMENT OF THE REGULATORY BODY

FANC is responsible for nuclear safety, security and radiation protection. In accordance with the FANC law, it has delegated to Bel V specific activities such as independent safety assessments and on-site safety oversight activities, so-called controls as, unlike FANC inspectors, Bel V experts do not have enforcement power. The performance of the activities delegated to Bel V is documented in a “management agreement" concluded between FANC and Bel V. The collaboration between FANC and Bel V in areas such as international affairs, security, regulatory oversight, support to FANC communication, technical advice in the drafting of regulation is documented in a ”collaboration convention” signed by the director general of FANC and by the director general of Bel V. Both documents were signed in 2019 and are valid for six years.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

FANC documented its commitment to safety through its mission “to ensure the protection of the population, workers and the environment against the dangers of ionizing radiation”, its vision and by setting its values, namely Responsibility, Respect and Integrity. FANC has also established a strategic plan that covers the period 2023 to 2032. The mission, vision and values are referenced in the Management System Policy and in the 2023-2032 strategic plan.

The strategic plan reiterated the mission and vision of the organization, it describes the five themes adopted: changing business; new technologies; stakeholders; expertise and funding and includes a commitment towards colleagues, licensees and society.

In compliance with the FANC law, Article 14c, the FANC board decided to delegate part of FANC monitoring activities and safety evaluations to Bel V. According to that decision and as mentioned in Bel V’s statutes and described in the Management Contract between FANC and Bel V, the mission of Bel V is “to contribute to the protection of public, workers and environment against the danger of ionizing radiation”.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

FANC Management System Policy (MGS) indicates that the organization’s management system is built on the strategic plan “Strategy 2023-2032”, on the three-year operational plans, and on policies that create a framework for the implementation of FANC’s activities. The Management System Policy indicates that the management system ensures that necessary actions are taken to achieve the strategic objectives. However, the “strategic objectives” are not described in the nine-year strategic plan 2023-2032. Thus, FANC 2023 – 2032 Strategy introduces “strategic themes” and commitments towards colleagues, licensees and society, but without identifying any strategic objectives.

The process for developing and implementing the strategic and three- and one-year operational plans, MGS-03, revision 1, describes the different steps of the development and the implementation of strategic plans and operational plans. This process highlights that the strategic plan enables FANC “to concretize its vision through a set of strategic orientations. These strategic orientations are translated into tangible objectives by means of 3-year operational plans”. The same document mentions that the strategic plan includes strategic indicators and their "target" values and that the strategic plan defines the common objectives of FANC and Bel V. However, the strategic plan 2023-2032 does not mention the objectives. FANC three-year operational plan “POP 3” sets objectives for every department within the organization starting from the generic themes mentioned in the strategic plan. The governance document on the missions of the FANC departments, code GD002-05 revision 0, describes the “generic mission” of FANC and its technical departments. The mission provided by this document is different from the mission set out in the FANC law, article 10g, ” to safeguard the health and safety of workers and the general public and to protect the environment from ionizing radiation”.

Each organization, FANC and Bel V has established their own policy or governing documents. The link between the objectives of the two entities of the regulatory body is documented in the GRR-2001 (art 38), the management agreement and the collaboration convention. Yearly objectives of Bel V are defined based on the "Controls & Safety Assessments plan" which is challenged and then approved by FANC senior management. Together with the delegation of the mission of FANC to Bel V, the strategic objectives of Bel V, in the field of nuclear and radiological safety, are automatically linked to FANC's objectives.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC strategic organizational objectives, necessary to fulfil its mission, as granted by the FANC law, are not clearly stated in the strategy.*	
(1)	**BASIS: GSR Part 2 Requirement 4 states that** *"Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy."*
(2)	**BASIS: GSR Part 2 para. 4.4 states that** *"Senior management shall ensure that measurable safety goals that are in line with these strategies, plans and objectives are established at various levels in the organization."*
R4	**Recommendation: FANC should clearly state the strategic organizational objectives necessary to fulfil its mission.**

The Bel V quality manual identifies three general objectives for the organization in section QM2. It refers to performing inspections, the advisory role in case of emergency situations and review and assessment in the field of nuclear safety and radiation protection. For each of the 13 processes established within Bel V, several quality objectives, each of them together with associated key performance indicators (KPI), are identified. The quality objectives are listed in the document entitled "List of Quality Objectives". Bel V identified as "core processes", processes three to six: A03 Perform conformity check; A04 Perform the inspections during operation; A05 Technical project management; and A06 Provide and manage expert services in nuclear safety and radiation protection. Key performance indicators are also assigned to each process.

Each year, FANC delegates a list of tasks to be performed by Bel V. These tasks are linked to Bel V core processes: inspections during operation; and review and assessments in nuclear safety and radiation protection.

The objective related to Bel V's advisory role in case of emergency situations is covered by subprocess A04.09 on Emergency Preparedness and Response (EPR). Besides, a specific TRC (within A06 process) is also dedicated to EPR.

4.3. THE MANAGEMENT SYSTEM

FANC

The structure of documents within FANC is described in the document MGS-SP01. According to it, there are three families of documents:

- Steering Documents – governances, directives, circulars, conventions and protocols;
- Specific Documents – documents produced only by FANC: the 15 policies, processes, procedures and specifications;
- Supporting Documents – user guides, information and glossary.

The management system Specific Documents support the operation of FANC and consist of policies, processes, procedures, and specifications. A policy document describes the operating principles and rules for a given domain.

For each policy, at least one process is associated. A process is a set of activities designed to produce a specific service or product. A process describes each step, contains a risk analysis, a flow-chart and a Responsible, Accountable, Contribute and Inform (RACI) table. The sequencing of the processes and the interactions between processes are specified in the flowchart of each process. If needed, subsequent procedures are issued for processes.

The MGS describes the basic rules governing the operation and organization of FANC. The policy also describes the vision, mission, values of FANC and sets out the basic rules, policy rules, the processes on how policies should be developed and implemented, as well as the decision-making process for the management system policy, and its objectives. The management system policy introduces the rules for developing and monitoring strategic plans and 3-year and 1-year operational plans, for monitoring strategic projects and for managing the documentation in the management system. For each policy, a policy owner is assigned.

The management system of FANC is based on 15 policies that describe the basic rules and associated processes. The policies are: Management System Policy, Human Resources Policy, Means Policy, Information and Communication Policy, ICT Policy, Inspection Policy, Authorization Policy, Significant Events and Crisis Management Policy, Radiological Surveillance Policy, Security Policy, Enforcement Policy, Regulatory Policy, International Relations Policy, Review & Assessment Policy, Internal Control Policy.

Bel V

Bel V has established a management system based on 13 processes, out of which five are resulting from the delegated regulatory activities by FANC. The Bel V management system integrates the quality management system, based on ISO 9001:2015 that is supplemented with the additional requirements from IAEA safety standard, GSR Part 2.

The processes defined, implemented and documented by Bel V are:

- an overall process A01 - Managing Bel V;
- a process for strategic development (A02);
- five processes resulting from the delegated regulatory activities: A03, A04, A05, A06, A07;
- four processes supporting the regulatory activities: A08, A09, A10, A11;
- a process for managing the QMS: A12; and
- a process for treating the risk analysis: A13.

Bel V reports periodically to FANC on the tasks that have been delegated. All reports on safety inspections (controls) and radiation protection are systematically sent to FANC. Results of the inspection & review and assessment programmes are communicated twice a year. Other reporting activities are systematically done by quarterly reports, an annual report, and financial statements. FANC has carried out annual audits on the functioning of Bel V since 2020 according to a six-year plan prepared by FANC.

4.4. MANAGEMENT OF RESOURCES

FANC

The governance document “Human Resources Policy (version 1)” is one of the 15 policy documents of FANC. The document describes FANC’s human resources policy, explains its basic principles and specifies how it relates to FANC’s mission, vision, strategy, and operational objectives. For the implementation of this policy, FANC identified three associated processes covering the following: work force planning, employee lifecycle, Payroll & Administration.

The IRRS team was informed that FANC management system documentation related to human resource policy will be updated in order to incorporate the results of the ongoing analysis of required competence and of the existing workforce as well as the new adopted strategy.

The current practices within FANC include the assignment of a coaching plan for each new employee in which necessary knowledge, skills and attitudes - KSAs – are defined, as well as the recognition process as qualified expert (the first step for getting the status of nuclear inspector) and the accreditation processes (the second step in obtaining the nuclear inspector status). These will then be reflected in their training plan. FANC also plans to implement a self-assessment tool and a performance review of the human resource process by the end of 2023. The establishing of behavioural competencies is not yet finalized: the related activities have been ongoing since January 2023, and the implementation is foreseen for the last trimester of 2023. The intention for development of an adapted human resource policy, including a knowledge management system, is recognized by FANC in the action plan developed in the course of the preparation of the mission.

Bel V

Bel V determines the necessary competences and has established a qualification system for its personnel. As required by Article 13 of the management contract, Bel V has set up a process for acquiring and maintaining its competence in the areas of safety and radiation protection. Bel V develops an annual and a 3-year human resources management plan that defines the number of people needed to carry out its assignments and functions. The plan covers recruitment, staff rotation and a strategy for compensating for personnel fluctuation when necessary.

Bel V has implemented training plans to ensure the necessary skills are maintained and developed. Bel V procedure Competence Gap Analysis describes the methodology used for managing the Bel V staff competences necessary to discharge its duties. The procedure Individual Basic Training Programme describes the way an individual is trained based on the SARCON methodology, when appropriate.

The employee training programme in Bel V includes several steps: one month welcome programme; one year individual basic training programme; two years Individual Specialized Training Programme which is tailored, using the IAEA four quadrant model and the SARCON methodology; three years feedback (also tailored using the IAEA four quadrant model and the SARCON methodology); when needed, an individual specialized training programme is prepared, that can include career development aspirations. Bel V has developed and documented an internal qualification programme, that includes qualification in basic radiation protection and nuclear safety, as well as certification for inspectors.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

FANC

The FANC process MGS-01 deals with the elaboration and the revision of the management system documentation. The process contains a flowchart and a RACI table. RACI indicates, for the different phases of the processes, the interface with Bel V where necessary. For high-level documents, such as policy or governance documents, two independent reviews are required whereas only one review is required for lower-level documents, such as processes and procedures. FANC has nominated policy owners for each policy, the interfaces between policies and / or processes are documented in the flowcharts attached to the processes / procedures.

Bel V

Bel V uses the instruction Mastering the Internal QMS Documents that describes the methodology for controlling the internal quality management system documentation, by ensuring that all documents are under control. Bel V sets annual quality objectives for the organization and has developed a set of KPI that are monitored quarterly using the KPI dashboard. Bel V monitors and assess its management system through:

- internal audits - the audit programmes cover the entire QMS, across all levels of responsibility, over a three-year period;
- bimonthly reports following an assessment of the operation of the management system;
- annual evaluation/loopback reports for all 13 processes (carried out by the process managers) ; and
- management review.

The Bel V processes are managed by process managers, who are accountable for the achievement of goals and the quality of the activities performed. Interfaces between processes are established in the flowcharts.

The results of all activities performed by Bel V for FANC are communicated and accepted by FANC. FANC together with Bel V perform most of the core regulatory functions in-house and only a few support services are outsourced.

4.6. CULTURE FOR SAFETY

FANC and Bel V have jointly adopted a Safety Culture Policy, a document signed by both parties. The current version 1 was issued on May 2017. The Policy lists the values adopted by both organizations and the methods to be used for the assessment of their safety culture.

According to this policy, FANC uses a "critical review methodology" meaning that specific events are reviewed and transposed into lessons learnt. Within Bel V, safety culture is assessed through a safety culture maturity tool developed internally. The first assessment was performed in 2016 and a second one took place in 2021 which was followed by a survey also in 2021 to complete the approach through quantitative results. The results, including the identified areas for improvement, were presented to the entire staff of Bel V. Bel V developed the model for assessing the safety culture maturity level using four safety culture areas: "bureaucratic", "individual commitment", "cooperative" and "holistic". During the assessment, the self-assessment group checks the five dimensions: leadership for safety, individual responsibility, safety oversight, open communication and continuous improvement – and their subsequent sub-dimensions. The methodology is based on a qualitative approach, aiming at assessing the level of safety culture maturity of Bel V. The assessment results are later used as input for the continuous improvement process of Bel V. Bel V appointed a "safety culture coordinator", responsible for the overall conduct of the assessment including the drafting of the final report.

The development of the model and implementation of the assessment of leadership for safety and of safety culture within Bel V, is considered remarkable for the effective development and continuous improvement of a culture of safety in the organization and recognized by the IRRS team as a good performance.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

FANC

The internal control policy of FANC (ICO), version 0, defines the policy in the field of internal control. The document sets out the basic rules that apply in general and that shall be applied across FANC. FANC organizes the control of its activities using the "3 lines of defence" ("3LoD") model:

- the first line consists of the operational management (heads of section and department) which is responsible for activities to be conducted in accordance with policies, processes and procedures (section or department);
- the second line ensures the adequate functioning of the first line. The second line is formed of the management of the quality system and the organization of processes related to performance and risk management; the implementation of the second line relies mainly on the "Management

Review" process (ICO-02) and the use of Risk Control Matrixes for each of its policies (and subsequent processes);

- the third line is a function carried out by the Internal Auditor, who reports to the General Manager and works independently, that checks whether the first and second lines are fulfilling their role correctly.

The process document management review (process ICO-02) foresees cycles of three years during which all the 15 policies are reviewed.
The document procedure for internal audits code ICO-03-01, revision 1, describes the methodology to be followed for conducting internal audits within FANC, namely the following elements: the audit plan; the responsibilities; the workflow; the reporting and the follow-up of audit findings. Section 4.3 of the procedure sets up the frequency of the routine audits: at least every five years for core activities; and at least every six years for operational activities and support activities. The structure of FANC's management system, based on the 15 policies, does not differentiate between core, support or management processes. In order to be sure that all processes are regularly evaluated for their effectiveness and for their ability to ensure safety, it is necessary that FANC uses the same terminology related to its activities – policy, processes and activities.

One of the governance documents for the internal audit is the Audit Charter, that manages the competences, values, and responsibilities of the internal audits. Currently one person is responsible for the audit programme. The FANC audit programme includes internal audits and audits of Bel V. The audits are conducted in Bel V according to a 6–year plan in line with the validity duration of the management contract from FANC and Bel V. This plan covers all articles from the management contract.

Bel V

Bel V has established a management system that includes the organization chart, processes and organizational entities that are named Technical Responsibility Centers (TRCs). For monitoring and assessing the quality management system, Bel V uses internal audits, bimonthly reports, annual evaluation/loopback reports for all 13 processes and the management review measurement. Assessment and improvement activities include internal audits and external audits - performed either by FANC or by the certification organization to verify the conformity of the system with the ISO 9001:2015 requirements. Bel V has about 10 internal qualified auditors that perform audits based on an annually approved audit plan to verify the conformity of the system with ISO requirements and as well as with Bel V management system requirements that are set in the management system documents. From the Bel V management system point of view, FANC is identified as the client. One of the QMS objectives set in the quality management manual is: "to continuously enhance client satisfaction". According to the manual, section 5.2, Bel V management should ensure that client requirements are determined and are met with the aim of enhancing client satisfaction. The Bel V management system review is performed annually and is concluded by the issuance of a report. The report comprises a chapter on "client satisfaction"; but the last management review did not mention any results related to FANC "satisfaction".

According to the safety culture policy, FANC and Bel V regularly exchange information on the results of the safety culture self-assessment, lessons learned and provide mutual assistance for performing the self - assessment. Until now the exchange of information was delivered during the regular meetings between FANC and Bel V but no specific meetings have been organized on the topic of safety culture of the regulatory body. FANC decided to adopt the model developed and implemented by Bel V and the first run of the self-assessment is ongoing; however, no plans have been yet documented, for example the issue of a procedure or an implementation schedule. This action has already been identified in the Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC and Bel V adopted a Safety Culture Policy, a document signed by both parties. FANC committed to adopt and implement the model developed by Bel V for the assessment of leadership for safety and of safety culture but no plans have been yet documented, for example the issue of a procedure or an implementation schedule.*	
(1)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
R5	**Recommendation: FANC should update the Policy on Safety Culture, further document the Leadership for Safety and Safety Culture self-assessment process, and then perform self-assessments regularly.**

4.8. SUMMARY

FANC and Bel V have established a management system, considering different approaches and implementation tools, in order to support each organization in fulfilling their responsibilities assigned by law and subsequent documents, in a documented and verifiable manner. The management systems of both organizations are centred on fulfilling the regulatory functions assigned by law and translated into specific management system documents.

The management systems implemented in FANC and Bel V defined, documented, and implemented tools and mechanisms that contribute to continuous improvement.

The two organizations exchange information in the field of nuclear and radiation safety on a continuous basis. FANC has established a series of control measures to supervise the delegated activities performed by Bel V in the field of nuclear and radiation safety.

Within the management systems of FANC and Bel V, throughout the processes implemented, leadership and culture for safety is promoted continuously at all levels.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The FANC law states that the King shall grant or refuse construction and operating licences before the construction can begin on any facility in which substances or devices capable of emitting ionising radiation are to be present. FANC is responsible for processing the licence application with due consideration of the opinion of the Scientific Council.

In terms of Article 17 of the FANC law, facilities are categorised according to the risk. GRR-2001 categorises facilities, including facilities under decommissioning, in one of the four classes in accordance with a graded approach.

Implementation is supported by two royal decrees, GRR-2001 and SRNI-2011. The general licensing regime of GRR-2001 provides overall requirements relating to construction and operation licences. This is applicable to Class I to III facilities. Article 17 of GRR-2001 addresses cessation of activities and dismantling. Dismantling activities can only commence for Class I and IIA facilities under a licence granted in terms of the provisions contained in GRR-2001.

The roles and responsibilities for licensing are distributed between the King, FANC with the support of the Scientific Council, and regional authorities. Regional authorities have some role during the licensing process. However, final decisions belong to the King for Class I or FANC for Class IIA, II and III. These roles and responsibilities are defined in the legal framework and further elaborated in the FANC Authorisation Policy and Process. In addition, FANC has established cooperation agreements with regional authorities.

The authorisation is managed according to the policies for Authorization (AUT) and Review and Assessment (REV), and implemented through the associated processes and procedures. The authorisation process includes provisions to appeal against an authorization granted by the FANC or the King.

Site evaluation is not specifically recognized as a distinct licensing stage. It is included in the review of the application for construction and operation, and is also part of the periodic safety reviews. Site characterisation and evaluation of new sites may require extensive effort and time. FANC should consider reviewing the regulatory framework as it relates to siting that would allow for evaluation of new sites or existing sites against current standards and practices in anticipation of new construction licence applications.

An application for decommissioning, including a Dismantling Safety Report, shall be submitted after cessation of operational activities. SNRI-2011 requires that the Safety Report includes inter alia the proposed methodology and monitoring for the end-state site characterisation. General clearance criteria are specified in GRR-2001. FANC and Bel V have developed a position paper that describes an integrated approach to clearance of sites from regulatory control. The position paper details the regulatory framework, roles and responsibilities of the various parties involved, site release categories, as well as specific tasks of both the licensee and FANC. This process was successfully implemented for the release of the French-Belgian Fabrication of Fuel (FBFC) site from regulatory control. The royal decree to lift all five authorisations of FBFC and remove FBFC from the list of Class I nuclear facilities was finalised in 2022. The position paper provides an integrated approach to release of sites from regulatory control and the implementation thereof has been proven to be effective with the release of the FBFC site from regulatory control. The IRRS team considered this approach as a good performance.

When the licensee of a Class I nuclear facility decides to move to the decommissioning stage, it shall comply with the provisions of GRR-2001. FANC may impose additional conditions and/or amend the conditions of the existing license to reflect the changed condition of the facility after the cessation of operations. The IRRS team confirmed this to be the actual practice for the NPPs which have been permanently shut down. In accordance with GRR-2001, Class I nuclear facilities must further obtain a dismantling licence before commencing the actual dismantling activities. The authorization for a

dismantling licence follows the same process as for a new application and includes amongst other things an EIA-Report and a public consultation. The IRRS team was informed that the SRNI-2011 does include relevant regulatory requirements to ensure safety during shutdown and decommissioning, and that no authorization for shutdown is required. A safety demonstration for shutdown was included in the shutdown notice in accordance with SNRI-2011, article 17/1.

Pre-licensing is a distinct option in the FANC law, with a clearly defined process. This option is used by FANC to gain insight and provide early feedback on projects, as well as the level of the readiness of the applicant. The pre-licensing process also allows the prospective licensee to get early knowledge of potential licensing issues, insight in expectations of the regulatory body and understanding of the relevant regulatory positions. The process is clearly defined and includes two variants catering for standard projects largely within the current experience and expertise which require a limited effort, and projects that may go beyond the current experience and expertise which require a large effort. Examples of five recent pre-licensing applications on nuclear facilities were provided. Four of them were completed and in construction phase at the time of the mission.

Notwithstanding, the pre-licensing process does not cater for direct vendor engagement on the review of new facility designs and requires a prospective licence applicant for construction and operation of the facility to be the applicant. The IRRS team encouraged FANC to consider revising the current pre-licensing regulatory provisions and processes with an option for direct engagement with potential vendors on the review of new Category I facility designs that will facilitate the review and assessment process and may reduce project related risk for a prospective construction and operation licence applicant.

The licensing regime for Class II and III facilities includes possibility of public to appeal against the decision as per articles 7.6 and 8.5 respectively of GRR-2001. For Class I facilities, when the royal decree is signed, the applicant, as well as all the parties and persons provided for in Article 6.8 of GRR-2001 are notified. The decision is also published in the Belgian Official Gazette and on FANC's website. Every notification includes a description of the appeal process to the State Council for annulment of the decision.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The legal basis for authorisation of NPP's are provided by the FANC law and the associated royal decrees as discussed in section 5.1.

For the construction and operation or decommissioning licence, public consultation is required, including on the EIA.

For a construction and operating licence, the application shall include relevant waste and decommissioning information commensurate with the stage of licensing. The format and content of the required information are specified in GRR-2001.

The licensee is required by a condition of authorisation to perform all operational activities in accordance with the approved licensing bases (safety report). Regional authorities require through local decrees that FANC provides advice on development applications involving hazardous facilities within specified radius around the site. This approach ensures that the licensing basis with respect to potential human induced external events are not compromised between periodic safety review periods.

A periodic safety review is required for continuous operation, long-term operation and eventual period of shutdown and decommissioning of the nuclear facility. Therefore, LTO of NPP's is regulated through the regulatory 10-year periodic safety reviews which shall be performed in compliance with Article 14 of the SRNI-2011. FANC is implementing its LTO strategy in anticipation of LTO of Doel 4 and Tihange 3. FANC is anticipating submissions relating to the scope and methodology from the licensee and the submission of the PSR for LTO for their facilities. The operator is still in discussion with the Government on the potential LTO of those two units. As it relates to conformity assessments of pressurized equipment, the IRRS team was informed that the Federal Public Service of Employment,

Labour and Social Concertation is responsible for the regulatory oversight of pressurized equipment in general and accredits Authorised Inspection Agencies (AIA). Vinçotte has been appointed by the operator as nuclear AIA. Where emergent issues related to nuclear pressurized safety equipment require services by the AIA, Bel V is also involved in the assessment and approval of this type of equipment. However, the documentation related to Authorization Policy and Process of FANC, AUT and AUT-01-09 (Rev 4) respectively, do not include provisions to involve all of the relevant government departments and authorities in the authorization process in order to provide their opinions on the applications involving pressurized equipment and/or fire protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Authorization Policy and Process of FANC, AUT and AUT-01-09 (Rev 4) do not recognise all relevant government departments to provide advice on applications involving pressurized equipment and fire protection.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev.1) para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation."*
(3)	**BASIS: GSR Part 2 para. 4.7 states that** *"Senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include: … (d) Appropriate means of considering in decision making processes the concerns and expectations of interested parties in relation to safety."*
R6	**Recommendation: FANC should identify all relevant government departments and authorities to be consulted or informed for new licence applications or operational assessments and update its internal processes and procedures as appropriate.**

The FANC note on "Requirements of the Safety Authority for the preparation and implementation of the construction and commissioning phases (including acceptance) of a new nuclear facility in a Class I establishment" details the regulatory requirements and expectations on supply chain management to be implemented by the licensee. The document however does not cater to or consider the situation where procurement of components requiring long lead times and procurement prior to a construction and operation licence being issued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC's requirements and expectations on supply chain management of Class I facilities do not cater or consider the possibility of procurement of components requiring long lead times prior to a construction and operation licence being issued.*	
(1)	**BASIS: SSG-38 para. 2.6 states that** *"All relevant authorizations should be obtained before construction starts. If this is not done, the licensee bears the risk that structures, systems and components may fail to meet the necessary regulatory requirements. However, in some instances, manufacturing of some items with a long lead time begins before authorization for the construction is granted by the regulatory body. Such activity should be brought to the attention of the regulatory body."*
S3	**Suggestion: FANC and Bel V should consider reviewing and revising as appropriate its regulatory framework and internal processes to cater for procurement of components prior to a construction and operation licence being issued.**

For Class I facilities, the head of the health physics department must be a recognized expert in health physics in accordance with Article 73 of GRR-2001. Several provisions related to the assurance of competence, qualification and training are included in the SRNI-2011. SRNI-2011, Article 19 specifically deals with employees of NPPs, including control room operators and their training programme. Control room operators require a valid certificate for a defined period. The requirements and process are detailed in a Bel V inspection document (B-SP-TQ-1, Authorisation Examination). The inspection covers Bel V's participation in accreditation or certification examinations, as well as the renewal of these accreditations and certifications. It has been further established that Bel V makes up 50% of the composition of the evaluation team with the Operator.

5.3. AUTHORIZATION OF RESEARCH REACTORS

The authorization process for research reactors is the same as for any Class I nuclear facility. A safety analysis report and an EIA are the main requirements for an application.

SCK research reactors are covered by one single licence and this document refers to the royal decrees, the regulations and the safety analysis report and provides the conditions for the licence.

If something changes in one of the facilities included in the licence (like new experiments, new or different experiment devices, changes in the reactor power, etc.) the licensee has to apply for a modification and if necessary, the licence conditions could change.

For new projects, FANC has implemented a pre-licensing stage. FANC requirements are included in the design specification of the facility. The objective of pre-licensing is discussed in section 5.1.

The licence of the SCK research reactors has no expiration date. The licensee performs periodic safety reviews each ten years, and this is the process to continue operation.

Only one research reactor, the BR3, is at the final stages of dismantling. The licensee has implemented an ageing management programme for BR2 and BR1 reactors, and is subject to the periodic safety review process.

FANC consults with the Scientific Council granting a license/authorization as discussed in section 5.1.

The licence is granted by the King and other relevant authorities are notified.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The authorization process for waste management and disposal facilities is the same for any Class I nuclear facility. GRR-2001 and SRNI-2011 lay out the general authorization process for Class I facilities. FANC has developed revisions to GRR-2001 related to the authorization process for disposal facilities which is expected to be published as a royal decree by the end of 2023. FANC has also developed safety requirements specific to disposal facilities in SRNI-2011 which are expected to be published as another royal decree by the end of 2023.

FANC recognized that its regulations in SRNI-2011 require facilities to minimize waste during decommissioning activities but not during other authorized activities (construction, operation, etc.). Therefore, FANC should update their regulations to make it explicit that licensees are expected to operate in a way that minimizes waste generation.

Earlier in 2023, the King authorized NIRAS/ONDRAF to construct and operate a surface disposal facility for Class A waste in Dessel, near the existing Belgoprocess waste management facility.

A royal decree was issued in November 2022 establishing the national policy decision to pursue deep geological disposal in Belgium for high-level and long-lived radioactive waste. A future decree will lay out the implementation framework, next steps and how the public will be involved in the deep geological disposal decision.

The changes to SRNI-2011 for disposal facilities are expected to be issued by the end of the year and therefore they will be able to be implemented by FANC when NIRAS/ONDRAF submits its

methodological Safety and Feasibility case for deep geological disposal, expected in 2025. In addition to the new regulations, FANC and Bel V have developed an integrated guide for a geologic disposal application.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC noted that GRR-2001 does not explicitly require licensees to operate in such a way as to minimize waste. There is a requirement about minimizing waste in Article 17/5 that is only applicable to facilities undergoing decommissioning but not for all facilities and activities.*	
(1)	**BASIS: GSR Part 5 para. 4.6 states that** *"Measures to control the generation of radioactive waste, in terms of both volume and radioactivity content, have to be considered before the construction of a facility, beginning with the design phase, and throughout the lifetime of the facility, in the selection of the materials used for its construction, and in the control of the materials and the selection of the processes, equipment and procedures used throughout its operation and decommissioning. The control measures are generally applied in the following order: reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as waste."*
R7	**Recommendation: Upon proposal from FANC, the Government should revise the royal decree GRR-2001, to incorporate a requirement that all authorized parties keep the generation of radioactive waste to a minimum.**

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

A licence is required for the construction and the operation of facilities with radiation sources in Belgium. The facilities, based on the associated risk, are classified as:

- Class IIA: high-risk facilities such as large irradiators and accelerators;
- Class II: industrial and medical facilities, where certain activity levels are deployed;
- Class III: industrial and medical facilities with lower risk than Class II;
- Class IV: facilities using radioactive sources of activities below the exemption levels.

The licences for Class II and III facilities are granted by FANC for a maximum period of 15 years. Class IV facilities are exempted from the requirement for a license.

At present, there are 6400 medical, 26 Class IIA, and 238 industrial facilities in the country.

FANC applies a graded approach for the information that shall be submitted with the license application, as well as to the conditions that can be included in the licensing document. The requirements are included in GRR-2001. Specific templates for the application form and guidance on the type and the content of the information to be submitted are available on FANC's website.

According to FANC's regulations, all non-exempted activities should be approved either by notification or by authorization, but FANC applies notification only for NORM activities. All other activities are authorised by licensing, and registration is not used as an authorization option.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *According to FANC's regulations, all non-exempted activities should be approved either by notification or by authorization, but FANC applies notification only for NORM activities. All other activities are authorised by licensing, and registration is not used as an authorization option.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para 2.5 (3) states that** *"The type of authorisation that is required for the operation of facilities and conduct of activities, in accordance with graded approach".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 3 para. 2.30 states that** *"The regulatory body shall establish a regulatory system for protection and safety that includes; (a) Notification and authorization".*
(3)	**BASIS: GSR Part 3 para. 3.8 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."*
S4	**Suggestion: FANC should consider updating the regulations to use notification and registration of facilities and activities with radiation sources, according to a graded approach.**

A safety report shall be submitted to FANC for the licensing of Class IIA facilities. For Class II and III facilities, a demonstration of safety is submitted which includes, among others, estimated exposures to workers during normal operations, identification of potential exposures, the probability of occurrence of potential exposures, etc. Licensees are required to keep an inventory of all radioactive sources. Certain data related to sealed radioactive sources and equipment shall be submitted to FANC monthly in accordance with technical regulation of 02/06/22. Moreover, there are specific legislative provisions for the manufacturers and licensees regarding disused sealed sources.

FANC has a formalized strategy for carrying out campaigns for the recovery of orphan sources. The related requirements for the strategy are defined in:

- a decree which establishes guidelines to be followed in the event of detection or discovery of an orphan source in non-nuclear sector; and
- a royal decree for the detection of radioactive materials in certain waste flow material and the management of orphan source sensitive facilities.

There are 749 orphan source sensitive facilities (metal industries, scrap yards, etc.) in the country. 279 of them have an active portal monitor.

A tool is available on FANC's website for reporting a found of orphan sources. FANC provides training to the personnel of orphan source sensitive facilities. In addition, related informative material is available on FANC's website in the form of posters, newsletters, etc. An agreement has been made between FANC and NIRAS/ONDRAF. According to this agreement, NIRAS/ONDRAF covers the cost for the export, recycling, etc. of radioactive sealed sources for which FANC cannot identify their owners.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

FANC regulations set out in SRNI-2011 and GRR-2001 provide the requirements for decommissioning. The requirements were updated in 2018 and will be implemented as FANC and Bel V prepare for authorizations for decommissioning at two shutdown NPPs.

After declaring their intent to cease operations, two nuclear power reactors have entered into a post-operational phase which will last until they receive their dismantling license.

FANC noted that the regulations did not specifically identify all decommissioning phases – such as the definition of shutdown or the post-operational phase. This is the first time NPPs have entered decommissioning and the post-operational phases. The period between shutdown notification and dismantling is expected to be longer for NPPs than the previous experiences of FANC, for example with fuel fabrication facilities.

Operators must submit two documents before they can begin decommissioning - the Final Dismantling Plan (PFD) for NIRAS/ONDRAF and the Dismantling Safety Report (RSD) for FANC. In practice, the RSD is prepared by the operator in parallel with the PFD. FANC developed guidance on the contents of

the two reports to help licensees prepare the reports and to facilitate coordination between FANC and NIRAS/ONDRAF.

The regulations in GRR-2001 do not establish a timeframe for when licensees have to submit their dismantling licence application. FANC therefore used its authority in GRR-2001 to change the license conditions for the two shutdown reactors as the mechanism to add a requirement for when the licence application should be submitted (2 years after permanent shutdown). NIRAS/ONDRAF requires licensees to submit their PFD within 3 years after shutdown. Thus, it is expected that NIRAS/ONDRAF will receive the PFD first and FANC will receive the dismantling licence application after approval of the PFD by NIRAS/ONDRAF.

In 2018, GRR-2001 was modified to require that applicants for authorization to construct and operate class I, II, or III facilities, except for disposal facilities, must include a "Subfile Dismantling". This subfile is part of the safety report and thus must be regularly updated by the licensee. NIRAS/ONDRAF provides its official opinion on the subfile.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The royal decree GRR-2001 does not provide a timeframe for when a licensee should apply to FANC for a dismantling licence. FANC, for the first two decommissioning reactors, used their ability to modify the licenses to insert requirements on when the licensees submit their dismantling licence application.*	
(1)	**BASIS: GSR Part 6 para. 3.3 states that** *"The responsibilities of the regulatory body shall include: …* - *Establishing criteria and the timeframe for the process of authorization for decommissioning."*
R8	**Recommendation: FANC should include in the regulations a timeframe for when the licensee of a Class I or IIA facility submits its application for a dismantling licence to FANC for review and approval.**

5.7. AUTHORIZATION OF TRANSPORT

The regulatory framework for transport of Class 7 (radioactive material) dangerous goods is formed by the FANC-law, the royal decree on the transport of Class 7 Dangerous Goods (RD Transport) and four technical regulations (TR). The FANC is the competent authority for the transport of radioactive material as recognized in the FANC-law.

The RD Transport establishes that the transport, the handling operated by organisations during multimodal transport of packages, containers or tanks containing radioactive material and the management of an interruption site may only be carried out by natural or legal persons recognized by FANC. The recognition decree for carriers, interruption sites and organizations handling radioactive material, during multimodal transport, is valid for maximum five years and can be amended and/or renewed according to the provisions of the RD Transport.

A license can be requested for one-off transport (1 per year) of radioactive material carried out by an unrecognized carrier and for sporadic handling (maximum 4 per year) of radioactive material by unrecognized organisations involved in multimodal transport. According to FANC technical regulation

of 2020 and in line with SSR-6 (Rev.1), approvals are also requested for shipments that pose a specific risk in terms of radiation protection, transport safety or security.

FANC issues approvals in line with IAEA SSR-6 (Rev.1). The approval of package designs may take the form of a certificate of approval or certificate of validation. For package designs of foreign origin, the FANC's independent assessment of the Package Design Safety Report (PDSR) could be limited to the specific analysis (e.g. criticality) related to the reason for multilateral approval. The TR of 2017 recommends the use of the most recent edition of the "Package Design Safety Report for the Transport of Radioactive Material" as published by the European Association of Competent Authority (EACA)

for the preparation and submission of the PDSR for approval. FANC's management system includes procedures for package and shipment approvals and templates for the approval certificates of package design.

It is expected that the foreseen decommissioning and dismantling of NPP's will produce an increase of the volume of radioactive waste (VLLW, LLW, ILW). Therefore, an increase of the workload, due to higher number of shipments for treatment or disposal of radioactive waste, is expected. As a consequence, new package designs should be approved, and new manufacturing of packaging will increase the number of inspections in the fabrication process. In the near future FANC should ensure that adequate competence and resources will be available to fulfil its functions and responsibilities for transport activities due to the decommissioning of NPP's. This issue is addressed by Suggestion S2 in Section 3.3.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The provisions in GRR-2001 establish the contents of a license application, determining that these shall include relevant information to assess the adequacy of protection requirements for radiation workers, e.g. provisions for protection of unborn children, optimization measures of protection and safety for occupational exposure, organization of a health physics department that oversees radiation protection and nuclear safety within the facilities and activities, measures for health surveillance, training and information of workers, as well as individual monitoring and personal protective equipment.

The application for a license is required to be signed by a health physics expert recognized by FANC, as well as by the representative of the applicant organization.

The regulation on wellbeing at work issued by the Federal Public Service Employment, Labour and Social Concertation together with the GRR-2001 and technical regulations establish the provisions for health surveillance of exposed workers and include requirements for recognition of occupational physicians by FANC. Occupational physicians are approved by FANC if they comply with the criteria established in the regulations, that include specific training and an internship.

Licensees are required to take technical, procedural and organizational measures regarding occupational exposure. These measures are based on an analysis of radiological risks. This risk analysis covers all risks in the facility both at the level of the workplace and the individual. The employers and licensees are required to make the individual dose results available to each exposed worker and to the health surveillance service.

The IRRS team was informed that there is a decreasing trend in the number of occupational physicians that are candidate for requesting FANC's recognition. This has an impact on the sustainability of the radiation protection university training programmes for occupational physicians because of the lack of students, which in turn makes the training of new candidates more difficult. FANC, within its responsibilities, is in the process of adopting measures to address this issue. These measures will nevertheless require the support of other government areas as they exceed FANC's scope of activities. This situation could lead to difficulties in the future, in maintaining national competence in this area.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The number of trained occupational physicians recognized by FANC is decreasing over time and may present a concern regarding the availability of such specialists in the country.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 2.36(c) states that** *"The government: (…)* *(c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev.1) para. 2.34 states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 1 (Rev.1) para. 2.76 (f) states that** *"Employers, registrants and licensees shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that: (…)* *(f) Necessary workers' health surveillance and health services for workers are provided;"*
S5	**Suggestion: The Government should consider developing and implementing a strategy for ensuring that the number of specialists for health surveillance of workers covers the country's needs.**

FANC is responsible for recognizing the services that perform workers' dosimetry on behalf of the operators. The obligation of approval of the dosimetry services is laid down in GRR-2001. FANC technical regulations stipulate criteria and conditions for recognition of dosimetry services for performing external dosimetry and for performing in vivo and in vitro measurements, that include ISO/IEC 17025 accreditation and requirements for participating in intercomparisons. Initial recognition is valid for three years, with extensions every six years after that. Currently, there are 11 services recognized by FANC for providing external dosimetry of workers, and two services recognized for providing in vivo/in vitro dosimetry of workers.

There are calibration services available in the country and the possibility to access foreign services. Approval of calibration services by FANC is not foreseen in regulations. FANC relies on the accreditation requirements of dosimetry services as it covers the adequacy of the calibration services.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no regulatory provisions for the approval of calibration services and associated criteria.*	
(1)	**BASIS: GSR Part 3 para. 3.73 (c) states that** *"The regulatory body shall be responsible, as appropriate, for: (…)* *c) Authorization or approval of service providers for individual monitoring and calibration services;"*
R9	**Recommendation: FANC should establish regulatory requirements for the approval of calibration services and the relevant criteria.**

Regarding protection of aircrews from exposure to cosmic radiation, there are provisions in place in a FANC technical regulation that require airlines to carry out dose assessments if:

- They operate more than 770h annual flight time at a maximum altitude of up to 6000 m; or
- They operate more than 100h annual flight time at a maximum altitude of up to 14000 m;
- On the basis of annual flight time, maximum flight altitude and the respective airlines, it is possible to conclude, using a graph based on calculations carried out in Germany, that flight crew members receive an annual dose equal to or greater than 1 mSv.

If these conditions are exceeded, it is considered by FANC that workers doses will likely exceed 1 mSv, and therefore the dose assessment must be carried out according to FANC technical regulations. The technical regulations include criteria for approval of codes to be used in the dose estimates. The airlines are required to take the assessment into consideration when establishing work schedules, assess individual doses and transfer them to the national dose registry. They are also required to inform concerned workers on the risks involved, ensure their health surveillance and to appoint a radiation protection officer. Measures for protection of pregnant workers are foreseen.

The IRRS team was informed that the number of aircrew workers with doses reported over the past few years has seen a growing trend from 2013 to 2018. However, in 2019, almost no aircrew worker doses were reported and in 2020 the number was reduced to less than a half, possibly due to the impact of the

COVID19 pandemic in airline operations. FANC has published on its website an extensive set of guidance and information on the topic, including an innovative communication toolbox for airlines with presentation materials that raise awareness to the risks for aircrews, as well as the protection actions that can be implemented, taking into account that this sector is the highest contributor to collective doses of the Belgian workers. The need for these communication initiatives was also identified in a joint work that was carried out in consultation with the Belgian Cockpit Association, leading FANC to develop an action plan aiming at raising awareness. The IRRS team acknowledged the efforts made by FANC in the innovative ways and extensive outreach to address the issue.

Belgium has developed a National Radon Action Plan that defines the workplaces where it is required to measure and then notify the radon concentrations to FANC. The forms for notification of workplaces where radon concentrations exceed the reference level are published on FANC's website, along with guidance and information. Further information on this issue is provided in Section 5.10.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

FANC is responsible for the regulatory control of medical exposures. Given that medical facilities fall under Classes II or III facilities as per FANC categorization, all activities and facilities with radiation sources in medicine need to be authorized (licenced).

The application to be submitted for authorization covers, among other things, aspects related to medical exposure, e.g. justification, medical practitioners' qualification and medical physics organisation, accompanied with related justification documents.

FANC also authorizes clinical trials or clinical investigations involving a radioactive product. The applicant must demonstrate that the principles of justification and optimization and dose constraints have been adhered to.

FANC authorizes or registers medical practitioners individually for the use of techniques involving medical exposures, based on basic and continuous training in radiation protection for medical exposures. For nuclear medicine and radiotherapy, patient instructions, clinical standard operating procedures and the patient release card are added to the above requirements.

FANC's website provides guidance for each type of authorization application, with specific indications on regulatory references and the application procedure. Each authorization application form describes the documents to be supplied for its support.

Authorizations for establishment and operation of Class II and III facilities are issued by FANC. The recognized health physics expert of the facility addresses to FANC a signed document "Minimum requirements for conditions acceptance" certifying, among other things, acceptance testing and commissioning by the medical physics expert. It should be noted that all procedures relating to the optimization of medical exposure are reviewed and approved by the recognized medical physics expert.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The authorization of public exposure is included in the licensing process for nuclear facilities, medical facilities and activities and other activities involving ionizing radiation or radioactive substances. The basic principles of radiation protection (justification, optimization and the use of dose limits/constraints) are implemented. The annual limits for discharges and emissions are specified for a given facility so that the resulting doses to the population shall not exceed 1 mSv per year.

When applying for a licence or when making any significant modification in a facility that impacts the radioactive discharges, the operator must complete a study describing the impact of discharges on workers, the public and the environment. This study covers routine radioactive discharges and (estimated) radioactive discharges in the event of an accident. Discharge limits are then set in the license after analysis of this study. Radiation dose limits to the public are in line with IAEA safety standards.

The general radiation protection principles also apply to consumer products, but the expected effective dose received by a member of the public due to exempted practices shall be of the order of 10 µSv/year or less. For building materials, commodities and for drinking water the registrants must meet the reference levels established for public exposure.

Belgium has developed a national radon action plan that identifies the workplaces where it is required to measure and declare radon concentrations to FANC. The employer must declare radon measurement results to FANC if they exceed the reference level of 300 Bq/m³. FANC will then evaluate the risk and impose corrective measures to ensure that the workers' radiation exposure remains below the level of 600 kBqh/m³ or 6 mSv per year. If not possible, the workplace will be under the regulatory provisions of a planned exposure situation, with specific measures (e.g., dosimetry, medical surveillance, health physics….) in function of the specific situation.

FANC has developed a radon risk map that shows the classification of the Belgian territory on a 1x1 km grid in terms of probability to exceed the indoor radon concentration reference level of 300 Bq/m³.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC has prepared and published two radon risk maps (one anthropogenic radon risk map and one natural radon risk map). The anthropogenic radon risk map is developed for zones with anthropogenic pollution (part of land registry) whereas the natural radon risk map is based on radon due to underlying geology.*	
(1)	**BASIS: GSR Part 3 para. 5.19 (b) states that** *"Relevant information on exposure due to radon and the associated health risks, including the increased risks relating to smoking, is provided to members of the public and other interested parties."*
S6	**Suggestion: FANC should consider combining the two Radon Risk Maps.**

FANC organises regular information campaigns to raise awareness on radon. This includes cartoons/videos that are posted on YouTube, mainstream press articles, television campaigns etc. The information campaigns promote the Belgium radon measurement season that runs from October to April. FANC offers radon measurements at a reduced cost of €15 that helps to improve the national radon survey.

Remediation operations on contaminated sites are subject either to a declaration for sites contaminated with NORM or to authorization for other contaminated sites. Depending on the risk of exposure, the corresponding requirements regarding workers radiation protection in planned exposure situations are also applicable.

5.11. SUMMARY

Belgium has an entrenched legal and regulatory framework requiring that all nuclear facilities and activities involving ionizing radiation requires prior authorization, which are granted through royal decrees by the King or in a graded approach by FANC. Facilities are classified according to their risk in four distinct classes. The licensing process for Class I and IIA facilities includes public consultation and provision for appeal against decisions by FANC and the King.

Licence conditions requires that the licensing bases are ensured through respective operational programmes and periodic safety reviews. Major modifications to Class I facilities follow the same process as an initial licence application. Similarly, decommissioning of Class I and IIA facilities requires a decommissioning licence that follows the same process as an initial licence application.

The shortcomings and improvement actions identified will further enhance the already established regulatory framework for nuclear authorisations in Belgium.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Bel V supports FANC activities for Class I (NPPs, research reactors, nuclear fuel cycle facilities and waste management facilities) and for Class IIA (high risk facilities in another use of radioactivity) facilities. The review and assessment process includes review and assessment of the documentation of the application as well as verification thereof. FANC performs review and assessment on routine and ad-hoc reports of the licensee and complementary on the documentation from the regulatory inspection activities.

FANC has an established Review and Assessment (R&A) policy and a process for reviewing and assessing documents submitted by an applicant as well as documents for other activities, including periodic safety reviews (PSR), incident reviews and reviews of modification requests. The process consists of the following subprocesses: in-house review; coordination of internal review; and the outsourcing of review activities to Bel V or other external experts. The request for external expertise is addressed first and foremost to Bel V. A system of work requests is used whereby the specific modalities of the review and assessment (topics, timing, scope etc.) are defined by FANC and communicated to Bel V. FANC sub-process on drafting and managing work requests is not yet finalized and therefore is not yet consistently applied. The finalisation of the process and practical arrangements for the establishment of work requests for the allocation of R&A tasks by FANC to Bel V should overall improve the implementation of the R&A process including in terms of priority management, use of the resources, and performance of the evaluations. FANC has identified this issue in its Action Plan.

Within Bel V, the process "deliver expert services in nuclear safety and radiation process" is the key process for the R&A activities performed by Bel V. The safety analysis document (SAD) template supporting the R&A process, is currently under revision as result of a continuous improvement. Bel V compiles the organizational expectations in different areas such as leadership, safety culture, graded approach, inspections, reviews and assessments, and project management in Bel V's fundamentals document. The fundamentals on review and assessment are in draft version in the time of IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The FANC sub-process on drafting and managing work requests is not yet finalized and therefore is not yet consistently applied. The Bel V fundamentals related to review and assessment are under development.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system.".*
S7	**Suggestion: FANC and Bel V should consider finalising and implementing the Sub-process on drafting and managing work request, and the Bel V's fundamentals related to review and assessment, respectively.**

The Bel V R&A findings can be transmitted directly to the licensee for submissions or modifications categorised as "non-important". For important submissions such as results of PSR or licensing projects, the final findings of the Bel V R&A are discussed with FANC, before FANC makes a regulatory decision and communicates it to the licensee. The prioritization of various submissions is mainly coordinated internally by Bel V, taking into account the other tasks and duties. Consultation between FANC and Bel V on priorities is possible through the periodic coordination meetings. In accordance with legal provisions, Bel V prepares the annual inspection & assessment plan. FANC approves and monitors Bel V's annual plan, including the priorities.

The progress of the R&A process at Bel V is also monitored by the FANC project leader in accordance with the specifications of the work request. Document control is facilitated by the Bel V's electronic document system, called "KOLIBRI".

Sometimes, FANC might call upon external expertise for analysing specific topics. This might be to remedy lack of workforce or to call upon expertise for a specific technical area.

The first step to implement a graded approach in the regulatory regime is the classification of the facilities according to the risk they pose. The Class I nuclear facilities include NPPs, research reactors, storage and treatment facilities for spent fuel and radioactive waste. These facilities are considered to be of highest risk and are therefore subject to a more elaborate process for R&A of their license applications than the lower-risk facilities of Class II or III. For example, the safety evaluation of Class I license applications is more detailed (documented using safety evaluation reports by Bel V and FANC) and is also reviewed by the independent Scientific Council. A second level of application of a graded approach is the categorization of the modifications of the existing facilities according to the technical regulation on modifications. For categorizing modifications, the safety significance has to be taken into account.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The main effort of R&A activities related to Class I and Class IIA nuclear facilities is provided by Bel V's safety assessment department. Bel V has divided the required technical expertise between the entire staff according to the qualifications and competences of each staff member, transcending the hierarchical structure and therefore reaping benefit from the technical expertise wherever it may be. The technical expertise is integrated in twenty Technical Responsibility Centres (TRCs) forming the main pillar of the knowledge management strategy of Bel V. The goal is therefore to involve the people, having the right expertise in a technical domain for conducting a R&A, wherever the staff is positioned in the Bel V organizational chart.

Bel V implements a comprehensive and systematic self-assessment process on R&A. The purpose of it is to contribute to continuous improvement. This self-assessment allows evaluation of the effectiveness of R&A workflow and the associated templates. In addition to the desk-top analysis, Bel V organised three interactive workshops among the staff of the Bel V's core processes to collect and consolidate the opinions of the staff and to ensure the common understanding of possible issues. The self-assessment process integrates a systematic and integrated knowledge management approach using the so-called Knowledge Critical Grid tool in a qualitative manner to support the identification of the future needs through staffing plan in order to determine the training and expertise development needs. Based on the systematic analyses, actions are formalised that management can act upon. The actions are formalized with defined schedule focusing on the medium-term period (3-5 years) and linked to the annual plan. The results are summarized in the Health Status Report (HSR). The evaluation is performed periodically, at least once a year. The IRRS team considered this practice as a good performance.

The Scientific Council is involved during the licensing process for new installations, major modifications or decommissioning projects as foreseen by Article 6 of GRR-2001 and on the final results of the PSR for the Class I facilities.

The LTO of nuclear power reactors is an option which can be considered in the national energy policy of Belgium. Above all, it requires a decision by the political authorities, and the willingness of the operator to embark on this path. The political decision has in the recent years been uncertain due to the changing environment. Given the frequent changes of situation, FANC had to revise their strategy several times and issue strategic notes accordingly. The last version includes some relaxation of the predefined timeline to provide the nuclear power operators with flexibilities to implement actions related to LTO of NPP. With the strategic notes FANC has informed the licensees, the Federal Public Service Home Affairs and other stakeholders of the potential impact on regulatory decisions due to uncertainty or delays with submission of applications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Given the evolving situation in relation to the nuclear energy policy, FANC had to revise their strategy several times and issue strategic notes accordingly, the last time with some relaxation of the predefined timeline to provide the nuclear power operators with flexibilities to implement actions related to LTO of NPP.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(2)	**BASIS: GSG-12 para. 5.49 states that** *"Reviews should identify weaknesses and obstacles that could affect the effectiveness of the integrated management system and should be used to identify whether there is a need to make changes and improvements to policies, goals, strategies, plans and objectives, as well as to the processes or activities. The schedule of reviews should facilitate the timely provision of information for the strategic planning of the regulatory body. Any weaknesses should be evaluated by senior management and should be remedied in a timely manner".*
S8	**Suggestion: FANC and Bel V should consider continuously maintaining the risk analysis associated with the regulatory oversight of LTO of NPPs.**

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The R&A requirements are derived from GRR-2001 and SRNI-2011 and FANC technical regulations. The R&A requirements include for license applications the conformity with the required contents (for example Article 6 of GRR-2001 for Class I nuclear facilities), the conformity with the requirements of SRNI-2011 for nuclear facilities and the application of the appropriate technical regulations (for example FANC technical regulation on safety demonstration, FANC technical regulation on PSR, and FANC technical regulation on modifications). SRNI-2011 has been developed based on the WENRA-harmonization process with respect to regulation and associated WENRA reference levels. It ensures the transposition of the European Directive 2009/71/Euratom on nuclear safety (as amended by the Directive 2014/87/EURATOM) for what concerns the licensee's obligations. SRNI-2011 requires the development and use of a full-scope PSA for all relevant operating modes in NPPs. Updates of Level 1 and Level 2 internal events PSA models have been completed for Doel 3 and Tihange 2 and are in progress for all other units and should be completed by 2025. These updates take into account a selection of modelling improvements coming from the PSR, as well as plant data and configuration for the plant status at the end of 2017. Mobile and portable equipment that have been installed following the stress tests, are also taken into account in the PSA modelling. The results of Level 1 and Level 2 internal events PSA are used to assess whether the plant risk is properly balanced and, where appropriate, to identify further improvements to safety of plant design and operation.

Level 1 fire and flooding PSA models have been established for all units in order to fulfil the requirements of the WENRA reference levels (2008), which have been translated into Belgian law under SRNI-2011. A fire safety improvement action plan is being implemented, which combines the actions identified through the Fire Hazard Analysis (FHA) and the fire PSA and will be implemented by 2025. No actions resulted from the flooding PSA. Level 2 fire and flooding PSA models have been elaborated for one representative unit. Some recommendations have resulted from the Level 2 fire PSA. Spent fuel pool PSA were available mid-2022. In case of LTO, external events PSA Level 1&2 (Seismic PSA and for Tihange external flooding PSA) are requested at the fortieth birthday of the units (around mid-2025 for Tihange 3 and Doel 4).

In relation to fire assessment, Belgium as an EU member states participated in the second EU topical peer review process on fire safety. For the self-assessment phase, FANC initiated a work request to Bel V to perform the assessment in the light of ENSREG terms of reference and WENRA technical specification. The assessment was based on the technical expertise of Bel V. The licensee's self-

assessment report is to be reviewed by the Bel V and FANC experts. On the other hand, the authority responsible for general fire protection has not yet been involved. The involvement of relevant authorities is addressed in Section 5.2.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Class I nuclear facilities are licensed according to Article 6 of GRR-2001, comprising two phases. The license application is examined by FANC. Bel V reviews and assesses the preliminary Safety Analysis Report (SAR) on behalf of FANC. The scope of the review during the initial licensing of a nuclear facility is based on the prescribed content of the SAR (site characteristics, applied safety principles, codes and standards, safety systems, radiological impact in operational and incidental/accidental conditions, list of internal and external events, operational limits, quality control, estimations of radioactive waste generated including during the dismantling phase, etc.) as required by GRR-2001.

The pre-licensing process is initiated by a future applicant on a voluntary basis when they want to inform FANC about the possible design of a future facility in advance and prior to a possible license application. The pre-licensing process has been introduced for Class I nuclear facilities and the related procedure was developed. For the regulatory body, the main advantages are to get an early knowledge of the proposed design, to express specific concerns, expectations or requirements and to establish them, if needed, and future needs in terms of expertise resources. In pre-licensing process the regulatory body can perform an iterative R&A process with the applicant. At the end, the regulatory body gives an opinion of the possibility to license the project whilst also issuing, where appropriate, a list of issues that still have to be resolved before the license application. Pre-licensing projects were applied for several projects (MYRRHA research reactor, new spent fuel storage buildings, etc.) and shown the usefulness of it for preparing for a license application. The IRRS team considered this pre-licensing as a good performance.

On a continuous basis, all safety related modifications must be reported to FANC in compliance with Article 12 of GRR-2001. A categorization process for modifications of Class I, IIA, II and III facilities is described in the FANC technical regulation on modifications. Major modifications require a procedure similar to the initial licensing. For less important modifications, it is required by Article 23 of GRR-2001 that an analysis, approval and verification of the modification is performed by the HPD and verified/approved by Bel V where applicable. Art. 15 of SRNI-2011 defines the elements to be treated by the licensee of Class I facilities for modifications.

PSRs are required for all Class I facilities with a periodicity of 10 years. Article 14 of SRNI-2011 prescribes the process to be followed. A FANC technical regulation on PSR for non-NPPs which was informed by SSG-25 details the approach to be followed. FANC and Bel V have specific roles during the different phases of PSR to ensure that all deliverables are adequately reviewed and assessed. Major findings discovered during inspections (for instance design deficiencies in a safety system) are subject to specific review and assessment. Integration of the feedback of experience is a longstanding practice.

For Class I facilities, the Operational Experience Feedback (OEF) is integrated in Process A04.08 of the Bel V management system. It covers OEF for internal (Belgian) and external (foreign) events. The Bel V process is complemented with the FANC procedure.

For Class I facilities, FANC and Bel V perform a yearly comprehensive safety assessment on the licensee safety performance based on the data obtained from licensee regular reports and results from oversight activities. However, the identification of trends is based mainly one year-long dataset and extrapolated to multi-year based on the engineering judgment. The systematic using of multi-year data is not required by the procedure related to operating experience feedback.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The identification of trends related to the annual comprehensive safety assessment is mainly based on one-year progress. The systematic use of multi-year data is not required by review and assessment procedure.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.46 states that** *"For an integrated safety assessment, the regulatory body shall first organize in a systematic manner the results obtained. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant.".*
S9	**Suggestion: FANC and Bel V should consider extending the annual integrated safety assessment process with systematic multi-year trend analysis.**

Dismantling of Class I and IIA facilities is subject to a license application according to Article 17 of GRR-2001. A similar review and assessment process is applied in this case.

For activities (e.g., transport activities, approval of transport containers), the licenses have a limited validity in time, which means that if the transport activity is to be prolonged, the review and assessment is performed again during the license renewal process.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

Nuclear Power Plants are Class I facilities for which the generic review and assessment processes for safety documents are described in GRR-2001. Article 6.2 prescribes the information to be provided as part of a license application for a nuclear facility, including the contents of the preliminary safety analysis report.

The preliminary safety analysis has to be finalized before the commissioning of the installation. During the operational phase, the licensee has the obligation to declare intended modifications to FANC which then decides on the procedure to be followed.

For important modifications the procedure is described in GRR-2001 and is similar to the procedure for the construction and operating license. A FANC technical regulation defines in more detail the treatment of modifications.

Bel V is responsible for the review and assessment of non-important modifications (NIM). Bel V developed a methodology on how a documented and traceable graded approach could be applied. Resident inspectors as well as safety analysts took part in this development. The NIM modifications are divided into three categories based on scoring, which considers safety importance and complexity of the modification as factors. Category 1 modifications are subject to a detailed technical analysis; category 2 modifications are analysed from specific aspects, while category 3 modifications are not analysed or only in limited scope.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The review and assessment for licensing/authorization of research reactors is performed taking into account the information included in the safety analysis report and the EIA report.

The FANC management system has a generic procedure for review and assessment, and there are work requests for specific projects. The main requirements for the application are the submission of the Preliminary Safety Analysis Report and the EIA Report.

The FANC requirements for the safety analysis report indicate that it shall include detailed descriptions of site, facility and experimental devices, activities with safety significance, safety principles, general criteria, protection to operating personnel and public, and environment, potential hazards, accident sequences, safety features, operational limits and conditions, operating organization, conduct of operations and management system, emergency arrangements, etc.

During the review and assessment process, FANC sends the license application and review and assessment report to the Scientific Council for their advice before a license is granted.

For new projects that are ongoing, FANC implemented a voluntary pre-licensing process. In the pre-licensing process, the analysis can be based on a preliminary safety analysis report.

Bel V is involved in the licensing and pre-licensing process.

A construction and operation licence for SCK research reactors was granted. The license makes reference to royal decrees, conditions and the safety analysis reports. The BR-1 and BR-2 reactors do not have a time-limited license and the licensee carries out a PSR each 10 years for each reactor. BR-3 reactor is at a decommissioning stage. A license for the modification of the VENUS installation was granted in 2010.

FANC mandates Bel V by specifying the task, staff needed, etc. using a system of work request as described in Section 6.1. FANC indicated that in general there is a good interaction between FANC and Bel V. FANC considers that the current process works well.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Waste management facilities in Belgium are Class I regulated facilities and therefore FANC regularly reviews and assesses the safety of the waste facilities in accordance with GRR-2001 and SRNI-2011. As mentioned in Section 5.4, FANC has developed new safety requirements specific for disposal facilities, including requirements for closure and post-closure phases. These new requirements are expected to be published by royal decree by the end of 2023.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The regulatory framework defines in detail the required information to be submitted to FANC for a construction and operation license for facilities where radiation sources are to be authorized for use. Moreover, FANC has developed and implemented a licensing procedure as part of its management system.

R&A for Class II and III facilities is performed by FANC personnel. Six employees from the industrial facilities and ten employees from the medical facilities sections are involved. For Class IIA facilities, Bel V is also requested to review and assess technical aspects of the submitted information. If needed, FANC inspectors can visit a facility as part of the review and assessment process.

As the licenses for Class II and Class III facilities are valid for 15 years, a license renewal request is required, and this will trigger a new review and assessment.

The information necessary for the licensing of facilities with radiation sources is required to be submitted in support of the application. The documents submitted for approval evaluating the safety of the facility are approved by the facility's RPE and investigated by FANC during the inspections.

The review and assessment are carried out using special electronic checklists in CIS where all the information submitted by the licensees is captured. The IRRS team observed CIS to be an effective tool for planning regulatory functions and performing the necessary follow up. It includes all data related to the licensing, review and assessment and inspections of the facilities and allows efficient analyses. All FANC's personnel has access to CIS.

To further facilitate the procedure, FANC applies a categorization of the facilities beyond that used for authorization purposes (i.e. Class I, II, III and IV). This additional categorization is based on the types of the facilities and was first introduced to define the frequency of inspections for each facility based on the associated risk. However, as the IRRS team noticed, no specific criteria have been established in a guidance document for the review and assessment for Class II and III industrial and research facilities with radiation sources in accordance with a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC has not established criteria to ensure that the review and assessment for Class II and III industrial and research facilities with radiation sources is conducted in accordance with graded approach.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
S10	**Suggestion: FANC should consider establishing criteria in order to conduct the review and assessment for Class II and III industrial and research facilities with radiation sources in accordance with a graded approach.**

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

FANC and Bel V developed a structured approach covering the operational domains of decommissioning (PVAO), which provides a comprehensive plan, including guidance and expectations regarding licensing during decommissioning. The PVAO documents were updated in 2018 to incorporate lessons learned from facilities decommissioned since 2012 (e.g., FBFC International and Belgonucleaire), see good performance in section 5.1. FANC uses its regulatory powers to create hold points and add additional license conditions as the NPPs progress through the decommissioning phases.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of transport activities in Belgium are performed considering the requirements established in IAEA SSR-6 (Rev.1) and implemented by the modal agreement and regulations (ADR, RID, ADN, ICAO TI and IMDG). The RD Transport and FANC technical regulations (TR) establish the modalities to apply for the recognition as a carrier, recognition as an organization involved in multimodal transport, recognition of an interruption site and for the licence of one-off transport (1 per year), of sporadic handling (4 per year) and for shipment approvals as well as the documentation that shall be included in the application. The application form and the documentation are reviewed and assessed according to the principles of the FANC Review and Assessment policy (REV). In case of shipment approval regarding the Class 7 high consequences dangerous goods, as defined in the modal agreement and regulations, the security aspects of the shipment are also assessed.

As part of the review and assessment process an audit of the applicant is performed to verify the correct application of the content of the documentation provided. The focus of the review and assessment of the application is on the radiation protection programme, the management system, the emergency procedures, and the training program. The compliance audit of recognized carriers or organizations involved in multimodal transport is repeated, based on the graded approach, between every three years for carrier transporting fissile material, including UF6, and every seven years for carrier transporting excepted packages.

According to RD Transport and FANC TR an application for approval of package design shall be submitted to FANC. In case of package design of Belgian origin or of foreign origin that will be loaded and stored more than one year on the Belgian territory the PDSR shall be provided with additional information requested by FANC during the previous approval. For package designs of foreign origin, in addition to the PDSR, the certificate of approval of package design from the country of origin shall also be provided. In these cases, the part of the PDSR dealing with the reasons for multilateral approval (criticality aspects, maximum normal operating pressure above 7 bar, ambient temperature range different from -40°C to 38°C, etc.) are also independently assessed by FANC.

The periodic assessment of doses to the workers and persons, due to the transport of radioactive material is part of the compliance assurance activities of the competent authority and may be used to evaluate the effectiveness of the transport regulations. This may also help in achieving and maintaining public confidence.

The Belgian regulatory framework for the transport of radioactive material that is based on the recognition of the carriers, of the interruption sites and of the organizations involved in the handling of packages in multimodal transport, ensures an adequate level of oversight of the radiological impact of the transport of radioactive material to the workers by the evaluation of the radiation protection programme of those recognized parties. Nevertheless, no periodic assessment is arranged by FANC for the doses to the members of the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Periodic assessment of radiation doses to the members of the public due to the transport of radioactive material, is not arranged by FANC.*	
(1)	**BASIS: SSR-6 (Rev.1) para. 308 states that** *"The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with GSR Part 3."*
(2)	**BASIS: TS-G-1.5 para. 4.51 states that** *"The competent authority is required to arrange for periodic assessments to evaluate the radiation doses to workers and to members of the public due to the transport of radioactive material (para. 308 of the Transport Regulations). Data from consignors and carriers that need to assess the doses arising from their transport operations may be used in such assessments of radiation doses by the competent authority. However, the competent authority should independently verify the data received from consignors and carriers. Questionnaires, analyses, site visits and measurements may be used to assess doses."*
R10	**Recommendation: FANC should arrange periodic assessment of the radiation doses to the members of the public, due to the transport of radioactive material, and verify that the doses remain below the dose limits.**

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

For Class I facilities, review and assessment for occupational exposure is embedded in the operation licence review and followed up in the periodic safety reviews.

For Class II and III facilities, FANC conducts review and assessment of license applications and supporting documents. The list of supporting documents needed for a licence application is included in a guidance issued by FANC and made available on its website.

The review of the application is carried out by FANC taking into account, as applicable, such aspects as:

- Number of exposed workers, adequacy of monitoring methods and health surveillance;
- Work procedures (approved by the recognized health physics expert) that take into account operation in normal and unforeseen circumstances, periodic verification of protective and security equipment;
- Assignment of controlled and supervised areas;
- Means for preventing exposure of workers and for preventing spread of contamination;
- Use and availability of personal protective equipment.

The application is required to be signed by a recognized health physics expert either internal or depending on a recognized health physics organisation, declaring that the documents have been assessed and are found to be in accordance with the corresponding safety requirements.

FANC has established internal procedures detailing the expectations regarding the contents of the safety assessment, that guide its review and assessment. These procedures take into consideration the assessment already carried out by the recognized health physics expert, who through this practical

delegation, carries out part of the review and assessment. While this process facilitates the review process, it can result in some safety gaps only being identified at a later stage through inspection actions, after the practice has been authorized and initiated. Thus, the IRRS team encouraged FANC to adopt further provisions to ensure the information provided in the applicant's submissions is accurate and is sufficient to allow the confirmation of compliance with regulatory requirements at the time of authorization.

Further review is carried out when the licenses are renewed or amended. While the validity of the licenses (15 years, for all practices) could lead to a long time between carrying out the review, in practice, this process is also triggered when carrying out amendments, which are occurring at more frequent intervals.

Another source of information for the review carried out by FANC is the information contained in the national dose register. The national dose register kept by FANC was formally established in 2017 and allows for different levels of online access:

- FANC has access to information for all occupationally exposed workers in the country;
- Workers have direct access to their own dose records;
- Licensees, employers, recognized health physics experts, radiation protection officers, occupational physicians, dosimetry services, etc. have access to doses of workers that are directly associated to them.

Furthermore, the system includes a function to automatically collect and record doses via the software associated with active dosimeters used by emergency workers and is developing tools for processing radiation passport requests for external workers. The number of exposed workers being monitored ranges up to 48000. FANC carries out regular reviews of recorded doses, allowing for identification of trends, verification of compliance with the dose limits, preparation of inspections or inspection campaigns, i.e. the review of worker doses for a given sector of activity is used for the purpose of deciding to implement thematic inspection campaigns. The IRRS team acknowledged the comprehensiveness of the efforts undertaken by FANC with a view to establishing the national dose register, with a wide-ranging access scheme, and coupled with direct outreach activities that raise awareness in all parties involved.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

Using a check list, technical and other documents submitted by the applicant are reviewed and assessed by FANC to determine whether the facility or activity or individual complies with the relevant safety requirements. This applies to the medical exposure as well.

FANC carries out review and assessment of medical exposure also on the basis of information received through various channels, e.g., information provided by the National Institute for Health and Disability Insurance (NIHDI), information related to continuous training submitted by practitioners for authorization or registration renewal, analysis of reported incidents, periodic reports from medical physics experts, national surveys of patient doses and the inventory of equipment.

Based on periodic national surveys of patient doses conducted by FANC to review the DRLs, personalized reports are sent to licensees where their results are compared with the most recent DRL's and benchmarked with equipment of the same modality. Licensees may use these reports as a base for investigation of the optimization of the dose delivered or activity administered to their patients is needed.

The evolution of DRLs over the last few years has shown a considerable reduction in the doses delivered and activities administered to patients.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Authorized practices are subject to specific discharge limits to guarantee acceptable levels of public exposure. For Class I facilities public exposure is assessed as part of the initial licensing process as well as routinely during operations and PSR.

Regular reporting (or reporting requested by FANC) on radioactive releases and doses of workers and the public are verified by FANC to ensure that operational limits and conditions are maintained to limit public exposure. For professional activities and existing exposure situations, regular reporting is required and the possible corrective measures imposed by FANC.

An independent control by FANC of discharges is, to the extent possible, in place by e.g., monitoring directly in the release channels of the facilities, monitoring the air, water, soil nearby facilities etc. Analysis of the data obtained by the national surveillance and environmental monitoring programme (offline and online) allows further review and assessment of activities to ensure that public dose constraints are respected.

6.11. SUMMARY

The legal basis and management processes for FANC and Bel V regulatory review and assessment of nuclear facilities and activities have been well established. FANC and Bel V are fully committed to performing comprehensive and systematic review and assessment which meets the expectations of the IAEA safety standards for regulatory review and assessment, and supports licensing and compliance verification as a part of the regulatory oversight programme.

The IRRS team identified some opportunities for improvement in areas such as: development of some internal documents at FANC, the procedure on drafting and managing work requests, and at Bel V the Bel V's fundamentals related to review and assessment, supplementation of the integrated safety assessment process with systematic multi-year trend analysis, further developing criteria for Class II and III industrial and research facilities R&A process.

Given the frequent changes in the position according to LTO of certain NPP, FANC had to revise their strategy several times and issue strategic notes, accordingly, including some relaxation of the predefined timeline to provide the nuclear power operators with flexibilities to implement related actions. In the strategic notes FANC informed the licensees, the relevant ministry and stakeholders of the potential impact on regulatory decisions due to uncertainty or delays with submission of applications. The IRRS team suggested to FANC and Bel V continuously maintain up to date regulatory risk analysis associated with LTO of NPPs.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1 INSPECTION PLANS AND APPROACHES

FANC and Bel V have clear and distinct roles in inspection. FANC has enforcement powers whereas Bel V does not. This distinction is reflected in the fact that interventions by FANC are termed "inspections" (and may result in enforcement) and interventions by Bel V are termed "controls" (and cannot result in enforcement). In addition, a process exists by which FANC may be informed of unsafe or non-compliant conditions by Bel V so that it can take appropriate action. Processes exist to facilitate the sharing of inspection results and other information between FANC and Bel V.

FANC and Bel V have developed and implemented an integrated process to develop the inspection programmes and plans. First a mid-term inspection programme is developed for all nuclear facilities.

For Class I facilities, the integrated inspection and control programme (GIC) covers a period of six years. The GIC systematically divides the requirements of the relevant legislation into thematic areas to ensure comprehensive coverage and specifies the frequency with which those thematic areas are to be inspected over this six-year period. The effectiveness of the GIC was reviewed after three years, with changes fed back into the program. It is being reviewed again in 2023 as it comes to the end of its first six-year cycle.

A six-year programme is also developed for Class IIA facilities, consisting of an annual inspection by FANC on one of six themes, and a series of Bel V controls with frequencies established in accordance with a graded approach.

For other facilities, the mid-term programme may cover a different number of years depending on the section, and inspection areas. The frequencies of the inspections are assigned in accordance with a graded approach.

From the mid-term programme, an annual plan is developed. This plan is then implemented by a qualified team of regulatory staff. Inspection plans incorporate both announced and unannounced inspections. A time allowance is made in the planning process for the conduct of reactive inspections.

FANC and Bel V coordinate in the production of their programmes and plans to avoid duplication of effort. For example, if FANC and Bel V have both proposed a similar inspection in the same year, the FANC inspection will often replace the Bel V one, although Bel V may then provide support to FANC during its inspection. All Bel V plans are ultimately approved by FANC.

In addition to FANC and Bel V, there are other government departments responsible for fire protection, pressure equipment, and conventional health and safety. Memoranda of understanding exist with these government departments with detailed roles and responsibilities captured in separate documents. Cross-purpose work can include occasional joint inspections. The IRRS team encouraged FANC and Bel V to consider further opportunities to conduct more cross purpose work.

7.1.2 INSPECTORS

Bel V and FANC adopt a tiered approach to the training and qualification of inspectors. FANC inspectors must be recognised by FANC and, depending on the field of expertise, by the Scientific Council or a dedicated Advisory Board as experts in their technical field, before being accredited by FANC as a nuclear inspector based on their knowledge, inspection experience and understanding of FANC's regulatory processes including on inspections and enforcement. FANC inspectors are appointed by royal decree. This process takes approximately two years, during which time inspectors can provide support to appointed nuclear inspectors but cannot exercise their regulatory powers.

On conclusion of the training programme the royal decree is published in the Belgian State Gazette and on the FANC Jurion website. The FANC inspector is then provided with a "legitimation card for nuclear inspectors".

Accreditation as a nuclear inspector is transferrable between sections of FANC, but recognition as an expert in their technical field is not; therefore, a nuclear inspector moving between sections of FANC will have to work towards recognition as an expert according to the requirements of their new section.

Although the initial training and qualification of nuclear inspectors is robust, the requirements for ongoing training and assessment of competence to remain a nuclear inspector are not fully formalised and therefore inconsistencies exist across the sections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Ongoing training and assessment of inspector competence is inconsistent across the sections of FANC.*	
(1)	**BASIS: GSR Part 1 (Rev.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 a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
S11	**Suggestion: FANC should consider developing and applying a consistent process to maintain necessary competence and skills of nuclear inspectors.**

Bel V inspectors are trained and recognised in a comparable manner, with all inspectors requiring accreditation as health physics experts (an accreditation with specific requirements for ongoing training and review) which is then supplemented by training in inspection processes and practices.

7.1.3 INSPECTION PROCESSES AND PRACTICES

In line with FANC's inspections policy, a handbook is prepared for the conduct of inspections. Each handbook addresses a focused thematic area. In case of reactive inspections specific objectives are defined prior to the inspection.

During observation of inspections the IRRS team noticed that inspectors use the full range of expected inspection methods, including monitoring and direct observation; discussions and interviews of both authorized party staff and contractors; examination of procedures, records and documentation; and confirmatory tests and measurements.

Inspection results are provided by the inspector during closing meetings at the end of the inspection, and are captured in an inspection report that is sent to the licensee and shared between FANC and Bel V.

Findings from FANC inspections are captured in the CIS database, which automates the tracking and closure of actions. Action closure is reviewed periodically by section heads. Each FANC inspector is expected to populate the CIS database following their inspection. There is an instruction for the use of the database, which was last revised in 2021.

The information contained in the CIS database is reviewed and used as an input for the mid-term programme and for more immediate inspection activities carried out within the short-term plan. FANC staff interviewed by the IRRS team indicated that the CIS database is convenient and makes it easy to manage inspection findings.

Ad hoc trending of inspection results is used by FANC at a section level to inform regulatory strategy. In addition, there is an annual FANC "Day of the Nuclear Inspector", as part of which different sections share their experience from the past year. Finally, ad-hoc workshops are organised on specific inspection topics (five such workshops were held or have been planned in 2023, for example).

The IRRS team considered that FANC makes good use of inspection feedback to inform its regulatory strategy.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

Inspections of NPP are conducted following the same general process described for Class I facilities in section 7.1.1. The annual plan also includes inspections that may be added based on operating experience. Each inspection is supported by a detail scope document that is shared with the licensee, supplemented by further guidance for the inspectors.

FANC and Bel V present their views on the effective management of the site, based on their respective activities over the previous year. The licensee then develops an action plan based on the outcomes of this review, the implementation of which is monitored by the regulatory body.

The IRRS team considered this annual management review carried out by FANC and Bel V to be a good performance.

As well as the annual management review, there are three standard inspections considering human and organisational factors which must be undertaken in the six-year GIC period, on:

- The human performance programme;
- Leadership and management for safety; and
- Assessment of safety culture.

At NPPs, Bel V inspections are predominantly unannounced, with resident inspectors being present on the site most weeks. Bel V maintains a resident inspector for each reactor at Doel and Tihange, and one resident inspector each for the wider Doel or Tihange site (including dedicated waste facilities at each site), whose responsibility is for cross-site services and interactions with the authorised party's representatives. Reactive inspections are uncommon; since Bel V resident inspectors are on site so frequently, reactive elements can easily be incorporated into their planned inspections.

Bel V aims to rotate resident inspectors between facilities, but in practice language issues make this difficult. To avoid regulatory capture, field observations are undertaken by peers and by Bel V management. In addition, benchmarking inspections are undertaken with the French and Dutch regulators. Finally, resident inspectors are often supported by non-resident inspectors or safety analysts who provide a different perspective on the site.

FANC does not have resident inspectors but does have Single Points of Contact (SPOC) for Doel and Tihange. The SPOC is responsible for the whole site. Like Bel V resident inspectors, there is no maximum period of residence for a SPOC, but the fact that observations in Class I facilities are usually undertaken by teams of inspectors mitigates the potential for regulatory capture.

FANC inspections are predominantly announced; of the approximately ten inspections undertaken by FANC on a given site annually, only one of them is likely to be unannounced (depending on the need for reactive inspections, which are more likely to be unannounced). FANC inspectors have, by law, unrestricted access to site at any time.

FANC has implemented Fast Limited Inspections with Thematic Scope (FLITS). These are team-based inspections that are largely unannounced (notice could be given to the licensee a full working day in advance to allow them to make administrative arrangements for access to the site and controlled areas). They are very precisely scripted and allow FANC to get a clear view across the site of working practices in the thematic area. FLITS are used sparingly (approximately once every two years) because the planning of them is resource-intensive but are considered as a powerful tool. The IRRS team considered FLITS as a good performance.

The technical competency requirements for inspectors from both Bel V and FANC are well-defined for NPP and include specific requirements for ongoing training and periodic re-recognition as an expert.

Site visit

Reviewers of the IRRS team visited the Tihange NPP to observe a Bel V inspection. The evening before the inspection, the NPP had alerted Bel V to a leak of diesel generator fuel and so the reviewers of the

IRRS team were able to observe Bel V incorporating a reactive element into its planned inspection. The scope of the inspection was taken from the annual plan but modified to incorporate feedback experience from the reactor fleet. Bel V inspectors were observed to use the full range of inspection methods, and effectively dealt with findings that were identified during the inspection.

The reviewers of the IRRS team also held a discussion with senior station management, who were complimentary of the relationship between the site and the regulatory body at both working and management levels. They considered that the regulatory body's expectations were clear and reasonable, and that when issues arose, they could approach the regulatory body with their concerns.

7.3. INSPECTION OF RESEARCH REACTORS

Inspections of research reactors are conducted following the same general process described for Class I facilities in section 7.1 and 7.2. Reactive inspections are not considered in the long-term plan but they are included in the CIS database These are performed according to the input information (operational experience, external and internal events, etc.).

FANC informed the IRRS team that, with Bel Vs support, it has sufficient number of inspectors and experts to support its research reactor inspection program.

FANC inspectors informed the IRRS team that they consider their training process enhances their inspections process. FANC inspectors observed inspections in other countries (France, Germany, etc.). FANC emphasized the importance of sharing experience with other inspectors at international level to improve the efficiency of their inspections.

Qualification of inspectors

For research reactors, expert recognition is done in the same way as described in Section 7.1.2. .

Site visit

The IRRS team observed an inspection on BR-2 and BR-1. The inspection was focused on health physics topics. One FANC inspector and one Bel-V inspector participated in this inspection. An inspector in training participated in the inspection.

The FANC inspector communicated to licensee the objective of the inspection, the planned tasks and the topics to be addressed. The inspection was successfully completed according to planned objectives.

The FANC inspector performed the following activities:

- Reviewed licensee's daily reports;
- Interviewed facility's staff;
- Performed facility walkdown;
- Checked radiation levels.

FANC had access to all requested information and all areas of the installations.

During the research reactor inspection, FANC detected some non-conformances related to personal protection equipment and addressed this during the site inspection. These findings however reflect a weak safety culture of the licensee staff that could be emphasized further by the inspector during inspections.

FANC will write a report for the inspection and follow the procedure to include the report and findings in the database.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC does not adequately focus on safety culture of licensee staff of research reactors.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *— …* *— Safety culture; …"*
(2)	**BASIS: GSG-13 para. 3.220 states that** *"Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:* *(a)…* *(b) The authorized party has in place…, a strong safety culture…for ensuring the safety of the facility or activity and the protection of people…;"*
S12	**Suggestion: FANC should consider further focusing on safety culture of licensee staff during research reactor inspection of operational activities.**

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

FANC and Bel V inspect radioactive waste management facilities. Bel V conducts thematic and systematic (performance based) inspections. For each licensee there is both an assigned FANC and Bel V inspector. There will be inspections during construction of the surface disposal site at Dessel once construction begins.

IRRS team members accompanied an inspection of Belgoprocess performed by Bel V. The inspection agenda included an update on incidents reported since the last Bel V inspection and follow-up on corrective actions related to reported events, and a systematic inspection of fire protection in one of the buildings. The IRRS team observed that the Bel V inspector demonstrated in-depth knowledge of the facility and current issues. The IRRS team members met with the facility management who discussed their views on regulatory oversight and inspection.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

FANC performs announced and unannounced planned, and reactive inspections to facilities with radiation sources. Most inspections are announced and planned, except for example those concerning onsite industrial radiography practices, which are unannounced.

The inspections are conducted by one qualified nuclear inspector, unless other FANC sections are also involved. In the latter case, joint inspections are performed. For Class IIA facilities, FANC's inspectors may be assisted by a Bel V inspector/expert.

FANC's industrial facilities section employs four nuclear inspectors and one inspector under training while medical facilities section has two nuclear inspectors, one inspector in training and three that will start their training in September 2023. Each inspector is assigned to inspect certain types of facilities based on his/her specialization and the place of residence. The IRRS team was informed that there is an increased turnover rate of FANC's inspectors. In this respect the number of inspectors is considered limited in order to effectively support the inspection campaigns organized by FANC's sections.

Class IIA facilities are inspected five times per year (four by Bel V and one by FANC). Other Class II industrial facilities are subject to inspection at frequencies ranging from one to eight years based on the associated risk. Although Class III facilities are randomly inspected, inspections to facilities operating unshielded X-ray devices with a peak voltage between 100 kV and 200 kV are conducted every eight years. Orphan source sensitive facilities with portal monitors are inspected every six years.

The medical facilities section carries out punctual and periodic inspections. The frequency of periodic inspections is based on a graded approach and ranges from three to ten years.

FANC implements a training programme to ensure new inspectors of facilities and activities with radiation sources have the necessary competence and skills to perform their duties. However, the programme, which is under review, does not include continuous training activities for the inspectors to maintain and enhance their competence and skills. A review of continuous training has been raised as a recommendation in Section 7.1.

Site visit

The IRRS team observed the inspection performed by FANC to the Brussels Imaging Pharmacy (BIP) cyclotron facility of the Vrije Universiteit Brussel (VUB). The observed inspection was planned and announced. The inspection was carried out to verify compliance against regulatory requirements to include license conditions.

The BIP facility operates one 18 MeV IBA Kiube cyclotron and produces a long list of radionuclides for medical and research purposes. Another 40 MeV CGR 560 cyclotron is currently being dismantled.

Three FANC inspectors from the industrial facilities section conducted the inspection. In addition, one Bel V inspector participated in support of FANC inspectors. The head of the health physics department, the BIP Director, the BIP Radiation Protection Officer and Quality Manager and other BIP staff members were also present.

During the initial meeting the BIP representatives were informed of the scope of the visit. The inspection was carried out according to FANC's inspection methodology. A handbook was used for the conduct of the inspection which covered specific thematic areas. The inspectors carried out their functions, professionally, to include interviews, investigations, walkdowns, etc.

At the end of the inspection FANC inspectors orally presented the findings to the BIP representatives. The IRRS team was informed that a report would be sent to the licensees after the completion of each inspection. The report would indicate the findings, suggested corrective actions, and related deadlines.

After the inspection, the IRRS team interviewed the BIP representatives who underlined the useful interaction and cooperation with the inspectors and the availability and prompt response of FANC personnel. Moreover, they noted the continuous improvement in their communication with FANC personnel during the last years. The IRRS team was informed that the templates for the application forms, the clarity of FANC's expectation and the availability of all this information on FANC's website facilitate the licensing procedure. However, they stressed out the large number of annual inspections (5) which are performed by FANC and Bel V inspectors to be a use of regulatory resources due to the risk nature of the operations.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

FANC has an existing inspection protocol for NPPs that are in shutdown status (post-operational phase). However, FANC currently does not have a decommissioning inspection protocol (currently no NPPs in decommissioning) although they expect to complete it next year in time for the 2024-2029 integrated inspection and control programme. The IRRS team was informed that certain themes would be removed while others would receive more focus, such as radiation protection and waste treatment.

7.7. INSPECTION OF TRANSPORT

Inspections of transport activities are performed according to the inspection policy of FANC. The planned inspections are carried out based on an annual inspection plan of the recognized parties involved in the transport of radioactive material according to a graded approach. Each recognized party (carriers, interruption sites and organizations involved in the handling of packages in case of multimodal transport) is inspected at a frequency determined by different criteria such as the number of shipments performed, the kind of packages and the radioactive or/and fissile material transported. Inspections are

carried out for all transport modes on the premises of the consignor, the consignee or the carrier or at the site in which the handling is performed.

A system inspection or compliance audit, covering the management system, the radiation protection programme, the working instructions, the training programmes, and the emergency procedures, is held before granting an initial recognition of the carriers, the interruption sites and the organizations involved in the handling during the multimodal transport of radioactive material. The inspection is repeated according to a graded approach for example each three years for carriers transporting fissile material, including UF6, and each seven years for carriers transporting excepted packages.

In case of road transport, the inspections are conducted based on the requirements and provisions of the Agreement on transport of dangerous goods by road (ADR), using the check list foreseen in the "European Directive 2022/1999 on uniform procedures for checks on the transport of dangerous goods by road". In this case the items inspected are the shipping documents, driver's certificates, vehicle equipment, marking and labelling of packages, proper stowage of packages, dose rate around the vehicle and in the cabin, emergency procedures. For the other transport modes similar check lists are adopted.

Joint inspections with the competent authorities of neighbouring countries are also performed, e.g. with the French and Dutch authorities for the transport of a large NPP component through Belgium by in-land waterway.

Transport inspections are being incorporated in a triennial and yearly inspection programme of FANC. Inspections are performed in case of manufacturing of approved and non-approved packages and during their maintenance and for all the other approvals requested by the IAEA SSR-6 (Rev.1) as transposed in the international modal agreement and regulations. Under these inspections FANC inspects the management system of the manufacturer and some manufacturing operations to ensure that all the requirements have been correctly implemented. Following the inspection, the inspection report is submitted to the inspected party. The FANC import and transport section has seven nuclear inspectors, conducting inspections on the transport activities.

Site visit

The IRRS team visited the TRANSRAD company in Fleurus to observe an ADR inspection of a vehicle loaded with six Type A and one Type B packages containing radioactive material. The TRANSRAD company is a recognized carrier for the transport of radioactive and fissile material. The company offers also logistic and engineering services linked to the transport of radioactive and fissile material. The inspection started with an entrance meeting followed by the planned activity. Other than the control of the documentation and driver license, measurements were performed by the inspector on the external surface and at two meters from the external surface of the vehicle and inside the cabin. The inspector performing the inspection acted professionally. As an outcome from the inspection the licensee will receive an inspection report.

During a separate discussion with the TRANSRAD management, the IRRS team was informed that communication and relationships with FANC are open, frank, and transparent.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

During the entire lifetime of the facilities and activities, FANC and Bel V (for Class I and IIA facilities), perform inspections addressing occupational exposure.

Inspections take into account, inter alia:

- The application of the optimization principle for occupational exposure, compliance with dose limits;
- Information and training of workers;
- Organizational, procedural and technical arrangements related to controlled and supervised areas;

- Existence of equipment, facilities, services and procedures for protection and monitoring of individuals and workplaces;
- Health surveillance of exposed workers;
- Protection of female and underage persons.

The Federal Public Service Employment, Labour and Social Concertation also conducts its own inspections relating to the well-being of workers during the execution of their work related to the application of the Code of Wellbeing at Work that also includes provisions relating to radiation protection. There are processes in place for both authorities to share observations and useful information in terms of radiation protection or nuclear safety observed and collected at workplaces during inspections. In addition, crossed or common inspections between the two authorities can be organized.

Inspection of occupational exposure is carried out through FANC's inspection plan. The plan was updated in 2022 and spans a period of ten years. Class II and III facilities should receive a full scope inspection every ten years, that can be divided into multiple thematic inspections and carried out more frequently, based on a graded approach.

The IRRS Team was informed that FANC considers the total number of inspectors foreseen for the departments that carry out occupational exposure inspections to be sufficient to implement this plan, in contrast with the situation in other review areas, i.e. medical exposures. However, the existing number of inspectors at present is about half of what is foreseen, with additional inspectors being recruited in the near term. Additionally, the new inspectors will require training. Therefore, the IRRS Team encouraged FANC to closely monitor the implementation of the inspection plan and to ensure sufficient resources are allocated, in order to ensure adequate inspection of all facilities and activities with regards to occupational exposure, based on a graded approach (see also the associated suggestion in Section 3.3).

The implementation and comprehensiveness of the inspection programme are of particular importance as the authorization and review and assessment of facilities, activities, and exposure situations is primarily based on the work carried out by recognized health physics organisations and recognized health physics experts. This may result in situations that require correction being identified only at the time of inspection, such as inadequate contamination prevention measures, that could have direct impact on the safety of workers.

The IRRS Team was informed that FANC is preparing an inspection campaign dedicated to the work carried out by these recognized health physics organisations and health physics experts in order to ensure their work is in line with safety requirements. This would ensure that when applicants submit license applications signed by these experts and services, their content is accurate and sufficient to allow for confirmation of compliance with regulatory requirements with regards to occupational exposure.

Site Visit

The IRRS team observed the inspection performed by FANC to the nuclear medicine department of the hospital Cliniques de l'Europe, site Sainte-Elisabeth. It was an announced and planned inspection and based on the related authorization documents.

Cliniques de l'Europe is authorised to carry out diagnostic radiology, radiotherapy and nuclear medicine. For this hospital, this was the first planned inspection to the nuclear medicine department under the updated inspection plan.

During the initial meeting, the hospital representatives were informed about the scope of the visit. The management of the hospital was present at the initial meeting, and staff members with relevant responsibilities were involved in the inspection.

The inspection was carried out according to the FANC inspection protocol and the inspectors conducted themselves professionally and openly discussed issues with the hospital representatives.

At the end of the inspection the FANC inspectors orally presented the findings to the hospital representatives. The IRRS team was informed that an inspection report would be sent to the licensee.

After the inspection, the IRRS team interviewed the hospital representatives who stated that they had few direct interactions with FANC, as this is regularly done through their recognized health physics expert. They highlighted that some legal and regulatory requirements are difficult to implement, citing examples related to security of radioactive sources and on training of workers. However, it was noted that they considered that the inspectors were not repressive but engaged in constructive dialogue.

7.9. INSPECTION OF MEDICAL EXPOSURE

Inspections relating to medical exposure are included in the inspection programme of the health protection section of FANC, based on a frequency established according to a graded approach and on the analysis of all the risks and actions managed by the health protection section. Reactive inspections can be included in the programme if required.

Planned inspections are composed of "punctual inspection campaigns" and "periodic inspection campaigns".

The choice of "punctual inspection campaigns" is made among the following topics:

- New operations, e.g. new technologies or new radioactive products for in vivo use;
- Systematic verification of the justification and/or optimization of patient’s exposure;
- Quality assurance;
- Organization of medical physics;
- Responsibilities of the practitioner and referral person;
- Unintended and accidental medical exposures;
- Periodic patient dose surveys;
- Training and certification of practitioners and entitled persons;
- Training and recognition of medical physics experts;
- Radiopharmacy; and
- Clinical trials.

FANC directs its "punctual inspection campaigns" towards facilities and healthcare professionals presenting or likely to present one or more non-conformities, identified on the basis of feedback from facility authorizations, analysis of reported incidents (or non-reporting facilities), periodic reports from medical physics experts, national surveys of doses received by patients etc.

Inspections as part of "periodic inspection campaigns" are carried out on a periodic basis and repeated based on the following frequency:

- Every three years for installations for radiotherapy and radionuclide therapy where the patient has to stay in a shielded hospitalization room and for facilities that have an internal health physics expert;
- Every five years for installations where radioactive substances are administered to patients and for installations that are used for interventional radiology (specifically cardiologic imaging);
- Every ten years for installations where radioactive substances are used for in vitro diagnosis, for mobile installations where portable dental X-ray equipment is used for dental radiography and for non-medical facilities where medical radiological equipment is used for non-medical imaging;

- All other installations are inspected on a sample basis (with no set frequency).

The health protection section does not currently carry out “periodic inspection campaigns” on its own initiative. All aspects of medical facility safety are managed by a periodic inspection programme by the medical establishments section. The site visit in section 7.8 is an example of this type of inspection.

The IRRS team was informed that given the large number of facilities and healthcare professionals, and the limited resources of the health protection section, FANC cannot perform inspections related to medical exposures with the above-mentioned periodicity. Therefore, punctual inspection campaigns with specific targets and scopes are a priority in the Health Protection section.

The IRRS team encouraged FANC to further implement the inspections related to medical exposure on a periodic basis. This issue is addressed by Suggestion S2 in Section 3.3.

7.10. INSPECTION OF PUBLIC EXPOSURE

An inspection cycle of announced inspections for NORM installations is established with a frequency, based on risk assessment, of one to five years (determined by a graded approach). The inspection frequency is influenced by sector and installation dependent parameters, such as the presence, and type, of NORM material and residues and the variability of raw materials used. A specific inspection programme on radon in workplaces exists, targeting workplaces in radon risk zones.

Inspections can be completed by assessing written documents, can be conducted on-line or on-site and can have a narrow or a broad scope, containing requirements related to public exposure (justification, optimization, procedures). The inspections included verification of the compliance with operational discharge limits, dose constraints etc.

There are no (on-site) inspections made or planned for producers or licensees of consumer products.

During the authorization process by manufacturers (or importers), basic criteria for exemption are applied, such as the radiological risks to individuals caused by the exempted practice are sufficiently low as to be of no regulatory concern. The collective radiological impact is sufficiently low as to be of no regulatory concern under prevailing circumstances.

The exempted practice is intrinsically without radiological significance with no appreciable likelihood of scenarios that could lead to a failure to meet the before-mentioned criteria. Waste disposal facilities registered by declaration of professional activities for the disposal of NORM waste are subjected to the inspection programme of professional activities which is planned annually in function of the declared received waste characteristics (volumes, activity concentrations, etc.).

7.11. SUMMARY

FANC and Bel V (Class I and IIA facilities) deliver inspections against an annual plan derived from a mid-term programme (the six-year GIC for Class I facilities, with other facilities having mid-term programmes of varying durations). Inspection planning follows a graded approach and is (as would be expected) more detailed in both planning and delivery for Class I facilities. For medical physics inspection in particular, the large number of authorised parties coupled with constraints on the number of available nuclear inspectors has led to difficulties in delivering inspections with a frequency commensurate with the risk.

FANC and, where appropriate, Bel V inspectors deliver inspections using the full range of methods expected. Their initial training and qualification are robust, but their ongoing development is more ad-hoc and varies between sections, particularly for FANC inspectors; it would benefit from being driven by a central, systematic process. This has already been recognised by FANC in the Action Plan.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Belgium has a comprehensive enforcement regime in place in accordance with the FANC law. The FANC law foresees a set of enforcement measures that are applied in case of infringements of the requirements or in case of a safety issue. The enforcement measures are applied in accordance with a graded approach.

These measures are safety measures or administrative measures and sanctions. The safety measures encompass the shutdown of facilities, cessation of activities, sealing of installations, evacuation of sources and other measures aiming to terminate or prevent dangerous situations and ensure the protection of the workers, the public, and the environment. Administrative measures are imposed due to violation of regulatory requirements or license conditions. This can include:

- warnings;
- fines;
- imposing measures;
- writing of legal reports to the prosecutor (that may lead to a criminal case).

FANC may establish a process of "enhanced supervision" of a licensee. This means that a higher frequency of inspections of activities or facilities is going to be applied in order to regularize the situation of the licensee. This enhanced supervision can be imposed based on:

- licensee is in financial difficulties, which may lead to reduction of safety or security level on the site;
- multiple recurring non-compliances with regard to the radiation protection, safety and/or security of workers, public of the environment; or
- observations and findings by the nuclear inspector.

The enforcement measures can be applied only by FANC staff with the "nuclear inspector" status. The IRRS team was informed that the enforcement aspects of the inspectors training programme are adequately addressed in education and continuous training of nuclear inspectors.

FANC has an enforcement policy that formulates the basic principles and general guidelines applicable to all FANC nuclear inspectors. The enforcement policy covers all areas of FANC regulatory responsibilities in nuclear and radiation safety as well as nuclear security. There are three processes associated with this policy:

- Process for drafting and managing security/safety and administrative measures, with underlying specifications;
- Process for managing legal reports, with underlying specification;
- Process for managing administrative fines, with underlying specifications.

The policy is also associated with the "Specification for handling non-conformities identified by Bel V as part of its statutory duties in installations of Class I and IIA".

The legislation and FANC management system ensure an appropriate documenting of findings and imposing of related enforcement measures as well as effective communication with relevant licensees concerning implementation of such measures. FANC imposes enforcement measures by FANC decision. Such decisions contain clear instructions and conditions for lifting of the imposed measures.

During FANC inspections, at least one nuclear inspector must participate in order to assure that possible enforcement measures can be applied, if any infringements are identified. Class I and class IIA facilities can also be inspected solely by Bel V inspectors. Bel V inspectors have no power to impose enforcement

measures due to infringements. Nevertheless, according to their procedures, Bel V inspectors may identify non-conformities and send them to the licensee. This is an effective approach to address findings to licensees in order to regularize violations or to prevent them.

The non-conformities identified by Bel V inspectors can be simple non-conformities or characterized non-conformities. Simple non-conformities are related to findings that can be easily resolved and do not introduce a higher risk for the safety and radiation protection. Such non-conformities are documented in relevant inspection report and Bel V inspectors are requesting the licensee to regularize them in an appropriate manner.

In case of characterized non-conformities, that are associated with infringements of regulatory requirements, the Bel V inspector has to contact FANC in a timely manner, taking into account the safety significance of the relevant findings. The procedures ensure possibility for quick communication by phone and e-mail with so called "Single point of contact" from FANC, who is a nuclear inspector assigned to the particular installation and can react to the situation, including imposing the necessary enforcement measures. If the "Single point of contact" is not reachable, the Bel V inspector may contact FANC management.

In accordance with the legislation, if the licensee does not agree with the imposed measures, an appeal to the FPS Home Affairs can be applied. It should be noted that administrative measures are imposed after hearing the licensee except cases linked to emergency situations.

8.2. ENFORCEMENT IMPLEMENTATIONS

For planning and performing inspections, FANC uses CIS. CIS allows FANC management and staff to follow up on findings that are still open. CIS sends automatic reminders (by e-mail) to licensees concerning warnings, generation of templates for e-mails and other documents, collection of documents on regularization of particular findings, and provides access to inspection reports etc.

In order to simplify and formalize the procedures, approved documents templates (for warnings, imposing fines etc.) are used. Approved matrixes are used to assess risks and other safety factors to define the amount of fines. This ensures a fair and transparent process to impose penalties to licensees.

During the visit at Tihange NPP, the IRRS team was informed by licensee's management that the communication of the findings from inspections and enforcement measures with FANC and Bel V takes place in a constructive manner. The IRRS team was informed by the licensee that FANC explains the decisions made concerning enforcements and exchanges views and options with the licensees on implementation of relevant improvements.

Enforcement measures can be lifted when instructions and conditions imposed in FANC decisions are fulfilled. To ensure that the necessary improvements are effectively implemented, FANC may require evidence (e.g. pictures, documents etc.) or may initiate follow-up inspections.

8.3. SUMMARY

The legal and regulatory framework has a comprehensive enforcement regime.

FANC has established an appropriate enforcement policy applied in its regulatory oversight of facilities and activities. The enforcement measures are imposed by FANC, in accordance with a graded approach. Necessary enforcement measures can be timely initiated by Bel V inspectors as well. FANC and Bel V initiate follow-up activities of findings and enforcement measures, as necessary.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Belgium has a well-established regulatory framework that enables FANC to enact regulations and guides to specify the principles, requirements and associated criteria for safety, upon which its regulatory judgements, decisions and actions are based on.

National regulations on nuclear safety and radiation protection are to a large extent a transposition and further elaboration of requirements laid down in European Directives, regulations and recommendations. As a member state of the European Union and Euratom, Belgium is obliged to transpose and implement these related EU Directives into national legislation within a defined period.

In accordance with the article 24 of the FANC law, FANC has the right and the duty to propose regulations to the competent political authorities. In addition, the FANC law empowered FANC to issue legally binding "technical regulations" in cases foreseen in a royal decree. However, these regulations must be of a technical and non-policy nature.

FANC can make proposals for regulatory binding documents. Nevertheless, Bel V can issue guidance (non-binding documents) in specific technical areas. To ensure that the guidance issued by Bel V is consistent with FANC's regulatory policy, a process has been developed for obtaining formal approval by FANC at the different stages of the development of these Bel V's guidance documents (initiating, first draft for stakeholder consultation, final draft, publication).

FANC has published an extensive number of high quality, and extensive guidance documents on different topics, including:

- Contents and scope of licensing applications;
- Roles and responsibilities of all parties involved in radiation protection, including workers, RPO's, RPE's and services;
- Radiation protection measures for workers in industrial and medical applications;
- Radiation monitoring and health surveillance of workers;
- Education and training of workers, including radiation protection officers;
- Criteria for notification to FANC of significant events concerning radiation protection and/or the safety of workers, the public and the environment during operations in Class I, II and III facilities as well as during transport;
- Inspection campaigns;
- Radon in workplaces, including a handbook;
- Exposure to cosmic radiation, including a communication toolbox for aircrews;
- NORM industries;
- Establishment of a radiation protection programme for the transport of Class 7 dangerous goods;
- Emergency procedures for the transport of class 7 dangerous goods.

GRR-2001, which specifies the authorization process, provides requirements on environmental impact assessment, and the information to be submitted to apply for a combined license for construction and operation for new nuclear facilities, does not cover all necessary requirements for site evaluation in line with SSR-1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The evaluation of the site suitability during the lifetime of nuclear facilities is conducted through the periodic safety review process against the regulatory requirements set up by SRNI-2011 which specifies the requirements for site evaluation. On the other hand, GRR-2001 which specifies the authorization process, provides requirements on environmental impact assessment, and the information to be submitted to apply for a combined license for construction and operation for new nuclear facilities, does not cover all necessary requirements for site evaluation in line with SSR-1.*	
(1)	**BASIS: SSR-1 para. 4.6 states that** *"In the assessment of the suitability of a site for a nuclear installation, the following aspects shall be addressed at an early stage of the site evaluation:* *(a) The effects of natural and human induced external events occurring in the region that might affect the site:* *(b) The characteristics of the site and its environment that could influence the transfer of radioactive material released from the nuclear installation to people and to the environment:* *(c) The population density, population distribution and other characteristics of the external zone. in so far as these could affect the feasibility of planning effective emergency response actions, and the need to evaluate the risk to individuals and to the population."*
(2)	**BASIS: SSR-1 para. 4.7 states that** *"The site shall be deemed unsuitable for a nuclear installation if one or more of the three aspects listed in para. 4.6 indicates that the site is unacceptable and the deficiencies cannot be compensated for by means of a combination of measures for site protection, design features of the nuclear installation and administrative procedures."*
R11	**Recommendation: FANC should complete regulations for site evaluation of future nuclear facilities in accordance with SSR-1.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The Belgium Nuclear Power Plants are regulated in accordance with the royal decrees GRR-2001 and SRNI-2011 and associated guidelines as Class I facilities. SRNI-2011 sets the requirements for the design and safety assessment, as well as site evaluation, and it contains both generic requirements for Class I facilities and specific requirements for NPPs. It also includes explicit requirements regarding the fundamental safety functions, defence in depth, reliability, design basis, design extension and postulated initiating events, operational limits and conditions, personnel qualification and training, accident management, operating procedures, maintenance, testing, surveillance and inspection, and monitoring and control of activities performed by vendors, subcontractors and suppliers.

GRR-2001 requires that the future licensee states which guides they will apply. These will be a part of their safety assessment report, referenced in the license and are therefore legally binding. During the licensing process, FANC assesses if these guides are sufficient.

Moreover, due to the decision of the Belgian Government in March 2022 opening the possibility for a long-term operation for the two most recent reactors, a project for revising SRNI-2011 to include the WENRA Safety Reference Level 2020 has been initiated and is in progress.

FANC and Bel V have established their internal regulatory oversight processes, documented in their respective management systems. Collaboration and exchanges between FANC and Bel V are organized under the framework of their Collaboration Agreement and Convention. In addition to Belgian regulations, there are various sources used, such as USNRC regulations, IAEA (Safety Standards, Safety Reports Series, Security Series, TECDOC), WENRA Safety Reference Levels, EC, ANSI/ANS, ASN, STUK, ENISS, ISO, IEEE, IEC and HERCA. There are processes for monitoring these sources regularly by dedicated personnel, carrying out a gap analysis. If necessary, specific teams will be formed to discuss cross-cutting issues, e.g. a WG involving FANC and the respective Bel V's Technical Responsibility Centre. This is the first step to develop or change regulations and guides.

The internal procedures to develop regulations and guides have been developed and are being effectively implemented. Furthermore, the collaboration between FANC and Bel V to this effect is considered by the IRRS team as a good performance.

There are a few aspects, specific requirements regarding site evaluation and design for NPP, that are not explicitly mentioned in SRNI-2011 or GRR-2001. Nevertheless, these aspects are taken into account in the Safety Analysis Report (SAR) and in the Periodic Safety Review (PSR) or are no longer applicable due to the nuclear phase-out law. A more specific assessment should be made to determine if such requirements should be implemented in SRNI-2011 and GRR-2001, taking into account the specific Belgian situation.

SRNI-2011 specifies detailed requirements for Operational Limits and Conditions (OLCs) in NPP. Most of the OLCs for NPP are adopted in the SAR and PSR. However, constraints on control systems and procedure constraints, and specified operational configurations are not explicitly stated in the regulation in line with SSR-2/1 (Rev. 1).

In addition, SRNI-2011 specifies detailed requirements for the design of the reactor core and associated features in NPP. The safety assessment of core design in NPP is performed in SAR and PSR, however, general design requirements are not explicitly set in the regulations in line with SSR-2/1 (Rev. 1).

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The research reactors are classified as Class I facilities. They are regulated in accordance with GRR-2001 and SRNI-2011 and associated guidelines. FANC applies a graded approach for licensing and modifications. FANC also uses a pre-licensing process for new research reactor projects. The Action Plan includes a commitment to publish research reactor specific requirements in an update to SRNI-2011.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

FANC has developed new safety provisions for disposal facilities, including closure and post-closure requirements as well as authorization changes. Requirements will be added to SRNI-2011 via royal decree which is expected to be issued by the end of 2023.

FANC, with Bel V, developed an integrated guide to facilitate future reviews of deep geologic disposal. FANC and Bel V have also developed a research and development framework that establishes an outline of research needs and priorities that are expected to be needed to support FANC and Bel V staff when they conduct the regulatory review of a future deep geologic disposal facility. The framework helps to identify expertise needed and potential gaps in technical knowledge early so that the strategic research needs (SRNs) can be established. For each SRN, an action plan is developed that includes key questions, literature studies, identified gaps in available research and recommendations for future work. The SRNs also provide means of training and knowledge management for new reviewers.

The IRRS team identified the use of this research and development framework as a tool for knowledge management and retention as a good performance, in addition to its value in identifying and resolving technical issues. Deep geologic disposal projects are long term. Knowledge management and retention is critical to support regulatory decisions for the full cycle of the project.

Another good performance identified was the collaboration of FANC and Bel V with the SITEX Network members to develop an interactive tool, a serious game called Pathway Evaluation Process (PEP). FANC and Bel V have also organized several PEP sessions in Belgium to facilitate a structured discussion amongst various interested parties on radioactive waste disposal and its various challenges. A collaboration with the university of Liège has been set up to organise PEP sessions on a regular basis with students in political science and applied sciences. FANC and Bel V plan to continue sessions in future public interactions.

Belgium has significant radium-bearing waste and contamination to be addressed. FANC and NIRAS/ONDRAF have established a common opinion on where radium-bearing waste can be disposed

based on reference levels. They have also developed an action plan that lays out steps for remediation and disposal.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The national regulatory framework includes requirements for facilities and activities with radiation sources largely in line with the safety standards.

FANC has developed and implemented specific procedures and guidelines to assist the personnel in the performance of their regulatory functions. However, as the IRRS team observed, no criteria have been established to ensure that the review and assessment for Class II and III industrial and research facilities with radiation sources is conducted in accordance with graded approach. This issue is addressed by Suggestion S10 in Section 6.5.

Apart from the basic legislative documents defining the framework for the regulatory control of facilities and activities with radiation sources, FANC has also published technical regulations.

The IRRS team was informed that a guidance document for licensees and FANC's personnel on the assessment of potential incidents and accidents in facilities with radiation sources is under development.

Furthermore, FANC has established specific requirements for the conduct of in situ industrial radiography.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

FANC informed the IRRS team that the uncertainty with the future plan for nuclear power plants, such as the potential re-start of a new LTO project for Doel 4 and Tihange 3, could impact the decommissioning strategy of the licensee and also affect the availability of resources. The IRRS team agreed with FANC's statement and noted that the uncertainty could also create a significant burden on the regulators and licensees to plan for various scenarios, including waste storage.

FANC and Bel V, however, have undertaken several initiatives to identify issues early and ensure coordination amongst them and with NIRAS/ONDRAF. In addition to the PVAO, for example, FANC, Bel V and NIRAS/ONDRAF are working to identify, track, and resolve issues. For FANC, these issues could be resolved at a later date but for NIRAS/ONDRAF it is important to resolve earlier (e.g. financial concerns). The licensee is also holding regular meetings with FANC, Bel V and NIRAS/ONDRAF to discuss decommissioning at Doel 3 and Tihange 2.

FANC developed an online toolbox for decommissioning to share documents and lessons learned amongst FANC and Bel V staff. This online toolbox also provides a form of knowledge management. The IRRS team encouraged FANC and Bel V to maintain focus on regularly updating their decommissioning toolbox and documents as they gain insights and lessons learned from the current NPP decommissioning experience. The IRRS team also encouraged FANC and Bel V to share this online toolbox with NIRAS/ONDRAF if possible.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The regulatory framework for the transport of fissile and radioactive material is based on the FANC law, on the royal decree on the transport of Class 7 dangerous goods (RD Transport) and on binding technical regulations (TR) that can be issued by FANC. The RD Transport determines that the transport of radioactive material must comply with the requirements of the international agreements and regulations governing the transport of dangerous goods. The modal agreements and regulations (ADR, RID, ADN, ICAO TI, and IMDG Code) transpose the IAEA Transport Regulations SSR-6 (Rev.1) for each mode of transport; therefore, all the requirements in SSR-6 (Rev.1) are implemented into the Belgian regulatory framework.

The binding TR establish provisions in terms of recognition of the carriers, of the interruption sites, and of organizations involved in handling during multimodal transport of radioactive material and shipment approvals (other than those required by international regulation). These TR also include the procedures to apply for the recognition and approvals.

The regulatory framework is supported by the Technical Guide "Package Design Safety Reports for the Transport of Radioactive Material", issued by the European Association of Competent Authorities (EACA).

The tests for industrial type IP-2, IP-3 or Type A packages are often performed at the premises of the designer or the consignor without any specific requirements or provisions for the test facility in terms of procedures, characteristics of the target for drop test, and reliability of instrumentation used for the tests. Guidelines for establishing and operating a test facility for non-approved packages should be issued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The designers or the consignors perform the tests of the non-approved packages, the results of which are made available to the competent authority. However, guidelines for establishing and operating the test facilities are not established.*	
(1)	**BASIS: TS-G-1.5 para. 4.83(d) states that** *"It should be clearly established that the test facilities comply with the regulatory requirements, particularly in the case of the targets used for drop and penetration tests, where the weight of the test specimen should not exceed the capacity of the test facility."*
S13	**Suggestion: FANC should consider developing and issuing guidelines for establishing and operating the facilities performing the tests of not approved packages.**

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

Provisions for protection of workers and the responsibilities of all parties involved are mainly established in GRR-2001 and in the Code on Wellbeing at Work issued by the Federal Public Service Employment, Labour and Social Concertation. GRR-2001 includes dose limits for occupational exposure for workers over the age of 18 years.

Requirements are established in the regulations for the dose measurements and dose assessments, the dose record keeping, the transfer of individual dose data to the national dose register and for the approval of dosimetry services by FANC.

Approval of calibration services by FANC is not foreseen in regulations. FANC relies on the accreditation requirements of dosimetry services as it covers the adequacy of the calibration services. Recommendation R9 in section 5.8 addresses this issue.

GRR-2001 includes requirements for optimization of occupational exposure, and dose constraints may be set by FANC for any source, practice or activity. The IRRS team observed that GRR-2001 includes provisions for protection of pregnant workers in line with IAEA safety standards. However, additional provisions are also established in the Code on Wellbeing at Work issued by the Federal Public Service Employment, Labour and Social Concertation, that determines that pregnant workers are forbidden from carrying out any work that involves exposure to ionising radiation. FANC informed the IRRS team that there is legal standing that determines provisions in GRR-2001 to take precedence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Provisions for the protection of pregnant workers are included in the royal decree GRR-2001 and in the Code on Wellbeing at Work issued by the Federal Public Service Employment, Labour and Social Concertation. The provisions in GRR-2001 are in line with IAEA requirements whereas the ones in the Code are not. While the legal standing between both documents gives precedence to GRR-2001, the conflicting requirements may cause confusion to the interested parties.*	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 2.18 (1) states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:* *(1) Safety of workers and the public;"*
(2)	**BASIS: GSR Part 1 (Rev.1) para. 2.19 states that** *"If responsibilities and functions do overlap, this could create conflicts between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant."*
(3)	**BASIS: GSR Part 3 para. 3.114 states that** *"Notification of the employer by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude the female worker from work. The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public."*
S14	**Suggestion: The Government should consider expanding the coordination between the Federal Public Service Employment, Labour and Social Concertation and FANC, to bring its regulatory provisions regarding the protection of pregnant workers in line with the IAEA requirements.**

GRR-2001 requires workers to comply with all the instructions and provisions regarding protection and safety requirements, contribute as far as possible to their own radiological protection and immediately report any anomaly or defect of protective equipment. However, the regulations do not require workers to provide to the employer or licensee information on their past and current work that is relevant to ensure effective and comprehensive protection and safety for themselves and others.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no regulatory provisions for workers to provide to the employer or licensee information on their past and present work relevant and needed for ensuring effective and comprehensive protection and safety for themselves and others.*	
(1)	**BASIS: GSR Part 3 para. 3.83 (d) states that** *"Workers: (…)* *d) Shall provide to the employer, registrant or licensee such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others;"*
R12	**Recommendation: FANC should establish regulatory provisions to ensure that workers provide to the employer or licensee information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.**

Regulations establish that all licensees, within their structure, organize an internal department (designated "health physics department") responsible for implementing radiation protection procedures at a local level, according to requirements established by FANC. The licensees designate local radiation protection officers that carry out activities under the responsibility of this department, and ensures consultation with recognized health physics experts, either belonging to the department, or under external contract.

Requirements for the establishment of controlled and supervised areas are also defined in GRR-2001. While GRR-2001 does not explicitly state that an employer cannot provide benefits to employees as a substitute for the necessary protective measures, this is still addressed through the provisions on the Code of Wellbeing at Work where the employer is obliged to carry out a risk analysis and to take preventive measures.

GRR-2001 also addresses occupational exposure in existing exposure situations. In those exposure situations, depending on the risk of exposure, the corresponding requirements regarding workers radiation protection are established.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Belgian regulatory framework for medical exposure control is mainly based on the royal decree on medical exposures and exposures for non-medical imaging purposes with medical radiological equipment (RD Medical Exposure) and on FANC technical regulations. These documents provide a legal basis for the oversight of medical exposures which is in line with the IAEA safety standards.

The royal decree introduces provisions for the training of Medical Physics Assistants. It also introduces requirements for licensees of medical facilities to establish a medical physics department (MPD) within their organization (except class III facilities without CT or interventional radiology equipment).

FANC regulations formalize the process for the justification of a new practice, that requires the performance of a justification study based on the estimated risk. Practices that are adopted for general use, as well as practices that are forbidden, are enumerated by FANC.

RD Medical Exposure requires the practitioner to determine dose constraints for the carers and comforters, taking account the ICRPs and FANC's guidelines and recommendations, and in consultation with the medical physics expert and the health physics expert. The IRRS team encouraged FANC to further strengthen enforcement of this provision by including verification of this requirement in the inspection handbook of medical exposure.

FANC has set out dose constraints in a technical regulation for persons participating in an experiment on human subjects and for whom no direct medical benefit is expected from this exposure. The dose constraints in this technical decree are based on the values given by ICRP publication 62 ("Radiological Protection in Biomedical Research"), and the radiation protection publication of the European commission RP 99, "Guidance on medical exposure in medical and biomedical research".

According to RD Medical Exposures, the reference measuring instruments for the calibration of radiotherapy units must be calibrated every two years against a national standard or in an accredited calibration laboratory against standards that are traceable to primary standards.

Independent verification of the calibration of a radiation unit prior to clinical use is not a legal requirement. This has already been identified by FANC in the Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no regulatory requirement for independent verification of the calibration of radiation therapy units prior to clinical use.*	
(1)	**BASIS: GSR Part 3 para. 3.167 states that** *"The medical physicist shall ensure that: …* *(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R13	**Recommendation: FANC should revise the regulations to require an independent verification of calibrations of radiation therapy units prior to their clinical use.**

RD Medical Exposures defines requirements for training and authorization of relevant parties with duties in relation to protection and safety for individuals undergoing medical exposures, but the requirement for the licensee to set up an up-to-date list of personnel with tasks relating to medical exposure in his facility is not addressed. This has already been identified by FANC in the Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no regulatory requirement for a licensee to have an up-to-date list of personnel with duties relating to medical exposure.*	
(1)	**BASIS: GSR Part 3 para. 3.150 states that** *"The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: …* *(c) Are named in a list maintained up to date by the registrant or licensee."*
R14	**Recommendation: FANC should revise the regulation to require licensees to keep an updated list of personnel with duties related to medical exposure.**

FANC periodically establishes and updates diagnostic reference levels (DRLs) for exposures incurred in medical imaging based on periodical surveys.

RD Medical Exposure requires an investigation to be launched if the DRLs are systematically exceeded. However, similar provisions don't exist in case the doses or activities of the radiopharmaceuticals administered fall substantially below the relevant DRLs and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no regulatory requirement to verify that the optimization of protection and safety for patients are adequate in case that the typical doses or activities are substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.*	
(1)	**BASIS: GSR Part 3 para. 3.169 states that** *"Registrants and licensees shall ensure that:…* *(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure: …* *(ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."*
R15	**Recommendation: FANC should establish a requirement for licensees to review whether** **a) patient protection and safety are optimized, or** **b) corrective actions are required** **if, for a given radiological procedure, typical doses or activities are substantially below the relevant diagnostic reference level and exposures do not provide useful diagnostic information or the corresponding expected medical benefit to the patient.**

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The legal basis for Belgium radiation protection and nuclear safety regulations is the transposition of relevant European Directives. These are complemented with input from other international organizations such as the IAEA, the WHO and the OECD-NEA. The legal and regulatory provisions for the oversight of the public exposure are in line with the IAEA safety standards.

FANC has documented the process for the development of regulations in the FANC management system.

9.11. SUMMARY

The Belgium legal and regulatory framework provides a comprehensive and robust foundation for the regulatory oversight of facilities and activities. FANC and Bel V implement and maintain a comprehensive set of regulations and guides that demonstrate a high level of quality in regulation for all nuclear facilities and activities.

The IRRS team observed that FANC and Bel V are fully committed to regularly updating its regulations and guides. FANC and Bel V actively participate in information sharing fora, collect and systematically explore national and international experience, and ensure that information regarding FANC's regulatory requirements is widely available.

The IRRS team identified some areas for improvement such as the adoption of international standards, and modification and update of regulations and guides with due consideration of relevant international experiences, retention of records and current IAEA safety standards.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

FANC is empowered by the national legal framework to issue on-site EPR regulations, such as the review and the approval of on-site Emergency Plans (OEP) of the operators. Moreover, the regulatory body performs an oversight of the implementation of those OEP through its inspection program. In addition, it monitors the regular emergency exercises that licensees must conduct as specified in the OEP.

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

The national regulations for EPR, which also cover onsite EPR aspects, include the following:

- National Plan for Nuclear or Radiological Emergencies in Belgium;
- FANC technical rule establishing the modalities and criteria for declaration of significant events in Class I facilities;
- Role, organization and operation of the National Crisis Centre.

However, the IRRS team observed that the EPR regulations and the OEP do not specify a target time for the notification to NCCN, following the recognition of an emergency. The notification should be done without delay, as stated in the regulation. However, it is not clearly defined what is the maximum allowed time.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The EPR regulations and the Onsite Emergency Plans (OEP) do not specify a target time for the notification to the appropriate notification point (NCCN), following recognition that there is an emergency. The notification should be done without delay, as stated in the regulation. However, it is not clearly defined what is the maximum allowed time. Current situation is that a maximum time for emergency notification is only established in licensee's procedures.*	
(1)	**BASIS: GSR Part 7 para. 5.17 states that** *"For facilities and activities in categories I, II and III, and for category IV, arrangements shall be made: (1) to promptly recognize and classify a nuclear or radiological emergency; (2) upon classification, to promptly declare the emergency class and to initiate a coordinated and preplanned on-site response; (3) to notify the appropriate notification point (see para. 5.11) and to provide sufficient information for an effective off-site response; and (4) upon notification, to initiate a coordinated and preplanned off-site response, as appropriate, in accordance with the protection strategy. These arrangements shall include suitable, reliable and diverse means of warning persons on the site, of notifying the notification point (see paras 5.41–5.43, 6.22 and 6.34) and of communication between response organizations."*
R16	**Recommendation: The Government should revise the relevant arrangements to establish a requirement of prompt notification of emergencies, including a specified time for notification to the authorities of emergency situations.**

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

FANC organizes, in collaboration with Bel V, the operator, the NCCN and other relevant stakeholders, emergency exercises to verify, among other things, the adequacy of EPR arrangements and the preparedness of the licensee's organization. These exercises are organized every year for nuclear power plants and every two years for the other class I facilities. These exercises are normally based on scenarios

involving nuclear safety related events. So far, only one exercise has been conducted concerning the response to an emergency triggered by a nuclear security event.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In 2017, the National Crisis Centre (NCCN) organized an emergency response exercise in Doel NPP based on a scenario involving a nuclear security event. There are currently no plans in place to organize similar exercises in the future, unlike the emergency exercises based on nuclear safety events that are conducted regularly between the licensees and the local police forces.*	
(1)	**BASIS: GSR Part 7 para. 6.30 states that** *"Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals….."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 2.39(d) states that** *"Specific responsibilities within the governmental and legal framework shall include:…Integration of emergency arrangements for safety related and nuclear security related incidents."*
R17	**Recommendation: The Government should ensure that emergency response exercises based on scenarios involving nuclear security events, and involving relevant parties, are carried out at regular predefined intervals.**
Observation: *Even if they reflect the current status of national & international EPR regulation, some materials used as basis for the training for FANC EPR staff were prepared 10 years ago.*	
(1)	**BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training".*
S15	**Suggestion: FANC should consider updating some relevant materials for FANC EPR staff to fully reflect the current status of national and international EPR related regulations, guidance and inspection procedures.**

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Federal Public Service of Home Affairs is responsible for the operation of the NCCN, which includes different cells. The Evaluation cell is responsible for providing an updated understanding of the situation of the emergency on-site and its possible off-site consequences and its possible evolution and for recommending to the authorities adequate actions to protect the public. Besides Bel V and FANC, other organizations supporting the evaluation cell with relevant experts are, e.g.:

- the operator of the affected site;
- SCK CEN;
- IRE;
- The Royal Meteorological Institute;
- The Federal Agency for the Safety of the Food Chain (FAVV/AFSCA).

The Measurement cell provides monitoring data based on:

- FANC's monitoring capabilities;
- the radiation monitoring network (TELERAD) around the Nuclear Power Plant (NPP) site;

- the operator's monitoring capabilities;
- the monitoring capabilities deployed in the field to ensure additional measurements.

In the event of an emergency, FANC chairs the Evaluation and Measurement cells. Moreover, it participates in the Information cell, which is responsible for the disclosure of official public information on the emergency. FANC also participates in the Management cell, responsible for the overall management of the emergency.

In addition to the four emergency classes defined in GSR Part 7, the national Emergency Classification System includes a fifth emergency class denominated "General Emergency in Reflex Mode", and the related operational criteria. The IRRS team considered the introduction of this fifth class as a good performance, since it clearly describes how to identify the emergency class and the associated urgent protective actions to be implemented in a timely manner. These protective actions should be implemented, when feasible, before the start of any release.

To support the National Nuclear Emergency Plan (NEP), FANC has access to various modelling and calculation tools and to meteorological data from the national meteorological service. The outputs of the calculation tools complement the necessary information used to determine protective actions which are based on plant conditions and radiological situation in the surroundings. This is in line with GSR Part 7 requirements.

FANC and Bel V have a significant number of trained staff (approximately 25% of expert staff) who are able to perform different response functions. There is an on call (24/7) duty that can be rapidly activated in case of a radiological or nuclear emergency to perform the required response functions.

10.5. SUMMARY

FANC's authority, and its capacity to issue regulations on onsite EPR and to oversee the licensees' activities in that field is clearly established in the national legislation. In addition, FANC and Bel V are required to assume different functions in the national EPR framework.

To discharge its responsibility in radiation monitoring during emergencies, FANC has in place trained staff equipped with adequate monitoring instruments to fulfil its duties. Fixed dose rate monitors (TELERAD) are deployed across the country, covering the surroundings of all Class I facilities. To allow for 24/7 conduct of those activities, FANC and Bel V have adequate number of trained staff ready to respond when necessary. In cooperation with relevant organizations, NCCN organises periodic exercises to test onsite EPR arrangements including coordination with offsite authorities.

The IRRS team noted some areas for improvement, such as:

- the regular conduct of emergency exercises based on nuclear security events;
- the update of regulations to include notification requirements;
- the update of the material used to train EPR inspectors.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The legal basis for the interfaces between nuclear safety and nuclear security is set by the royal decree on the physical protection of nuclear material and nuclear installations, and the royal decree on safety requirements for nuclear installations, including the management of conflicts and modifications. The legal basis for interface of safety with the safeguards of nuclear material is the FANC law and the law of 1 June 2005, that implements the Additional Protocol to the comprehensive safeguards agreement. FANC acts as a facilitator between the licensees, IAEA and EURATOM safeguards.

The royal decree on the physical protection of nuclear material and nuclear installations, the royal decree on the transport of Class 7 Dangerous Goods (RD Transport) and FANC's internal document for review and assessment addresses the interfaces of safety and security for the transport activities. See more description in Module 6.

11.2. REGULATORY OVERSIGHT ACTIVITIES

Under the royal decree on the physical protection of nuclear material and nuclear installations, the licensee performs a comprehensive assessment of the interfaces of safety and security, which include aspects of the emergency response arrangements and parts of a safety and security inspection. FANC verifies the outcome of the assessment.

FANC has an internal document titled "The 3S Approach and the Safety Security interface in Class I facilities" (3S Strategy Note) that describes their vision and approach for safety, security, and safeguards for Class I facilities. The 3S Strategy Note has a dedicated section that covers the interface between safety and security. It provides expectations on FANC, Bel V and the operators on how the interface should be addressed and a conflict should be resolved.

FANC approaches the interfaces between safety and security in accordance with one of the fundamentals of the Convention on the Physical Protection of Nuclear Material (CPPNM), namely "confidentiality and the principle of a "need-to-know". While security SPOCs are cautious with their security information about the facilities, it does not apply to their safety colleague who is required to work with them. Safety SPOCs who are aware of the security information are not to share with individuals who are not authorised to receive the security information and have no "need to know".

As part of the overall inspection programme, Bel V performs annual inspections on interfaces between safety and security at all NPPs. For other Class I facilities, these inspections are performed every two years. These inspections are not performed in facilities of other classes. At any time, FANC and Bel V inspectors can report any unusual observations or events that may impact interface with nuclear security by using a reporting process.

The purpose of the planned inspections is to confirm scope of the inspections will cover safety and security interface, such as target identification (those components critical to safety aspects), studies related to design basis threats (DBT) (resistance of structures, etc) and changes to installations and facilities.

The scope of planned inspections is to identify the impact (complementarities, interferences and antagonisms) of the physical protection measures (including cyber security) on nuclear safety and radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *FANC approaches the interfaces between safety and security in accordance with one of the fundamentals of the CPPNM, namely confidentiality and the principle of a "need-to-know". FANC's 3S Strategy Note describes the scope of safety and security interfaces and how a conflict between safety and security interfaces would be addressed.* *FANC has developed an inspection guide for all Class I facilities that identifies areas for inspections on the interfaces between safety and security. Potential challenges and impacts are assessed as part of the preparation of these inspections. Bel V performs annual inspections at all NPPs using this guide to identify the impact of the physical protection measures, including cyber security, on nuclear and radiation safety.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.52. states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections."*
(2)	**BASIS: GSR Part 1 (Rev.1) Para 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:…* *(b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;…"*
(3)	**BASIS: GSR Part 1 (Rev.1) Para. 2.40 states that** *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."*
GP1	**Good Practice: The regulatory body oversight approach to regulate the interfaces between safety and security, based on their unique use of "confidentiality and the principle of a need-to-know" and the conduct of dedicated inspections at all NPPs is effective.**

FANC and Bel V share a process for addressing modifications that may impact the interface between safety and security. This process describes the roles and responsibilities of FANC and Bel V, how to assess the impact of modifications and how to address these impacts, if needed.

In general, during emergency response exercises, both FANC and Bel V are involved. The IRRS team was informed that the last emergency response exercise involving nuclear security was performed in 2017. See Recommendation R17 in Section 10.3.

11.3. INTERFACE AMONG AUTHORITIES

A Directorate of Security (DAB) was established within the Federal Police under the law of 2017. The same law and the ministerial circular OOP36 bis on the security of class 1 nuclear installations require law enforcement to be present on site. Due to a recent amendment to the royal decree on physical protection, it is mandatory for licensees of Class I facilities to cooperate with law enforcement to the best of their abilities.

FANC has developed a protocol to guide the interface and cooperation between FANC and other authorities in assessments and emergency response exercises and during nuclear safety incidents. The IRRS team was informed that local authorities participate in emergency response exercises.

11.4. SUMMARY

Belgium has put in place a legal framework for the interfaces of safety with nuclear security. FANC has an internal strategy (3S Strategy Note) that provides guidance and expectations on how to address interfaces of safety and security of Class I facilities. FANC and Bel V also have measures in place ensuring that safety and security are effectively integrated, and do not compromise each other. In this regard, the oversight of interfaces between safety and security at all NPPs is a good practice.

The IRRS team considered that the efficiency of these arrangements could be practically checked during an emergency exercise including interfaces between security and safety.

12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

The scope of the mission covered the national regulatory implications of the COVID-19 pandemic with a focus on business continuity to maintain delivery of statutory duties and responsibilities for safety. This section presents relevant feedback and main conclusions drawn by the IRRS team from the discussions and evaluations made during the mission, to identify ways to strengthen governmental, legal and regulatory frameworks for safety.

12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

Upon the outbreak of the COVID-19 pandemic, the Government issued a ministerial decree in October 2020 to identify the health and safety measures to be taken. It established a list of critical services that need to continue such as inspections and control services, energy sector, radioisotope production, and nuclear and radiological sector including dosimetry, environmental monitoring and calibration. Hence, the Government provided the adequate legal basis to FANC for maintaining its regulatory duties with additional measures.

The number of recovered radioactive sources in Belgium was slightly lower in 2020 than in 2019 or 2021, but a causal relationship to the pandemic restrictions could not be proven. Regarding financial provisions for the management of disused sources, there were no problems or disruptions identified.

12.2 REGULATORY FRAMEWORK

The principle “business as usual” was implemented as much as possible by FANC and Bel V. The pandemic did not significantly impact the effectiveness of the regulatory control, even if some adjustments were needed in some places. In this respect, FANC established a crisis committee that laid down the rules to be followed by FANC employees.

FANC already had a Business Continuity Plan in place, originated from the event of hydrogen flaking in nuclear reactor pressure vessels, in order to face disruptive situations. This plan was based on the scenario of a nationwide blackout. It was reviewed and updated to address the pandemic situation. The updated version was approved in March 2020. The new plan specifies the working arrangements in the event of a pandemic.

Regarding the management system documentation, the procedure for the cleaning of the measurement devices was revised to comply with the national sanitary guidelines. The modifications were about the cleaning frequency and storage spaces to follow the distancing rules. FANC also developed a procedure and a special plan for the management of its 24/7 duty role (RGG-AWR) and the organization of nuclear crisis management in the event of pandemic. In addition, FANC used specific tailored Business continuity plan check lists. In the course of the pandemic, these documents were adapted to the evolving sanitary guidelines when needed.

In 2016, a terrorist attack occurred in Brussels. Consequently, FANC had already taken and implemented measures to strengthen its IT infrastructure to allow 100% of its staff to work from home. During the early stage of the pandemic, some challenges were identified such as the presence of the family members at home. FANC staff reported that communication was improved using tools such as Teams and SharePoint when the updated versions were installed. Since the pandemic, the FANC staff have been allowed to work from home 3 days a week.

As critical services, FANC and Bel V relevant staff are registered to a dynamic telecommunication service that prioritizes their phone calls using all communication mobile networks, including during national emergency situations.

To minimize the spread of the disease among FANC personnel, contingency instructions were issued to ensure that any suspected or real case of infection, the person had to quarantine for a prescribed term. Some staff exhibited the symptoms of COVID-19; as per the national protective measures, they were

required to be tested and if positive to quarantine for the required quarantine periods. However, no health incidents caused by the pandemic took place in FANC during this period.

For the individuals within FANC and the authorised parties that required to undertake medical check-ups with defined frequencies, they were exempted from the required medical check-up. Likewise, the frequency of routine dosimetry badges returns or exchanges was lowered to reduce the potential for contamination.

The communication between FANC and Bel V continued nearly at the same level as pre-pandemic due to the enhancements made to the IT system. Bel V continued to provide technical support and services as necessary to FANC.

During the pandemic, FANC, Bel V and the class I facility licensees held meetings using video conferencing facilities, initially daily but evolving over time to become weekly or bi-weekly. These alignment meetings were designed to ensure that FANC had an up-to-date understanding of the pandemic situation on site, which changed rapidly. Class I facility licensees had to produce contingency plans for use if critical individuals contracted COVID-19. These were reviewed by Bel V and discussed with the authorised party's health physics department. A licensee stated that having a good IT infrastructure before the pandemic facilitated the transition to full time teleworking. The Business Continuity Plan in place and prompt actions taken by FANC allowed to maintain a stable and consistent control over the COVID-19 pandemic period.

12.3 REGULATORY FUNCTIONS

During the pandemic, authorization and R&A processes were mostly conducted by regulatory staff from home. The technical meetings were arranged as online virtual meetings. Where important site visits were required, FANC and Bel V, as critical services, had the possibility to organize them.

The Scientific Council also adapted its working arrangements, e.g. in holding meetings between experts remotely, and was able to deliver their conclusions to FANC.

Inspection of Class I facilities

Inspections of NPP and other class I facilities continued throughout the pandemic. Inspectors in both FANC and Bel V were considered critical staff under the national arrangements and, as such, were allowed to travel during lockdown. However, many inspections were postponed from their original dates according to national lockdown requirements, to protect staff in both the regulatory body and the authorised parties.

The authorised parties introduced their own measures to mitigate the impacts of the pandemic, and these were subject to oversight by FANC, either through sampling on site or discussion with the authorised party. FANC and Bel V inspectors were required to comply with licensees' measures.

Both FANC and Bel V made extensive use of video conferencing facilities to deliver their inspections. Inspections were undertaken entirely remotely where possible, e.g. if they were largely based on interviews and document reviews. Where this was not possible, footfall on site was minimized as far as practicable. Often, only the inspector on-site was the single point of contact for the licensee, supported remotely by specialists. Bel V also made requests of the licensee's health physics department, asking them to undertake particular activities and report the results back to Bel V in order to avoid Bel V inspectors to go on site.

To protect control room personnel, Bel V halved the number of control room inspections and applied appropriate protocols.

The only NPP outage during the lockdown period of the pandemic was at Doel 4. To minimize the footfall on site, the outage scope was reduced to the minimum necessary, with work that could be postponed with a suitable justification, along with elective work, being postponed to a later date. Doel 4 planned a specific outage once the peak of the pandemic had passed to catch up on the deferred work. The regulatory body carried out inspections during the outage as normal but, as detailed above, the

inspection teams were minimized as far as practicable. In fact, there was an increased amount of assessment as a result considering the justifications produced to defer some of the work.

Inspections of non-class I facilities

During the initial lockdown, only reactive inspections were undertaken. Before each inspection, an assessment was undertaken to determine whether it was necessary for the inspection to be done in person and at that time, or if it could be postponed or conducted remotely.

After this initial phase, different approaches were taken for the industrial and medical sectors. In the industrial sector inspections continued but were conducted remotely. The inspection programme and plans were amended so that inspections that lent themselves to virtual conduct were brought forward, and inspections that would require site visits were postponed.

In the medical sector, FANC recognized the particular burden placed on hospitals during the pandemic, and determined that pausing planned inspection activity was in the public interest. Reactive inspections were still undertaken when required. For hospitals the mid-term inspection programme was also amended, and with inspections of facilities less critical to the pandemic effort (for example, dentists and vets) were brought forward, while inspections of hospitals were postponed.

Routine activities

Reactor operators are required to undertake continuous training. As a result of the pandemic, there was a three-month pause to this training programme. This was reviewed by Bel V, but they considered that, in fact, there was sufficient float in the programme that this had negligible impact.

Significant maintenance activities continued on site as required. There were some disruptions in the level of contract support that was available, and these were monitored by the regulatory body at routine contact meetings.

Licensees were unable to carry out supply chain audits during the pandemic, building up a backlog. The significance of this backlog, and the licensees' plans to manage it, were monitored by FANC through specific (virtual) meetings.

The radiation protection experts (RPE) continued their site visits at the facilities with radiation sources. The operation of radioactivity detection portals in critical facilities was maintained. However, problems for the response to the alarms were raised, as the right person could not always respond or be present at the facility site.

In general inspection continued at the most safety-significant nuclear installations, in accordance with a graded approach. The exception was at hospitals, which were recognized as already being under a particularly high burden. Inspection practices did change because of the pandemic, with more use being made of remote monitoring and video conferencing. Footfall was reduced on site as far as practicable. Inspectors on site followed the protective measures required by the authorised parties. In the longer term, the mid-term inspection programmes were amended so that, overall, the planned inspections could still be delivered, albeit at different times.

12.4 EMERGENCY PREPAREDNESS AND RESPONSE

During the COVID-19 pandemic, management of the situation, in part, benefited from the experience of the business continuity procedures prepared after the terrorist attacks that took place in March 2016. However, the pandemic introduced many limitations to the normal work of the regulatory body.

To minimize the spread of the pandemic among essential FANC staff, and when feasible, working from home was mandatory. Also, provisions were adopted to define backup personnel to replace any essential staff member. Thus, FANC 24/7 emergency response team staff-level was doubled to have full time deputies on both junior and senior positions.

Some emergency exercises were reduced in scope and/or postponed. In addition, FANC introduced a hybrid approach for exercise participants (some staff were in the office and some were online). This

(hybrid) approach is still being used and is regularly tested in every second exercise as such as the use of the FANC's back-office crisis infrastructure (once per year). FANC noted that the hybrid approach also allows emergency response team staff-level to remotely connect quickly and avoid delays travelling to Brussels. This approach is seen as a major positive outcome (lessons-learned) of the pandemic.

No request was received from any licensee requesting reduction of essential personnel required for EPR purposes. Neither there was any reduction on the staffing of the national EPR system.

APPENDIX I – LIST OF PARTICIPANTS

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VAN CALOEN Cédric	Federal Agency for Nuclear Control (FANC)	cedric.vancaloen@fanc.fgov.be

GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

First Week

<table>
<tr><th>Time</th><th>SAT</th><th>SUN 18.06</th><th>MON</th><th>TUE</th><th>WED</th><th>THU</th><th></th><th>FRI</th><th>SAT</th><th>SUN</th><th></th></tr>
<tr><td>9:00-10:00</td><td rowspan="16">Arrival of Team Members</td><td rowspan="3">Lunch</td><td>Entrance Meeting</td><td rowspan="3">Interviews
Visits</td><td rowspan="3">Interviews
Visits</td><td rowspan="3">Interviews
Visits</td><td rowspan="3">Coordinator(s) write(s) introductory parts</td><td rowspan="3">TM write Report

Drafts sent to Team Leads</td><td rowspan="3">Discussing between TM and improving Draft Report

TL, DTL, TC and DTC read everything

Secretariat edits the report</td><td rowspan="16">Free day, Social Tour</td><td rowspan="16">Review of the Report by the Team Leads</td></tr>
<tr><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td><td>Interviews</td></tr>
<tr><td>12:00-13:00</td><td rowspan="2">Lunch with Host</td><td colspan="5">Lunch</td></tr>
<tr><td>13:00-14:00</td><td rowspan="5">IRRS Team Entrance Meeting
• Welcome
• 5 minutes/TM self-intro
• Refresher training
Initial Team Meeting
• Meet host liaison officer
• Mission logistics
• Discussion of first impressions
• Closing</td><td rowspan="4">Interviews
Visits</td><td rowspan="3">Interviews
Visits</td><td rowspan="3">Interviews
Discussions with Team Lead if necessary</td><td rowspan="3">TL and DTL review introductory part</td><td>Policy Discussions</td><td>Secretariat edits the report:
New Draft Report Ready</td></tr>
<tr><td>14:00-15:00</td><td rowspan="3">Interviews
Visits</td><td rowspan="3">Secretariat edits the report
First Draft Report Ready

Cross-reading by TM</td><td rowspan="4">Finalisation of the Draft Report (focus only on Observation Boxes)</td></tr>
<tr><td>15:00-16:00</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="2">Daily Team Meeting</td><td>Daily Team Meeting</td></tr>
<tr><td>18:00-20:00</td><td>Team Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td colspan="2">Dinner</td><td>Dinner</td><td>Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td>Writing of the report</td><td>Writing of the report</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="2">Writing of the report</td><td>TM cross-read Draft</td><td>Secretariat edits the report</td></tr>
</table>

Second Week

<table>
<tr><th></th><th>MON</th><th>TUE</th><th>WED</th><th>THU</th><th>FRI 30.06</th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">'Pandemic' Contributions to IAEA

Discussion of Recommendations, Suggestions and Good Practises with Counterparts by module
Report drafting and reviewing</td><td rowspan="2">Cross-Reading of the Report
TL, DTL, TC and DTC read everything
Finalisation</td><td>Common read through and finalisation of the Report by the Team</td><td rowspan="2">Host reads Draft Report</td><td>Submission of the Preliminary Report</td></tr>
<tr><td>10:00-12:00</td><td>Submission of the Draft to the Host</td><td>Team discusses the Mission and provides IAEA with feedback</td><td>Exit Meeting
Publication of Press Release</td></tr>
<tr><td>12:00-13:00</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-15:00</td><td>Policy Discussions (if necessary)</td><td rowspan="3">Discussion of the Report by the Team</td><td rowspan="3">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft Report</td><td rowspan="3">TL finalises Executive Summary and Exit Presentation</td><td rowspan="3">TC Drafts the Press Release</td><td>Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="2">Departure</td></tr>
<tr><td>15:00-17:00</td><td>Discussions of Recommendations, Suggestions and Good Practises with Counterparts (cont'd)</td><td>Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Finalization of Executive Summary</td><td>Briefing of the Senior IAEA Manager; Finalisation of the press release and of the Preliminary Report</td><td></td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td rowspan="2">Farewell Dinner</td><td rowspan="3"></td></tr>
<tr><td>20:00-21:00</td><td rowspan="2">Secretariat updates Report</td><td rowspan="2">Secretariat finalises Report</td><td rowspan="2">Free</td></tr>
<tr><td>21:00-24:00</td><td>Free</td></tr>
</table>

APPENDIX III – SITE VISITS

- Tihange Nuclear Power Plant, Tihange (Inspection & Enforcement)
- Belgoprocess, Dessel (Radioactive Waste, Decommissioning & Public Exposure)
- SCK CEN, Mol (Research Reactors)
- Transrad, Fleurus (Transport)
- Universitair Ziekenhuis (UZ), Brussels (cyclotron for isotope production - radiation sources)
- Cliniques de l'Europe - St-Elizabeth site, Brussels (Occupational & Medical Exposure)
- National Crisis Centre (NCCN), Brussels (EPR)

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	FANC Counterparts	Bel V Counterparts
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**		
	Serhat Alten	Frank Hardeman, Rony Dresselaers, An Wertelaers, Olivier Zemb	
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Mok Cher Fong	Frank Hardeman, Rony Dresselaers, An Wertelaers, Olivier Zemb	Dirk Asselberghs
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Janne Nevalainen	Frank Hardeman, Rony Dresselaers, An Wertelaers, Olivier Zemb	Dirk Asselberghs
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Maria Oprisescu	Vincent Nys, Nicolas Van Mele	Marika Roobaert, Martine Detry, Benoît Bernard
5.	**AUTHORIZATION**		
	Peter Bester Maria de Lourdes Serrano Ramirez Jessie Quintero Sotiris Economides Sandro Trivelloni Pedro Rosario Houda Idihia Kilian Smith	Frederik Van Wonterghem, Jolien Berlamont, Guy Lourtie, Kristel Geerts, Nathan Lemahieu, Robin Klein Meulekamp, Geert Volckaert, Daan Van Der Meersch, Sophie Léonard, An Fremout, Luc Verpoorten, Jurgen Claes, Boris De Handschutter	Dirk Asselberghs, Olivier Smidts, Didier Degueldre, Piet De Gelder, Nicolas Noterman, Pierre Barras, Valéry Detilleux, Tom Van De Velde, François Henry, Sofie Vermote

	IRRS EXPERTS	FANC Counterparts	Bel V Counterparts
6.	**REVIEW AND ASSESSMENT**		
	Eszter Retvalfi Maria de Lourdes Serrano Ramirez Jessie Quintero Sotiris Economides Sandro Trivelloni Pedro Rosario Houda Idihia Kilian Smith	Frederik Van Wonterghem, Jolien Berlamont, Guy Lourtie, Kristel Geerts, Nathan Lemahieu, Robin Klein Meulekamp, Geert Volckaert, Daan Van Der Meersch, Sophie Léonard, An Fremout, Luc Verpoorten, Jurgen Claes, Boris De Handschutter	Dirk Asselberghs, Olivier Smidts, Didier Degueldre, Piet De Gelder, Nicolas Noterman, Pierre Barras, Valéry Detilleux, Tom Van De Velde, François Henry, Sofie Vermote
7.	**INSPECTION**		
	Daniel Gregory Maria de Lourdes Serrano Ramirez Jessie Quintero Sotiris Economides Sandro Trivelloni Pedro Rosario Houda Idihia Kilian Smith	Frederik Van Wonterghem, Jolien Berlamont, Guy Lourtie, Kristel Geerts, Nathan Lemahieu, Robin Klein Meulekamp, Geert Volckaert, Daan Van Der Meersch, Sophie Léonard, An Fremout, Luc Verpoorten, Jurgen Claes, Boris De Handschutter	Dirk Asselberghs, Olivier Smidts, Didier Degueldre, Piet De Gelder, Nicolas Noterman, Pierre Barras, Valéry Detilleux, Tom Van De Velde, François Henry, Sofie Vermote
8.	**ENFORCEMENT**		
	Evaldas Kimtys	Frederik Van Wonterghem, Jolien Berlamont, Guy Lourtie, Kristel Geerts, Nathan Lemahieu, Robin Klein Meulekamp, Geert Volckaert, Daan Van Der Meersch, Sophie Léonard, An Fremout, Luc Verpoorten, Jurgen Claes, Boris De Handschutter	Dirk Asselberghs, Olivier Smidts, Didier Degueldre, Piet De Gelder, Nicolas Noterman, Pierre Barras, Valéry Detilleux, Tom Van De Velde, François Henry, Sofie Vermote

	IRRS EXPERTS	FANC Counterparts	Bel V Counterparts
9.	**REGULATIONS AND GUIDES**		
	Tsuyoshi Nakajima Maria de Lourdes Serrano Ramirez Jessie Quintero Sotiris Economides Sandro Trivelloni Pedro Rosario Houda Idihia Kilian Smith	Frederik Van Wonterghem, Jolien Berlamont, Guy Lourtie, Kristel Geerts, Nathan Lemahieu, Robin Klein Meulekamp, Geert Volckaert, Daan Van Der Meersch, Sophie Léonard, An Fremout, Luc Verpoorten, Jurgen Claes, Boris De Handschutter	Dirk Asselberghs, Olivier Smidts, Didier Degueldre, Piet De Gelder, Nicolas Noterman, Pierre Barras, Valéry Detilleux, Tom Van De Velde, François Henry, Sofie Vermote
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Ramon de la Vega	David Rasquin	Didier Degueldre, Stéphane Palmaerts
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Mok Cher Fong	Stéphane Célestin	Benoît Bernard, Daniel Marloye
12.	**REGULATORY IMPLICATIONS OF PANDEMIC SITUATION**		
	Jean Rene Jubin	Simon Coenen	

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	**S1**	The Government should consider revising the National Statement on Nuclear Safety, Nuclear Security and Radiation Protection to reflect the importance of the availability of financial resources for the regulatory functions and a framework for research and development for safety.
	R1	The Government should ensure in a timely manner that adequate financial resources will be available for FANC to fulfil its mandate under any circumstances.
	R2	The Government should render its decisions in a timely manner so that the Regulatory Body may have time to ensure its readiness for establishing adequate regulatory control of the emerging activities.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S2**	FANC should consider completing the analysis on its needed competences and act upon to ensure the availabilities of the necessary competences in the organization.
	R3	The Government should establish regulations or other legal means to require the authorized parties to inform the public about the possible radiation risks associated with the operation of a facility or the conduct of an activity.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R4**	FANC should clearly state the strategic organizational objectives necessary to fulfil its mission.
	R5	FANC should update the Policy on Safety Culture, further document the Leadership for Safety and Safety Culture self-assessment process, and then perform self-assessments regularly.
5. AUTHORIZATION	**R6**	FANC should identify all relevant government departments and authorities to be consulted or informed for new licence applications or operational assessments and update its internal processes and procedures as appropriate.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S3	FANC and Bel V should consider reviewing and revising as appropriate its regulatory framework and internal processes to cater for procurement of components prior to a construction and operation licence being issued.
	R7	Upon proposal from FANC, the Government should revise the royal decree GRR-2001, to incorporate a requirement that all authorized parties keep the generation of radioactive waste to a minimum.
	S4	FANC should consider updating the regulations to use notification and registration of facilities and activities with radiation sources, according to a graded approach.
	R8	FANC should include in the regulations a timeframe for when the licensee of a Class I or IIA facility submits its application for a dismantling licence to FANC for review and approval.
	S5	The Government should consider developing and implementing a strategy for ensuring that the number of specialists for health surveillance of workers covers the country's needs.
	R9	FANC should establish regulatory requirements for the approval of calibration services and the relevant criteria.
	S6	FANC should consider combining the two Radon Risk Maps.
6. REVIEW AND ASSESSMENT	**S7**	FANC and Bel V should consider finalising and implementing the Sub-process on drafting and managing work request, and the Bel V's fundamentals related to review and assessment, respectively.
	S8	FANC and Bel V should consider continuously maintaining the risk analysis associated with the regulatory oversight of LTO of NPPs.
	S9	FANC and Bel V should consider extending the annual integrated safety assessment process with systematic multi-year trend analysis.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S10	FANC should consider establishing criteria in order to conduct the review and assessment for Class II and III industrial and research facilities with radiation sources in accordance with a graded approach.
	R10	FANC should arrange periodic assessment of the radiation doses to the members of the public, due to the transport of radioactive material, and verify that the doses remain below the dose limits.
7. INSPECTION	**S11**	FANC should consider developing and applying a consistent process to maintain necessary competence and skills of nuclear inspectors.
	S12	FANC should consider further focusing on safety culture of licensee staff during research reactor inspection of operational activities.
9. REGULATIONS AND GUIDES	**R11**	FANC should complete regulations for site evaluation of future nuclear facilities in accordance with SSR-1.
	S13	FANC should consider developing and issuing guidelines for establishing and operating the facilities performing the tests of not approved packages.
	S14	The Government should consider expanding the coordination between the Federal Public Service Employment, Labour and Social Concertation and FANC, to bring its regulatory provisions regarding the protection of pregnant workers in line with the IAEA requirements.
	R12	FANC should establish regulatory provisions to ensure that workers provide to the employer or licensee information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.
	R13	FANC should revise the regulations to require an independent verification of calibrations of radiation therapy units prior to their clinical use.
	R14	FANC should revise the regulation to require licensees to keep an updated list of personnel with duties related to medical exposure.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R15	FANC should establish a requirement for licensees to review whether a. patient protection and safety are optimized, or b. corrective actions are required if, for a given radiological procedure, typical doses or activities are substantially below the relevant diagnostic reference level and exposures do not provide useful diagnostic information or the corresponding expected medical benefit to the patient.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R16**	The Government should revise the relevant arrangements to establish a requirement of prompt notification of emergencies, including a specified time for notification to the authorities of emergency situations.
	R17	The Government should ensure that emergency response exercises based on scenarios involving nuclear security events, and involving relevant parties, are carried out at regular predefined intervals.
	S15	FANC should consider updating some relevant materials for FANC EPR staff to fully reflect the current status of national and international EPR related regulations, guidance and inspection procedures.
11. INTERFACE WITH NUCLEAR SECURITY	**GP1**	The regulatory body oversight approach to regulate the interfaces between safety and security, based on their unique use of "confidentiality and the principle of a need-to-know" and the conduct of dedicated inspections at all NPPs is effective.

APPENDIX VI – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

European Directives

1.	Council Directive 2011/70/euratom of 19 july 2011 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste
2.	Council Directive 2013/59/euratom of 5 december 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
3.	Council Directive 2014/87/euratom of 8 july 2014 amending directive 2009/71/euratom establishing a community framework for the nuclear safety of nuclear installations

Laws

4.	Law of 15 April 1994 on the protection of the population and the environment against the dangers of ionising radiation and on the Federal Agency for Nuclear (FANC-law)
5.	Law of 31 January 2003 on the gradual phase-out of nuclear energy for industrial electricity production
6.	Loi du 7 mai 2004 relative aux expérimentations sur la personne humaine
7.	Loi coordonnée du 10 mai 2015 relative à l'exercice des professions des soins de santé
8.	Loi du 10 juillet 2008 relative aux hôpitaux et à d'autres établissements de soins
9.	Loi du 22 avril 2019 relative à la qualité de la pratique des soins de santé (1)
10.	Loi du 22 août 2002 relative aux droits du patient
11.	Loi du 4 août 1996 relative au bien-être des travailleurs lors de l'exécution de leur travail
12.	Loi du 20 novembre 2022 relative à la gestion des sols contaminés par des substances radioactives
13.	Law of 8 August 1980, Art 179 – Creation of NIRAS/ONDRAF (management of spent fuel and radioactive waste) and its underlying royal decree of 30 March 1981, regarding NIRAS/ONDRAF.

Royal Decrees

14.	Royal decree of 20 July 2001 laying down the General Regulation for the protection of the public, workers and the environment against the hazards of ionising radiation (GRR-2001)
15.	Royal decree of 22 October 2017 on the transport of dangerous goods of class 7
16.	Royal Decree of 30 November 2011 on the safety requirements for nuclear installations (SRNI-2011)
17.	Royal decree of 13 February 2020 on medical exposures and exposures in non-medical imaging with medical radiological equipment (RD Med)
18.	Royal dDecree of 12 July 2015 on radioactive products for in vitro or in vivo use in medicine, veterinary medicine, a clinical trial or clinical investigation
19.	Arrêté royal du 1 mars 2018 portant fixation du plan d'urgence nucléaire et radiologique pour le territoire belge
20.	Royal decree of 20 July 2020 setting out the format, content and access and usage methods and restrictions for the exposure register and the radiation passport, amending the royal decree of 20 July 2001 laying down the general regulations for the protection of the public, workers and the environment against the hazards of ionising radiation
21.	Royal decree of 24 March 2009 regulating import, transit and export of radioactive substances
22.	Arrêté royal du 30 juin 2004 déterminant des mesures d'exécution de la loi du 7 mai 2004 relative aux expérimentations sur la personne humaine en ce qui concerne les essais cliniques de médicaments à usage humain

23. Arrêté royal du 4 avril 2014 fixant les mesures d'exécution de la loi du 7 mai 2004 relative aux expérimentations sur la personne humaine, concernant le comité d'éthique
24. Arrêté royal du 22 décembre 2017 relatif au titre professionnel et aux conditions de qualification requises pour l'exercice de la profession de technologue en imagerie médicale et portant fixation de la liste des prestations techniques et de la liste des actes dont celui-ci peut être chargé par un médecin
25. Arrêté royal du 18 juin 1990 portant fixation de la liste des prestations techniques de l'art infirmier et de la liste des actes pouvant être confiés par un médecin ou un dentiste à des praticiens de l'art infirmier, ainsi que des modalités d'exécution relatives à ces prestations et à ces actes et des conditions de qualification auxquelles les praticiens de l'art infirmier doivent répondre
26. Arrêté royal du 28 novembre 1986 fixant les normes auxquelles un service d'imagerie médicale où est installé un tomographe axial transverse doit répondre pour être agréé comme service médical technique au sens de l'article 6bis, § 2, 6°bis, de la loi sur les hôpitaux.
27. Arrêté royal du 5 avril 1991 fixant les normes auxquelles un service de radiothérapie doit répondre pour être agréé comme service médico-technique
28. Arrêté royal du 25 avril 2014 modifiant l'arrêté royal du 14 décembre 2006 fixant les normes auxquelles un service de médecine nucléaire où est installé un scanner PET doit répondre pour être agréé comme service médico-technique au sens de l'article 44 de la loi sur les hôpitaux, coordonnée le 7 août 1987
29. Arrêté royal du 15 décembre 1978 fixant des normes spéciales pour les hôpitaux et services universitaires
30. Arrêté royal du 3 mai 1999 relatif au dossier médical général
31. Arrêté royal du 14 octobre 2011 relatif à la recherche de substances radioactives dans certains flux de matières et de déchets, et relatif à la gestion des établissements sensibles en matière de sources orphelines
32. Royal decree of 17 February 2023 on industrial radiography
33. Code du bien-être au travail
34. Royal decree of 17 October 2011 on the physical protection of nuclear material and nuclear installations
35. Arrêté royal du 2 juin 2021 modifiant l'arrêté royal du 17 octobre 2011 relatif à la protection physique des matières nucléaires et des installations nucléaires et l'arrêté royal du 30 novembre 2011 portant prescriptions de sûreté des installations nucléaires
36. (*Project*) Arrêté royal portant régime d'autorisation des établissements de stockage de déchets radioactifs
37. Royal decree of 14 octobre 2011 concerning the detection of radioactive materials in certain materials and waste flows and the management of orphan source sensitive facilities

FANC Directive

38. Arrêté du 1e mars 2012 de l'Agence fédérale de Contrôle nucléaire fixant les activités professionnelles visées à l'article 4 de l'arrêté royal du 20 juillet 2001 portant règlement général de la protection de la population, des travailleurs et de l'environnement contre le danger des rayonnements ionisants
39. Exigences de l'Autorité de sûreté pour la préparation et la mise en œuvre des phases de construction et de mise en service d'une nouvelle installation nucléaire dans un établissement de classe I (2016-09-09-SCZ-5-3-8)
40. Technical Guide on Surface Disposal of Low and Intermediate Level Short-Lived Waste on Belgian Territory (007-228 F)
41. Technical Guide on risk of human intrusion - Surface disposal of low and intermediate level short-lived radioactive waste on the Belgian territory – (007-087-EN)

42. Technical Guide on 'Safety Analysis: Groundwater Aspects' - Surface disposal of low and intermediate level short-lived radioactive waste on the Belgian territory (008-255 E)
43. Guideline on external events - Surface disposal of low and intermediate level waste on Belgian territory (008-241)
44. Guidance on earthquakes - Near surface disposal, on Belgian territory, of short-lived low and intermediate level radioactive waste (007-125-E)
45. Guide intégré de sûreté des stockages définitifs géologiques (2014-09-23-FB-5-3-2)
46. Safety assessment: biosphere (008-217-E)
47. Guide on the radiological protection during the operational period of a facility for the disposal of radioactive waste (008-007 EN)
48. Technical Guide "Radiation Protection Criteria for Post-Operational Safety Assessment for Radioactive Waste Disposal" (2011-06-28-CAD-5-4-3-EN)
49. (*Project*) Guide technique "Analyse de la sûreté post-fermeture des établissements de stockage définitif de déchets radioactifs" (2012-02-28-FLE-5-4-4-FR
50. Explications portant sur la table des matières, le contenu attendu et la structure du rapport de sûreté destiné à couvrir l'ensemble des périodes et phases de la vie d'un établissement de stockage définitif en surface de déchets radioactifs de faible et moyenne activité et de courte demi-vie sur le territoire de la commune de Dessel (2011-06-06-PDC-S-4-1-FR)
51. FANC technical regulation of 17 November 2014 - Guidelines to be observed in the event of detection or discovery of an orphan source in orphan source sensitive facilities in the non-nuclear sector

FANC Technical Regulation

52. FANC technical regulation of 8 November 2021 setting the quality criteria relating to the methods for assessing the doses resulting from exposure to cosmic radiation of aircrew
53. FANC technical regulation of 7 October 2021 setting the criteria on the basis of which the dose received by aircrew may be considered to be less than 1 mSv per year
54. FANC technical regulation of 18 January 2022, establishing radon risk zones, Annexe 1 : Classification schématique des communes belges en classes radon
55. Technical regulations of 27 May 2021 specifying the practical arrangements of the nuclear safety objective in accordance with Article 3/1 of the royal decree of 30 November 2011 on the safety requirements for nuclear installations
56. Technical regulation dated 5 July 2019 of the Federal Agency for Nuclear Control setting out the conditions and criteria for declaration of significant events relating to nuclear safety and the protection of natural persons and of the environment in Class I facilities
57. Annex to technical regulation dated 5 July 2019 of the Federal Agency for Nuclear Control setting out the conditions and criteria for declaration of significant events relating to nuclear safety and the protection of natural persons and of the environment in Class I facilities
58. Fixation des critères et modalités de déclaration des modifications dans le cadre de l'article 12 du règlement général Règlement technique de l'Agence fédérale de Contrôle nucléaire du 6 décembre 2021 fixant les critères et modalités de déclaration des modifications dans le cadre de l'article 12 du règlement général
59. Précision des modalités des révisions périodiques de sûreté des établissements de classe I, à l'exception des réacteurs de puissance Règlement technique de l'Agence fédérale de Contrôle nucléaire du 2 février 2021 précisant les modalités des révisions périodiques de sûreté des établissements de classe I, à l'exception des réacteurs de puissance
60. Technical regulation of the FANC dated 31 January 2019 setting out the criteria for declaration to the FANC of significant events relating to radiation protection and/or safety of workers, the public, patients and the environment in procedures in Class II and III facilities and during transport.

61. Technical regulation of 17 November 2020 setting out the methods for compiling dose reports and for sending the results of individual dose monitoring to the Agency, and methods for consulting doses contained in the exposure register and for obtaining the radiation passport
62. Technical regulation of 21 May 2021 establishing the conditions and criteria for recognition of dosimetry services for the purposes of carrying out external dosimetry
63. Technical regulation of 21 May 2021 establishing the conditions and criteria for recognition of dosimetry services for the purposes of carrying out radiotoxicology analysis
64. Règlement technique du 30 mars 2020 fixant les contraintes de dose pour les personnes participant à des expérimentations sur la personne humaine qui impliquent des expositions médicales et pour lesquelles aucun avantage médical direct n'est attendu de ces expositions
65. Règlement technique du 29 juin 2020 fixant le modèle de la carte de sortie après l'administration à une personne d'un produit radioactif à des fins radiothérapeutiques
66. Règlement technique du 15 décembre 2021 établissant le modèle et les modalités de l'étude de justification en faveur de l'adoption pour utilisation généralisée d'une pratique impliquant une exposition à des fins médicales ou une exposition à des fins d'imagerie non médicale avec des équipements radiologiques médicaux
67. Règlement technique du 7 septembre 2020 établissant les critères minimaux d'acceptabilité pour les équipements radiologiques médicaux ayant recours aux rayons X à des fins de fluoroscopie (appareils de fluoroscopie)
68. Règlement technique du 19 février 2020 fixant les critères d'acceptabilité pour les activimètres utilisés en médecine nucléaire ou à des fins d'imagerie non médicale avec des équipements radiologiques médicaux ainsi que les procédures concernées
69. Règlement technique du 19 février 2020 fixant les critères d'acceptabilité pour les gamma-caméras utilisées à des fins d'imagerie médicale ou non médicale avec des équipements radiologiques médicaux ainsi que les procédures concernées
70. Règlement technique du 19 février 2020 fixant les critères d'acceptabilité pour les équipements radiologiques médicaux utilisant des rayons X à des fins d'imagerie
71. Règlement technique du 19 février 2020 fixant les critères d'acceptabilité pour les équipements radiologiques médicaux utilisant des rayons X à des fins de radiographie dento-maxillo-faciale simple
72. Règlement technique du 19 février 2020 fixant les critères d'acceptabilité pour les scanners PET utilisées à des fins d'imagerie médicale ou non médicale avec des équipements radiologiques médicaux ainsi que les procédures concernées
73. Règlement technique du 30 mars 2020 établissant les critères minimaux d'acceptabilité pour les équipements radiologiques médicaux destinés à la tomodensitométrie (scanners CT)
74. Règlement technique du 19 février 2020 fixant les modalités des études périodiques de dose au patient en radiodiagnostic utilisant des rayons X et en radiologie interventionnelle
75. Règlement technique du 19 février 2020 fixant les modalités des études périodiques de dose au patient en médecine nucléaire
76. Règlement technique du 20 octobre 2022 fixant les niveaux de référence diagnostiques en radiodiagnostic utilisant des rayons X
77. Règlement technique du 19 février 2020 fixant les niveaux de référence diagnostiques en médecine nucléaire
78. Règlement technique du 30 juillet 2020 fixant les modalités de la notification à l'Agence fédérale de Contrôle nucléaire des expositions accidentelles ou non intentionnelles visées aux articles 60 et 117 de l'Arrêté expositions médicales
79. Règlement technique du 19 février 2020 portant les modalités des audits cliniques des installations radiologiques médicales où sont mises en œuvre des pratiques radiologiques médicales sous la responsabilité médicale d'un praticien autorisé en vertu des articles 64, 66, 67 et 70 de l'arrêté expositions médicales

80. Règlement technique du 19 février 2020 portant les modalités et fréquences des audits cliniques des installations radiologiques médicales où sont mises en œuvre des pratiques radiologiques médicales sous la responsabilité médicale d'un nucléariste
81. Technical regulations of 6 October 2020 on training programmes for radiation protection officers
82. Technical regulation issued by the Federal Agency for Nuclear Control on 01/07/2020 concerning Chapter 4 of the royal decree of 22 October 2017 on the transport of Class 7 dangerous goods, amended on 3 July 2019
83. Technical regulation issued by the Federal Agency for Nuclear Control on 19 June 2020 concerning Chapter 5 of the royal decree of 22 October 2017 on the transport of Class 7 dangerous goods, amended on 3 July 2019
84. Technical regulation issued by the Federal Agency for Nuclear Control on 14 July 2020 concerning Chapter 6 of the royal decree of 22 October 2017 on the transport of Class 7 dangerous goods, amended on 3 July 2019
85. Technical regulations issued by the Federal Agency for Nuclear Control on 13 December 2017 concerning Chapters 7, 8 and 9 of the royal decree of 22 October 2017 on the transport of Class 7 dangerous goods

FANC Management System documents

86. FANC policies: Authorization (AUT); Communication (COM); Enforcement (ENF) ; Financial resources (RES) ; Human resources (HR) ; Significant events & crisis management (INC) ; ICT; Inspections (INS); International (INT); Internal Control (ICO); Management system (MGS); Regulation (REG); Review & assessment (R&A); Radiological monitoring (SUV); Safety Culture Policy (STE-17-05-EN)
87. Tableau des représentations internationales de l'AFCN et de BEL V (INT-SP01)
88. Procedure for drafting texts on the regulatory framework (REG-01-01)
89. Process for managing emergency and crisis situations for which a local (provincial or municipal) Emergency Preparedness and Response Plan applies and for which support from the FANC is requested (INC-03)
90. FANC Note - 3S Approach and the Safety Security interface in Class I facilities (0200303-RD-6-3-035)
91. FANC Note - Strategy 2023-32
92. Cooperation Agreement between the Federal Agency for Nuclear Control and Bel V
93. Management Contract between the Federal Agency for Nuclear Control and Bel V

Bel V Management System documents

94. Competence Gap Analysis (Q080503-01-00-p-org-e)
95. Define inspection programmes and plannings (Q040100-01-00-p-all-f)
96. Deliver Documents and Reports related to expert services (Q060300-01-00-p-org-e)
97. Graded Approach (Q040201-01-00-i-c12-b)
98. Grade Approach non-NPP (Q040201-02-00-i-c12-b)
99. Inspector's Fundamentals (Q040000-01-02-f-all-e)
100. Inspector Programme (Q040100-01-01-p-cl1-n)
101. Knowledge Critical Grid (Q070102-01-02-i-org-e.doc)
102. Managing operating experience feedback (REX) (Q040800-01-00-p-org-e)
103. Procedure List (Q120103-01-06-f-org-x)
104. Producing the inspection reports (Q040400-01-00-p-all-f)
105. Quality Manual (Q120102-01-00-m-org-e.docx)
106. Response to event (Q040903-01-00-p-org-f)
107. Individual Basic Training Programme (Q080503-01-03-t-org-e)

108.	Organizing the Technical Responsibility Centers (TRC) (Q060001-01-00-p-org-e)
109.	Codes and naming of TRCs (Q060001-01-02-f-org-e)
110.	Regulatory Body Safety Culture Assessment (Q010200-01-01-p-org-e)

Other documents

111.	Annual Report of the FANC, 2022.
112.	Belgian National Report for the 9th Review Meeting of the Convention on Nuclear Safety, 2022.
113.	Antropogenic Radon risk, 2022.
114.	Interactive map on Radon in Belgium, 2022.
115.	Technical guidance for operators of facilities for processing and recycling of NORM residues (2013-02-05-SP-7-4-3-NL)
116.	Manuel de mesure du radon dans les lieux de travail et habitations (afcn.fgov.be/fr/system/files/manuel_mesure_radon.pdf)
117.	Belgian National Radon Action Plan 2020-2025.
118.	Application for license to add radioactive substances to consumer goods.
119.	IRRS Report of Belgium, IAEA, 2013.
120.	IRRS Follow-up Report of Belgium, IAEA, 2017.
121.	Advanced Reference Material (ARM) Report for IRRS Follow-up of Belgium, 2017.
122.	Belgian National Report for 7th meeting of the Contracting Parties to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, 2020.
123.	National Declaration of 31 August 2018 on Nuclear Safety, Nuclear Security and Radiation Protection.
124.	Inspections programme of the Belgian competent authority (FANC) for non-approved and approved package designs, PATRAM, 2019.
125.	Guidance dépôts géologiques SR3 - Exigences relatives aux composants naturels (2011-07-01-FB-5-6-3-FR)
126.	Note de convergence optimisation (2013-12-18-FB-5-1-2-FR)
127.	Note AFCN/Bel V- ONDRAF décrivant une réflexion commune sur les notions de réversibilité, récupérabilité et concepts associés (2019-12-18)
128.	Advies van het FANC betreffende NIRAS documenten: Ontwerp van Afvalplan (AP) en bijhorend Strategic Environmental Assessment (SEA) (010-149-N)
129.	Positions de l'AFCN relatives au stockage géologique et à la gestion à long terme des déchets B&C (2015-03-06-FB-5-1-3-FR)
130.	Avis de l'AFCN sur le Programme National du 10 avril 2015 (2015-04-29-AW-5-4-1-FR)
131.	Avis de l'AFCN sur la première partie de la Politique nationale en matière de gestion à long terme des déchets radioactifs de haute activité et/ou de longue durée de vie et le processus d'institution par étapes des autres parties de cette Politique nationale (2021-05-20-FB-5-4-1-FR)
132.	Avis de l'AFCN sur le plan de gestion à long terme des déchets radioactifs conditionnés de haute activité et/ou de longue durée de vie, le rapport d'incidences sur l'environnement qui l'accompagne et le résumé non technique (2020-05-29-FB-5-4-1-FR)
133.	Strategic issues underlying the development of expertise and skills of FANC/Bel V in geological disposal of radioactive waste and spent fuel (2016-12-16-FB-5-4-2-EN)
134.	Principes d'examen SFC1 (2013-06-27)
135.	Werkprogramma 2020-2022 in het kader van de samenwerkingsovereenkomst FANC-NIRAS

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. **INTERNATIONAL ATOMIC ENERGY AGENCY –** Leadership and Management for Safety, General Safety Requirements Part 2, No GSR Part 2, IAEA, Vienna (2016)
4. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No GSR Part 3, IAEA, Vienna (2014).
5. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety assessment for facilities and activities, General Safety Requirements Part 4, No GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Predisposal Management of Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
7. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
8. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
9. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Specific Safety Requirements No SSR-1, IAEA, Vienna (2003)
10. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements No SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements No SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Specific Safety Requirements No SSR-3, IAEA, Vienna (2016)
13. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements No SSR-4, IAEA, Vienna (2017)
14. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Disposal of Radioactive Waste, Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
15. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018)
16. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No GSG-1, IAEA, Vienna (2009)
17. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide No GSG-2, IAEA, Vienna 2011)
18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide No GSG-6, IAEA, Vienna (2017)
19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide No GSG-7, IAEA, Vienna (2018)
20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide No GSG-9, IAEA, Vienna (2018)
21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide No GSG-12, IAEA, Vienna (2018)

22. INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide No GSG-13, IAEA, Vienna (2018)
23. INTERNATIONAL ATOMIC ENERGY AGENCY Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide No GSG-16, IAEA, Vienna (2022)
24. INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide No GS-G-2.1, IAEA, Vienna (2007)
25. INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide No SSG-71, IAEA, Vienna (2022)
26. INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide No NS-G-2.8, IAEA, Vienna (2002)
27. INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide No RS-G-1.8, IAEA, Vienna (2005)
28. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide No RS-G-1.10, IAEA, Vienna (2008)
29. INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide No SSG-1, IAEA, Vienna (2009)
30. INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides No SSG-2, IAEA, Vienna (2010)
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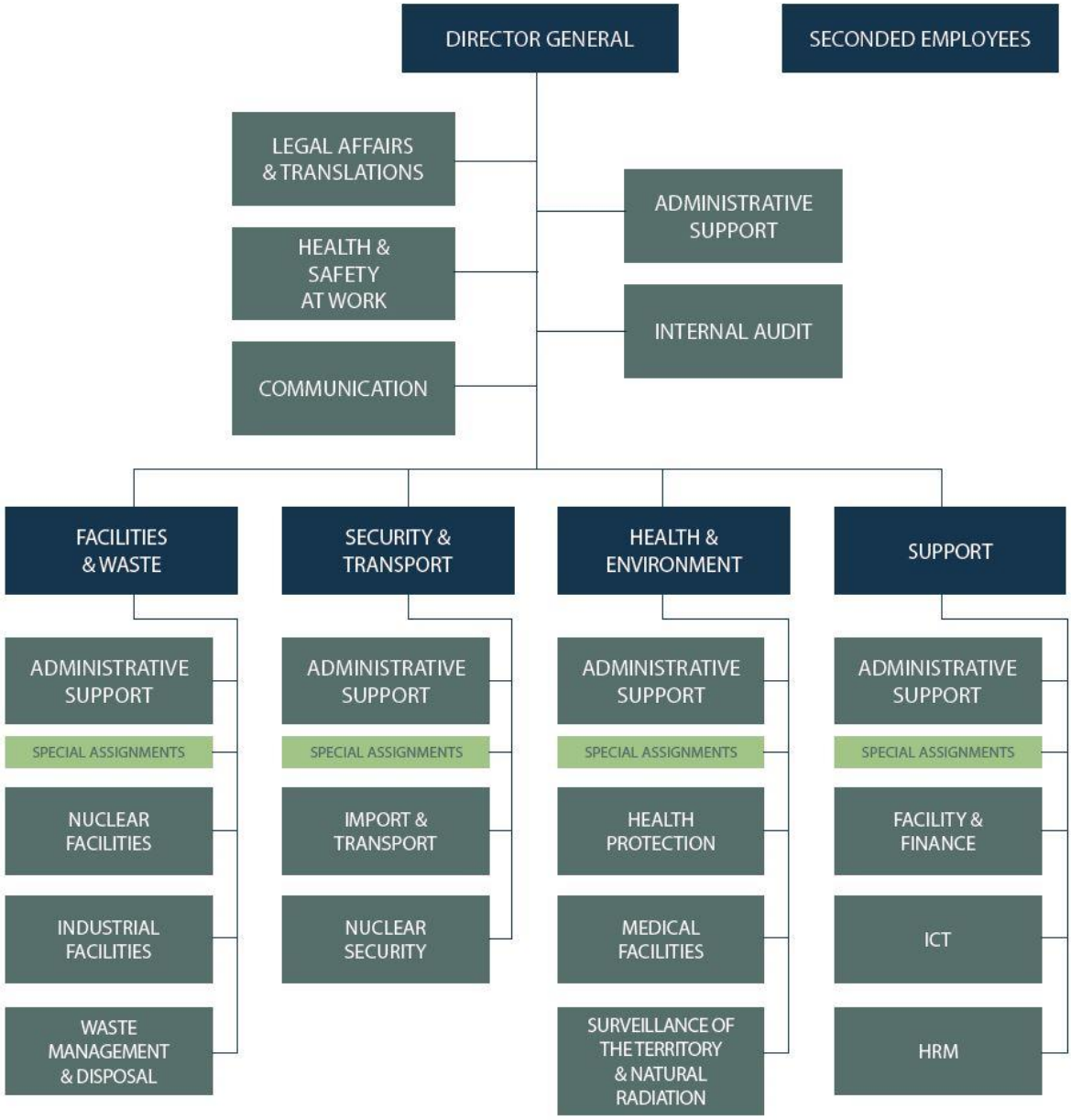
APPENDIX VIII – ORGANIZATIONAL CHART

FANC
FEDERAL AGENCY FOR NUCLEAR CONTROL



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