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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE NETHERLANDS

The Hague, The Netherlands

5-16 June 2023

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Authority for Nuclear Safety and Radiation Protection

IAEA Integrated Regulatory Review Service IRRS

Ministry of Infrastructure and Water Management

Integrated
Regulatory
Review Service

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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THE NETHERLANDS

Mission dates:	*5-16 June 2023*
Regulatory body visited:	*Authority for Nuclear Safety and Radiation Protection (ANVS)*
Location:	*Koningskade 4, 2596 AA Den Haag, the Netherlands*
Regulated facilities, activities, and exposure situations in the mission scope:	*Nuclear power plants, research reactors, waste management facilities, uses of radiation sources in research and industry, transport, as well as medical, occupational and public exposure.*
Organized by:	*IAEA*

IRRS TEAM	
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DE OLIVEIRA MARTINS João	Reviewer (Portugal)
ION Mihaela-Alina	Reviewer (Romania)
JUHASZ Laszlo	Reviewer (Hungary)
LIETAVA Peter	Reviewer (Czech Republic)
PETCU Maura	Reviewer (Romania)
POLITI Adriana Angela	Reviewer (Argentina)
RAMASAMY Uma	Reviewer (Australia)
TRIVELLONI Sandro	Reviewer (Italy)
TUOMAINEN Minna	Reviewer (Finland)
ZAZZI Åsa	Reviewer (Sweden)
SIMOLA Kaisa Anneli	Observer (EC)
MACSUGA Geza	IAEA Team Coordinator
PACHECO JIMENEZ Ronald	IAEA Deputy Team Coordinator
REBIKOVA Olga	IAEA IRRS Administrative Assistant

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.

CONTENTS

EXECUTIVE SUMMARY

An international team of senior safety experts met representatives of the Authority for Nuclear Safety and Radiation Protection (ANVS), the Ministry of Infrastructure and Water Management (I&W), the Ministry of Social Affairs and Employment (SZW), the Netherlands Labour Authority (NLA), the Ministry of Health, Welfare and Sports (VWS) and the Health and Youth Care Inspectorate (IGJ) from 5 June 2023 until 16 June 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Dutch regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the Netherlands on 6 February 2019. The preparatory meeting of the IRRS mission was organized in The Hague, the Netherlands, at the Headquarters of the ANVS on 17-18 January 2023 to discuss the purpose, objectives, scope and detailed preparations of the review in connection with regulated facilities and activities in the Netherlands and their related safety aspects and to agree the scope of the IRRS mission.

The mission took place at the ANVS Headquarters in The Hague. The IRRS mission covered all civilian nuclear and radiation facilities and activities in the Netherlands. The review compared the Dutch regulatory framework for nuclear and radiation safety against IAEA safety standards as an international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Dutch counterparts in the areas covered by the 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 on 19-28 November 2023. To avoid unnecessary duplications 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 Chapter 1.7 of this IRRS mission report are to be reviewed by the upcoming ARTEMIS mission.

The IRRS team consisted of 16 senior regulatory experts from 13 IAEA Member States, 4 IAEA staff members and 1 observer from the European Commission. 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; regulatory aspects of emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The IRRS mission also included a policy discussion on the governmental and regulatory challenges with respect to new nuclear facilities.

The ANVS and the Ministries of I&W, SZW and VWS 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 for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the advance reference material, conduct of interviews with management and staff from the different authorities and by direct observation of some regulatory inspections at a nuclear power plant, research reactor, radioactive waste management facility and a hospital. The IRRS mission was a full-scope mission that was intended to cover all relevant regulatory bodies and government departments. However, the ARM only contained comprehensive information on the management system for ANVS, for this reason only the management system of the ANVS could be reviewed. The IRRS team met with representatives from the Ministry of SZW, NLA, Ministry of VWS and IGJ to address the legal framework, policy matters and inspection for occupational and medical exposure.

The IRRS report includes a number of recommendations and suggestions to improve the Dutch regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The IRRS team acknowledges that many of its findings confirm the actions for further improvement that were identified in the self-assessment by the regulatory authorities.

The IRRS team concluded that the following issues are representative of those which, if addressed by the Government of the Netherlands and the regulatory authorities, should further enhance the overall performance of the regulatory system.

The Government should:

- develop a national strategy for safety that sets out the mechanisms for implementing the national policy for radiation protection and nuclear safety, considering a graded approach, in line with the IAEA Safety Fundamentals.
- evaluate and improve, as required, the regulatory framework and ensure that there are provisions for sufficient resources to regulate future facilities and activities, in line with national priorities.
- consider ensuring the establishment of formal working agreements between all authorities responsible for assuring the regulatory framework for safety.

The Ministry of VWS should:

- ensure that diagnostic reference levels for medical exposure, dose constraints for carers and comforters and for volunteers participating in a programme of biomedical research are established.
- consider ensuring the completion of referral guidelines for individual medical exposures.

The ANVS should:

- implement the improvements of the ANVS Integral Management system (AIM), in order to identify and develop its processes and procedures in a coherent manner, integrate them in its management system, and ensure that the management system is consistently used throughout the organisation.
- continue the development and implementation of a multi-annual inspection programme for nuclear facilities.
- further develop regulations and guides to be consistent with current IAEA safety standards.

The IGJ should:

- develop a regulatory inspection programme for medical exposures and implement it through the annual inspection plans following a graded approach.

In recognition of an outstanding programme, the IRRS team identified two good practices in ANVS's activities related to

- developing a guide on the use of level 3 probabilistic safety assessment for research reactors and implementing it during the licensing process of the PALLAS Research Reactor.
- developing the information system Calamiteiten Net (CalNET) that forms a robust basis for coordination of national and cross-border protective actions during the early phase of a nuclear accident.

Furthermore, the IRRS team was made aware of several areas of good performance, examples being the ANVS's robust risk informed inspection planning which targets potential vulnerabilities in the operation of a radiation source facility or performance of an activity, as well as objectively researching areas where it recognizes its own lack of knowledge or potential blind spots to further optimise its regulatory inspection program of radiation sources and facilities.

To conclude, by inviting the IAEA to conduct this IRRS mission and providing a transparent self-assessment, the Government of the Netherlands and the regulatory bodies have demonstrated their commitment to continuous improvement, a basic principle for excellence in nuclear and radiation safety. This report, in particular its recommendations and suggestions, should be viewed in that context.

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

An international team of senior safety experts met representatives of the Authority for Nuclear Safety and Radiation Protection (ANVS); the Ministry of Infrastructure and Water Management (I&W); the Ministry of Social Affairs and Employment (SZW); the Netherlands Labour Authority (NLA); the Ministry of Health; Welfare and Sports (VWS) and; the Health and Youth Care Inspectorate (IGJ) from 5th June 2023 to 16th June 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Dutch regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of The Netherlands on the 6th of February 2019. The preparatory meeting of the IRRS mission was organized in The Hague, the Netherlands, at the Headquarters of the ANVS on 17-18 January 2023 to discuss the purpose, objectives, scope and detailed preparations of the review in connection with regulated facilities and activities in the Netherlands and their related safety aspects and to agree the scope of the IRRS mission.

This mission was organized with a back-to-back to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled on 19-28 November 2023. To avoid unnecessary duplications 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 IRRS mission report are to be reviewed by the upcoming ARTEMIS mission.

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The ANVS, Ministry of Infrastructure and Water Management (I&W), Ministry of Social Affairs and Employment (SZW), and Ministry of Health, Welfare and Sports (VWS) 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 for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the advance reference material, conducted interviews with management and staff from the different authorities and by direct observation of some regulatory inspections at a nuclear power plant, research reactor, radioactive waste management facility and a hospital. The IRRS mission was a full scope mission that was intended to cover all relevant regulatory bodies and government departments. However, the ARM only contained comprehensive information on the management system for ANVS, for this reason only the management system of the ANVS could be reviewed. The IRRS team met with representatives from the Ministry of SZW, NLA, the Ministry of VWS and IGJ to address the legal framework, policy matters and inspection for occupational and medical exposure.

All through the mission the IRRS team received excellent support and cooperation from the Host Country.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Netherlands 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. The agreed scope of this IRRS review included all facilities and activities regulated in the Netherlands. It is expected this IRRS mission will facilitate regulatory improvements in the Netherlands and other Member States, utilising the knowledge gained and experiences shared between Host counterparts and IRRS reviewers and the evaluation of the Dutch regulatory framework 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 the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (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 the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country 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 the Netherlands, an IRRS preparatory meeting was conducted from 17 to 18 January 2023. The preparatory meeting was carried out by the appointed Team Leader Mr Cantemir Ciurea-Ercau, Deputy Team Leader Ms Nancy Greencorn, the IAEA Coordinator Mr Geza Macsuga and Deputy IAEA Coordinator Mr Ronald Pacheco.

The IRRS mission preparatory meeting had discussions regarding the regulatory programmes and one policy issue with senior management and staff of the Ministry of Infrastructure and Water Management, represented by Mr Joris van der Voet, Deputy Director of the Environmental Risks and Safety Directorate, and the ANVS, represented by Ms Annemiek van Bolhuis, Chair of the ANVS Board. 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 IAEA safety guides:

- Nuclear power plants;
- Research Reactors,
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal); and
- Selected policy issues.

Mr Joris van der Voet, Deputy Director of the Environmental Risks and Safety Directorate at the Ministry of Infrastructure and Water Management, and Mr Marco Brugmans, Vice Chair of the ANVS Board made presentations on the national context, the current status of the Regulatory Programme and the self-assessment results to date. IAEA staff Mr Geza Macsuga presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in the Netherlands in June 2023. The proposed composition of the IRRS team was discussed and confirmed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Dutch Liaison Officers for the IRRS mission were confirmed as Mr Louk Bracco Gartner (ANVS) and Mr Wouter Van Lonkhuyzen (Ministry of I&W).

The Host representatives provided the IRRS team with the advance reference material (ARM) for the review by the 4th of April 2023. In preparation for the mission, the IAEA review team members reviewed the Host Country advance reference material and provided their initial impressions to the IAEA Team 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 VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS Team meeting took place on Sunday, 4 June 2023 in Hotel Novotel Den Haag City Centre, directed by the IRRS Team Leader and the IRRS IAEA Team 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 team by the Team Coordinator. 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, 5 June 2023, with the participation of senior management and staff of the Dutch Authorities. Opening remarks were made by Ms Afke van Rijn, Director-General of DG Environment and International Affairs, Ministry of Infrastructure and Water Management and Mrs Annemiek Van Bolhuis, Chair of the ANVS Board. Mr Cantemir Ciurea-Ercau, the IRRS Team Leader presented the IRRS team's expectations and Mr Geza Macsuga, the IRRS Coordinator introduced the mission schedule.

Mr Marco Brugmans, the Vice Chair of the ANVS Board and Mr Joris Van der Voet, Deputy Director of Environmental Risks and Safety Directorate gave an overview of the host country context, regulatory activities and the action plan as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing the host country and regulatory body with recommendations and suggestions for improvement and 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, 16 June 2023. Acknowledgements at the exit meeting were made by Ms Vivianne Heijnen, State Secretary of the Ministry of Infrastructure and Water Management and Ms Afke van Rijn, Director-General of DG Environment and International Affairs at Ministry of Infrastructure and Water Management. Followed by the presentation of the results of the mission by the IRRS Team Leader Mr Cantemir Ciurea-Ercau. To conclude, remarks from the ANVS were made by Ms Annemiek van Bolhuis, Chair of the ANVS Board. Closing remarks were made by Ms Anna Hajduk Bradford, IAEA, Director, Division of Nuclear Installation Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Netherlands has established a governmental and regulatory framework for nuclear and radiation safety. This framework is set across multiple legislation that define and allocate responsibility for safety.

The Dutch policy for nuclear and radiation safety is expressed in the Nuclear Energy Act (KeW) and the underlying decrees and regulations. The responsibility for national policy and legislation on nuclear safety, security and radiation protection falls within the jurisdiction of the Ministry of I&W.

The national policy document "Guidance to national policy for nuclear safety and radiation protection 2022" includes: the statutory framework; the graded approach for licensing; supervision and enforcement issues; emergency preparedness and response; security and safeguards; radioactive waste management; safety culture; communication initiatives; knowledge management and financial resources. The Dutch policy and legislation has incorporated the IAEA's Fundamental Safety Principles, transposition of the EURATOM directives and other binding international legal instruments.

In order to set out the mechanism for implementing the national policy for radiation protection and nuclear safety, the policy needs to be supported by a national strategy for safety. Elements of a strategy are present in several documents (e.g. letters to the Parliament, policy documents and programs).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Elements of a strategy are present in several documents (e.g. letters to the Parliament, policy documents and programs), however the Government has not yet developed a holistic national strategy for safety setting out the mechanisms for implementing the policy.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 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".*
(2)	**BASIS: GRS Part 1 (Rev. 1) para 2.3 (a) states that** "*In the national policy and strategy, account shall be taken of the following: (a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles".*
R1	**Recommendation: The Government should develop a national strategy for safety that sets out the mechanisms for implementing the national policy for radiation protection and nuclear safety, considering a graded approach, in line with the IAEA Safety Fundamentals.**

The policy document was elaborated by the Directorate-General for the Environment and International Affairs, Ministry of I&W and the ANVS, in cooperation with the other departments involved. This document is considered the Government's commitment to safety and a way to promote the leadership for safety and safety culture.

The graded approach is applied in principle in regulations and underlying guides promulgated under the KeW. The graded approach in the ANVS is applied both in the management of available resources and in the regulatory oversight activities.

In addition, there is a National Programme for the management of radioactive waste and spent fuel. This was issued in 2016 and is currently under revision. The national programme on waste management will be considered as part of the upcoming ARTEMIS mission in November 2023.

In December 2021, the Government sent letters to the Parliament about the next steps for the Dutch nuclear sector. These include the plans to construct two new nuclear power plants, the extension of the lifetime of Borssele nuclear power plant and intended ensuring the safe management of radioactive waste on the long-term. Attention has been paid to the inclusion of new technology of small modular reactors. A new letter "Conditions for new build Nuclear Power Plants in the Netherlands" has been prepared by the Government and sent to the Parliament.

The ANVS uses the term “safety first” in its high-level documentation and aspires to implement safety culture principles throughout the organisation. The ANVS implemented some elements of safety culture, such as the open-door policy, feedback on the results of weekly management team meetings, employee perception surveys, apart the leading principles for the organisation “safety first”, individual responsibility and justified trust, continuous improvement, risk oriented, separation of functions/roles. The IRRS team was provided with a report on an Annual plan on Working Conditions. This report provides the aim for maintaining and improving durable and safe working conditions both inside and outside office-locations. For example: special driving skills training, how to handle aggression and violence on the job, and personal protection equipment.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Dutch framework for nuclear safety and radiation protection is comprised of several pieces of legislation (laws, decrees, ministerial regulations, the ANVS regulation, licence conditions, guidelines and codes) which form a safety framework for controlling risks arising from the use of ionising radiation to workers, patients, public and the environment.

There are several ministries whose responsibilities are stated in the legislative framework: Ministry of I&W having the primary responsibility for the system, legislation and policy development in the area of nuclear safety, security and radiation protection, including radioactive waste and geological disposal; Ministry of SZW being responsible for protecting employees against dangers from ionizing radiation in non-nuclear installations; Ministry of VWS being responsible for protecting patients, and the availability of medical isotopes; the Ministry of Economic Affairs and Climate (EZK) being responsible for energy policy and mining, including the use of nuclear energy; the Ministry of Defence being responsible for nuclear facilities, fissionable and radioactive materials intended for use in the armed forces; and the Ministry of Foreign Affairs responsible for non-proliferation and safeguards.

The main document governing the area of nuclear and radiation safety is the KeW issued in 1963, with subsequent modifications. It has specific provisions for radiation protection, referring to exposure situations, environmental protection, safety of the public, safety of workers, safety of patients, transport, emergency preparedness, safeguards and security, but also designates the competent authorities and outlines their responsibilities. This Act sets up the ANVS as the primary nuclear and radiation safety regulatory authority having legal authority for conducting the regulatory processes, including issuing authorizations, supervision and enforcement, and thereby regulating areas such as nuclear safety, security and safeguards, radiation protection, radioactive waste management and spent nuclear fuel, transport safety, emergency preparedness.

Nuclear and radiation safety in the Netherlands is overseen by several regulatory authorities. Apart from the KeW, there are decrees specifying general administrative provisions, roles and responsibilities for these authorities to carry out their work. Other regulatory authorities include: NLA overseeing the protection of the safety of workers against radiation exposure; IGJ overseeing the protection of patients; and the Dutch State Supervision of Mines (SodM) overseeing the safe and environmentally sound exploration and exploitation of natural resources.

The relevant decrees are Basic Safety Standards for Radiation Protection Decree, Nuclear Installations, Fissionable Materials and Ores Decree, Fissionable materials Ores and radioactive Materials Transport Decree, Radioactively Contaminated Scrap Metal Detection Decree, Radioactive Waste and Fissionable materials (Import, Export and Transit) Decree. In addition to these decrees, there are several regulations covering aspects of nuclear safety and radiation protection. The IAEA safety standards are also used by the ANVS as a reference in the licensing process.

The Dutch legal framework reflects the European legislation, the national and international legal developments in the nuclear field (e.g. transfer of the policy task from the ANVS to the Ministry of I&W; consultation for long-term operation; removal of long-term operation restrictions, transposing the IAEA standards and WENRA reference levels).

With respect to financial provisions for decommissioning for both nuclear and non-nuclear installations and high activities sealed radioactive sources there are requirements in the legislation (KeW and the Basic Safety Standards for Radiation Protection Decree). The financial security for nuclear installations is approved by the Ministry of I&W and the Ministry of Finance and is subject to periodic updates. The funds are protected from bankruptcy proceedings.

The licence holders hold the prime responsibility for the safe management of spent fuel and radioactive waste generated. The waste transfer to COVRA includes the transfer of responsibilities, including financial liabilities.

COVRA is a state-owned organization which stores radioactive waste produced in the Netherlands. Ongoing and future costs associated with waste management at COVRA are covered by the fees paid by waste generators upon transfer of the waste to COVRA. The fees paid by waste generators on transfer to COVRA cover ongoing and future costs associated with waste management at COVRA, including research costs.

In December 2021, the Coalition Agreement outlined the Government priorities on nuclear energy.

It has been recognized in the ARM as part of the action plan, that an evaluation of the regulatory framework for nuclear safety is necessary in order to create the basis to ensure the nuclear safety for the new projects: "Evaluate the regulatory framework for nuclear safety in order to ensure nuclear safety for possible new projects with respect to nuclear energy in The Netherlands. This evaluation should not only cover Generation III reactors, but also Small Modular Reactors and more innovative/revolutionary reactor technology in the more distant future".

To ensure the appropriate conditions for the implementation of the new projects envisaged by the government, the regulatory framework should be assessed. The KeW obliges the Minister of I&W to provide sufficient financial resources and competent staff for the ANVS. In order to cope with the future challenges it should be ensured that this is maintained for all relevant authorities with responsibilities in nuclear and radiation safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government's nuclear energy plan with respect to future facilities and activities poses a challenge on regulation, knowledge, expertise and human resources. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 3, 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) Requirement 4, para 2.8 (b) states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:… Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities"*.
(3)	**BASIS: GSR Part 3, Requirement 2, para 2.17, states that** *"The government shall ensure that the regulatory body has the legal authority, competence and resources necessary to fulfil its statutory functions and responsibilities".*
R2	**Recommendation: The Government should evaluate and improve, as required, the regulatory framework and ensure that there are provisions for sufficient resources to regulate future facilities and activities, in line with national priorities.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Government has established the ANVS as the main responsible regulatory authority for nuclear safety and radiation protection under the KeW.

The ANVS is empowered with legal authority for conducting nuclear and radiation safety regulatory processes, including issuing authorizations, inspections and enforcement. The law requires that the ANVS carries out its duties independently (article 3 of the KeW) and can establish regulations with respect to technical and organizational subjects for nuclear safety, security and radiation protection (articles 4).

Its responsibilities are summarised in articles 3-12 of the KeW, as follows:

- issuing licences, after a safety assessment is performed successfully;
- regulating all radiation practices by licensing or notification and registration;
- supervising and enforcing compliance with requirements by or under the KeW;
- advising on policies, acts and regulations;

- together with various partners maintaining an Emergency Preparedness and Response organisation;
- informing interested parties and the general public;
- participating in relevant activities of international organisations and initiatives, as far it concerns the tasks under the KeW;
- maintaining cooperation relationships with similar foreign authorities and relevant national and international organisations;
- supporting national organisations with the provision of expertise and knowledge;
- undertaking research in support of the implementation of its tasks.

The Ministry of I&W is primarily responsible for the legislation and policy development in the area of nuclear safety, security and radiation protection. The Ministry of I&W is responsible for the KeW and ensuring the effective functioning of the ANVS. The Ministry of I&W does not have a role in promoting nuclear technology nor responsibilities for nuclear facilities or activities.

The IRRS team was informed that there is a clear separation between the ANVS and the Ministry of EZK responsible for energy policy for ensuring independent regulatory decision making. The ANVS does not have involvement in the development of energy policy. The ANVS gives unsolicited advice and recommendations on policy, legislation, but independently develops its regulation based of its knowledge and expertise.

The Ministry of I&W is responsible to provide the ANVS with sufficient financial resources to perform its tasks (article 9 of the KeW). The budget and the working programme of the ANVS are periodically established further on the discussions between the ANVS and the Ministry of I&W. Also, Ministry of I&W has the duty to develop the legislation in the area of nuclear safety, security and radiation protection, including radioactive waste and geological disposal. However, Ministry of I&W does not have the right to issue general guidelines concerning the fulfilment of the ANVS duties or to annul decisions of the ANVS unless it is contrary to law.

A dedicated procedure "Procedural regulation conflicts of interest ANVS" for the prevention and resolution of conflicts of interest has been established. Separate provisions for the board members (Board Regulation ANVS-2017/8574) and the staff (ANVS decision ANVS-2018/20017) exist in order to prevent or resolve conflicts of interest exist.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The first principle of the IAEA safety fundamental principles, namely "The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks" is provided in the legislative framework at several levels.

The Nuclear Safety Regulation for Nuclear Installations (RnvK), Governmental Decree on Basic Safety Standards for Radiation Protection (Bbs) and licence conditions give effect to the application of IAEA safety fundamentals and Safety Standards. That is, the prime responsibility for safety is laid down with the Licence Holder.

The Rnvk states that responsibility for safety is extended to contractors, subcontractors and suppliers whose activity could influence the nuclear and radiation safety. The authorised parties are required to develop an institutional safety policy at the corporate level, including a management system describing that priority is given to safety and pursue continuous improvement, e.g. through periodic safety reviews. This includes an obligation for continuous improvement of safety and the necessity to have a transparent communication to the public, both by the regulatory authority and the licence holder.

The Bbs provides requirements for licence holder to keep exposure of the population and workers as low as reasonably achievable, including requirements related to the competence of the licence holder.

There are requirements requiring the licence holder, to evaluate the nuclear safety and radiation protection conditions on a regular basis, including reporting to the ANVS. The licence holder's own Management System is an important mechanism enabling it to adhere to the licence and achieve its corporate safety objectives. The responsibility for safety continues until the activity is terminated or the licence has been transferred to a third party.

With respect to prime responsibility for nuclear and radiation safety, and based on an evaluation, the ANVS is able to require the licensee to have adequate financial and human resources.

The ANVS has the power to verify the compliance with the legal requirements, having legal instruments and the ability to initiate investigations into a potential criminal offence.

The licence holder has additional duties, such as ensuring optimization of the radiation protection, that the equivalent doses of individuals respect ALARA principle, all measures are taken to prevent a source being lost or stolen and to implement measures to restore the control, and that appropriate measures to minimize the consequences of a radiological emergency are in place.

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

The legislative framework provides for the regulatory functions of the different administrative authorities. The KeW establishes the main competent authorities involved in the field of nuclear safety and radiation protection and also provides their responsibilities and duties.

The ANVS acts as a competent authority with respect to nuclear safety, nuclear security, radiation protection, transport safety, safeguards, management of radioactive waste and nuclear spent fuel, and emergency preparedness and response. The ANVS is entitled with legal authority to conduct regulatory processes including authorizations, inspections and enforcement.

Legislation specifies the roles and administrative duties of several other independent entities. These entities and their responsibilities are as follows:

- The NLA oversees the protection of the safety of workers against exposure of radiation in non-nuclear facilities
- The IGJ oversees the protection of the safety of patients against exposure of radiation
- The SodM oversees the protection of workers against the hazards on ionizing radiation in mining works, safe and environmentally sound exploration and exploitation of natural resources like natural gas and oil
- The Netherlands Food and Consumer Product Safety Authority (NVWA) monitors food and consumer products to safeguard public health and animal health and welfare. The NVWA controls the whole production chain, from raw materials and processing aids to end products and consumption.
- The Human Environment and Transport Inspectorate (ILT) has general supervision responsibilities for the compliance with the requirements of modal transport regulations.
- The Inspectorate Military Healthcare (IMG) oversees a healthy and safe work environment for its civilian and military staff. Its scope includes applications of ionizing radiation and accounting for the use of radioactive sources within the military.
- The Customs Administration has duties and powers on monitoring the movement of goods across the EU's external borders and oversees the movement of radioactive material.

In some cases, multiple authorities have a role in regulating a particular issue, for example: transport, dosimetry services, etc.

Interdepartmental consultation takes place in the High-Level Working Party on the Nuclear Landscape, which is involved in cross-cutting nuclear and radiation protection issues. The ANVS is advisor for this group. The aim of this consultation is to increase the cooperation and information sharing which is particular important with respect to the new nuclear ambitions of the Government.

In practice, cooperation takes place through meetings between the parties, both among staff and management level. Technical and organizational aspects are under the topics of the discussions.

In 2017, a Cooperation Agreement for Radiation Protection (Cooperation Covenant) was concluded. The signatories are the Ministries of EZK, I&W, SZW, VWS, Ministry of Defence and the ANVS. It provides for the cooperation of the parties to work together with the view to improve safety. It has resulted in several covenants on cooperation being established:

- Covenant on cooperation between the ANVS and SodM (2021)
- Covenant on cooperation between the ANVS and NLA (2022)

- Covenant on cooperation between the ANVS and Customs Administration, Ministry of I&W and Ministry of Finance (2018)
- Covenant on cooperation between the ANVS and Netherlands Traffic Center on cooperation on monitoring nuclear transports (2022)
- Covenant of cooperation between the Ministries of SZW and VWS and the ANVS on policy development and implementation, information exchange, external communication and participation in international forums.

However, other covenants are still under preparation, for example those between the ANVS and IGJ, ILT, IMG and NVWA. To ensure appropriate coordination and liaison between the various authorities for nuclear and radiation safety the Government should complete and implement the covenants. Special attention should be given to avoiding overlaps and conflicting requirements between authorized parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The covenants on working agreements between all the authorities with responsibilities for nuclear and radiation safety have yet to be completed.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 7, paragraph 2.18 (11), states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:… Safety in the transport of dangerous goods, including nuclear material and radioactive material".*
S1	**Suggestion: The Government should consider ensuring the establishment of formal working agreements between all authorities responsible for assuring the regulatory framework for safety.**

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

The responsibilities for implementing a system to reduce risks from exposure to ionizing radiation based on justification and optimisation principles, are given in the legislation, starting with the KeW and the Bbs.

The KeW provides the procedure to be followed in case of discovery and recovery of nuclear or radiation sources. The ANVS is authorised to prevent and reduce radiation risks, including imposing an administrative enforcement order and taking possession to ensure its safety and possible transfer to an entity designated by the ANVS.

The Bbs indicates the mechanisms to reduce the risks associated with sources out of regulatory control and those of high activity, and that of the financial security mechanism.

When orphan sources are found, there are procedures to notify the ANVS. In response, the ANVS is authorised to take all necessary measures for ensuring the radiological safety, and further notify the Institute for Public Health and the Mayor. Further, there are provisions to secure the sources at a temporary location. There are several organisations that have been designated and have a licence to collect and possess unregulated radioactive material. Ultimately, if necessary, the sources may be stored at COVRA.

Specific regulations are in place for detection and management of radioactive contaminated scrap metal. The regulations also specify the need for financial assurance. Arrangements are in place for monitoring the detection of orphan sources. These consist of both legal and mutual agreements. The ANVS may further investigate the discovery and share the findings through ECURIE, ITDB, USIE or INES, as appropriate.

The rules for dealing with intervention situations (accidents, radiological emergencies and/or an act that took place in the past) are given in the Bbs. These requirements stipulate that the responsible ministries should establish rules with regard to the implementation of interventions, including to request the authorised parties to execute the intervention according to their plan priory approved. The ANVS oversees the execution of the intervention.

The IRRS team has been informed about the existence of a national surveillance programme performed by the

Institute for Public Health. Requirements on the national action plan for radon are included in the Bbs.

On a continuous basis, the ANVS is available for assistance through the reporting centre.

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 forthcoming ARTEMIS mission.

1.8. COMPETENCE FOR SAFETY

Given the range of facilities and activities in Netherlands, e.g. with a nuclear power plant, a research reactor, an enrichment facility, and numerous radiation sources facilities and activities, there is a need for a knowledge programme to be in place and implemented.

It is essential for the competent authorities to have the necessary knowledge and expertise available for the proper performance of regulatory functions. This requirement is found in the KeW, Bbs and subsequent legislation.

An inter-ministerial working group was established to analyse, expertise, and staffing needs for the new nuclear energy plans, the extension of the Borssele facility lifetime and the radiation applications in the Netherlands. Emphasis is placed on reinforcing knowledge management.

The Ministry of Education, Culture & Science and the broader Government partially fund courses, research and consultancy institutes (NRG, RIVM) to develop and maintain knowledge on relevant nuclear safety and radiation protection topics.

The Bbs and relevant subsequent legislation give the requirements to be met in terms of knowledge, expertise and qualification by the persons involved in the radiation protection field, including by the radiation protection expert.

The RnvK states that a licence holder should have a plan for the education and training of the employees. The adequate level of staff competence, including the existence of an appropriate management and organisation of the licensee, are pre-requisites in the licencing process.

The RnvK requires that the ANVS takes appropriate measures to ensure appropriate training and instruction to its staff for acquiring, maintaining and further developing their expertise and competence. In this process, international cooperation is also used.

In 2020, the ANVS started to implement a Knowledge Management Programme. The main output of this programme is to create the basis for continuous maintenance of knowledge and competence in the ANVS, achieved through research and education with a goal of continuous improvement. As a consequence, the ANVS Academy has been created. This is an online tool, a learning and development portal that contains the required training that new staff members need to complete.

The IAEA requirements have been incorporated into the development of a Strategic Personnel Plan which define the core competences needed in the ANVS, and the education and training requirements for each professional degree.

During the annual meetings with the management, the annual training plan is discussed and evaluated. A training programme suitable for each individual has been elaborated based on the annual review of the performance.

Several steps have been undertaken in the ANVS to implement a functional knowledge programme and to evaluate and maintain the staff competence and skills.

1.9. PROVISION OF TECHNICAL SERVICES

The Netherlands has established the technical services necessary for safety and radiation protection, mainly for personnel dosimetry, environmental monitoring, medical-radiological equipment and nuclear pressure equipment. There are provisions in the legislation indicating the availability of these services in different areas, as well as the requirements that should be met by the equipment.

The technical services are authorised by the ANVS following a specific procedure as described in the General Administrative Act (Awb). There are two dosimetry services accredited by the ANVS and the National Dose Registration and Information System (NDRIS) which is appointed for the dose registration for exposed workers. The designated organization of the NDRIS is the Nuclear Research and consultancy Group (NRG), which is under the responsibility of the Ministry of SZW.

The Van Swinden Laboratory manages and develops national measurement standards for the Government.

Three companies are designated as notified body for nuclear equipment under pressure, whose activity is supervised by the ANVS.

1.10. POLICY ISSUES DISCUSSION ON NEW BUILDS

The Coalition Agreement (2021-2025) of the Dutch government formulated new ambitions with respect to the use of nuclear energy. It is announced that Borssele NPP could extend its operations beyond 2033, with due consideration for safety. In addition, the Government is envisaging the construction of two new nuclear power plants. There is a budget of €5 billion available to support these developments. Additionally potential licence applicants have started preliminary discussions with the ANVS on the plan for the advancement of SMRs.

The Government is reviewing its readiness for such ambitious proposals. In this regard, the Government has sought to understand experience of other countries in relation to roles and responsibilities of the various national entities including actions they should take to be adequately prepared in relation to safety policy needs and safety assessments to ensure their readiness for the future needs.

The Netherlands expressed interest in a focused discussion on the following topics:

- National coordination and shared responsibility;
- Capacity and knowledge building challenges of regulating new facilities;
- Regulatory flexibility for various technologies;
- Best practices for long-term operations of nuclear power plants;
- Trust building initiatives and increasing confidence in the government.

Different approaches by several regulatory bodies in the respective countries of the IRRS team were presented in the discussions and the outcome of the discussions are summarized below:

- Government policy and partnerships across the government and regulatory body is key to efficiency and harmonization across the Netherlands. Firm commitments are needed from the Government to support nuclear developments and the role of the regulatory body to ensure that the nuclear programme is regulated taking into consideration safety and security issues.
- Capacity and capability building must be aimed at the Government, regulatory body and future generations to be ready to regulate and operate new NPPs and SMRs effectively and efficiently without comprising the safety.
- Regulatory frameworks should be flexible, technology neutral and not be an impediment to innovative technologies. Funding and resources are needed to support regulatory development activities of new initiatives. While still making independent regulatory decisions, regulators should be encouraged to find innovative ways to leverage other like-minded regulators technical information and expertise.
- Regulatory bodies should not underestimate the degree of external pressure likely to be experienced when the decision to proceed with new builds is granted. In this regard engaging with members of public throughout the entire lifecycle of projects and facilities builds trust in Government and regulator. Trust building is key to social acceptance of nuclear projects.

- Being transparent and demonstrating safety are key to building trust. Strength in regulatory processes builds confidence in the independence and competence of the regulators. The Governments and regulators need to be committed to meeting with interested communities to build meaningful relationships.

1.11. SUMMARY

The IRRS team found that the Government of the Netherlands has a governmental and regulatory framework for nuclear and radiation safety, in general alignment with IAEA safety standards. The framework, however, is set out across multiple pieces of legislation and assigned to several authorities. Given the Government plans for the nuclear sector, following areas of improvement have been identified:

- issuing a national strategy for setting-out the mechanisms for implementing the national policy
- ensuring sufficient resources for addressing future regulatory challenges
- evaluating the regulatory framework from the perspective of new projects in nuclear sector

The policy discussion was conducted on Friday, 9 June 2023, on the role and responsibilities of the government in preparation for new builds with the participation of host counterparts' representatives and members of the IRRS team with interest and experiences in the area.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Netherlands actively participates in the global nuclear and radiation safety regime. International cooperation represents one of the pillars of the 2022-2025 ANVS vision. The cooperation activities were reconsidered and realigned following changes to the national Dutch policy and priorities for nuclear energy.

The Government of the Netherlands is a contracting party for treaties/agreements/conventions with relevance for nuclear and radiation safety and applies their provision through the activities carried out by the national organisations and ministries.

Several arrangements are in place, describing the roles and division of responsibilities in the process of international representation. The Government of the Netherlands has committed itself to both the Code of Conduct on the Safety and the Security of Radioactive Sources, and the Code of Conduct on the safety of Research Reactors and is currently strongly considering commitment to Guidance on the Import and Export of Radioactive Sources but not yet to the Guidance on Management of Disused Radioactive Sources. These are non-legally binding international instruments, well-accepted and implemented in practice.

The ANVS has an active role in contributing to international cooperation arrangements by working with the IAEA, EU and other regulatory bodies. The ANVS participates among others in IAEA activities, European Nuclear Safety Regulators Group (ENSREG) working groups, Western Nuclear Regulator's Association (WENRA) working groups, Heads of European Radiological Protection Competent Authorities (HERCA) working groups and networks, and NEA/OECD committees and working groups.

The ANVS participates in the IAEA Safety Standards Committees (NUSSC, RASSC, WASSC, TRANSSC, EPReSC) contributing to the development of IAEA Safety Standards. ANVS Chair of the Board Annemiek van Bolhuis was recently appointed co-chair of the Gender Champions Impact Group on Gender Equality in Nuclear Regulatory Agencies (IAEA).

Based on the national policy, the ANVS staff is actively involved in a growing number of activities and international initiatives related to SMRs, such as the European pre-partnership, IAEA NHSI, OECD/NEA EGSMR, WGNT. This also includes WENRA RHWG subgroup New Reactors.

It is acknowledged that, the Netherlands has made strong efforts to engage with the EU (participating in ENSREG topical peer-review), IAEA (hosting IRRS missions in 2014 and 2018 and participating in peer review missions of national regulatory frameworks). Examples of such other peer-review missions are: Integrated Safety Assessment of Research Reactors at Institute Delft in 2021, Continued Safe Operation at High Flux Reactor in 2022, Operational Safety Review Team at Borssele NPP, IPPAS and ARTEMIS in 2023).

Adequate arrangements have been made by ANVS to fulfil and benefit from international cooperation and assistance to enhance safety globally. Examples of such arrangements include cooperation with FANC amongst others on inspection and detection of incidents; with CSNC on exchange of regulatory experience and arrangements with USNRC also with regard to collaboration on SHINE.

Another example of close regulatory cooperation is the "KWU regulator group" (KWUREG). This group is dedicated to the exchange of information and works with regulators from countries (Brazil, Germany, the Netherlands, Spain, and Switzerland) that operate Siemens/KWU NPP.

There is a governmental agreement in place between the Netherlands and Germany (NDKK) which aims to promote the exchange of information between the two countries. Bilateral meetings between these two countries take place with focus on exchange on safety matters and emergency preparedness measures.

Attention is also paid to increasing bilateral cooperation with regulators from countries, like the Czech Republic, Poland, UK, France, Finland, USA, Sweden, Canada, Republic of Korea, covering various aspects, e.g. licensing and oversight of new builds, adoption of SMR technology.

The IRRS team noted the willingness of the Government to enter into bilateral and multilateral cooperation and formalizing agreements with European and other countries.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The ANVS uses operational and regulatory experience feedback (OEF and REF) through its international network via bilateral contacts and participation in multilateral groups and associations such as WENRA, HERCA, ENSREG and KWUREG.

The ANVS supervises the OEF programmes of the licensees, which are legally required to use the lessons learned from operational experience and incidents. Accordingly, the ANVS is the national contact point for international reporting systems IRS (on international nuclear safety), IRSRR (for nuclear installations) and FINAS (concerning fuel cycle facilities – fuel incident notification and analysis system), and has a national INES officer. Information received using these established processes are internally disseminated. The ANVS manages a database with all national events and yearly informs the Minister of I&W who in turn informs the Parliament.

The information received from other states and organisations is discussed internally during working meetings but also with the licence holders, if needed. These meetings are at the core of expertise exchange, sharing licensing and oversight experience, and learning how to apply the information on the new projects. The most relevant information is made known to all interested parties and published on the ANVS' website. The priorities for implementing the identified actions are included in the annual working plan of the ANVS.

The management of the OEF is documented in a written procedure included in the Management Manual.

The REF activities are a priority for the ANVS, in light of the new Dutch policy on nuclear energy. Therefore, the interactions at bilateral and level multilateral are significantly improved and expanded. This is not limited to the exchange of information on nuclear technology, but also includes exchanges on capacity building and organizational structure.

The ANVS has started an assessment of the actual REF-activities and initiatives, using IAEA TECDOC-1899 as a reference. This assessment aims to align the current system with daily practice, including appropriate involvement of the Ministry of I&W.

2.3. SUMMARY

The Netherlands is an active participant in the international community to promote globally safety. As part of continuous improvement, Netherlands is seeking to be involved in a wider range of activities that deal with its national priorities, with the intention to maximize the benefit from the existing experience and information sharing forums.

The ANVS also stated its commitment to improve the existing processes and arrangements for operating and regulatory experience feedback.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The ANVS had an internal re-organisation in early 2023. The new organisation includes the Board and three departments under it: Competent Authority Department, Assessment and Advice Department and Business Operations and Information Department. The departments have several teams according to the functions they perform. The Board has two members, one is responsible for Inspection and Enforcement and the other for Authorisation.

The Competent Authority Department is structured in a similar way, having separate teams for Inspection and Enforcement and Authorisation. On the other hand, in the Assessment and Advice department, the experts can support both departmental functions.

Authorization decisions, and decisions related to Inspection and Enforcement, are taken at different levels of the organisation (Team leaders, Department Directors or the Board members) depending on the impact, scope and complexity of the decision.

In total, there are approximately 150 staff members at the ANVS. The organisation has grown significantly, in 2022 more than 40 new staff members were recruited, and plans exist for further recruitments in 2023-2024. New staff has been hired for positions across the whole organization. The new developments (new facilities for production of medical isotopes, cybersecurity issues, construction of the PALLAS research reactor, potential NPP projects) are considered in planning the resources and recruitments.

The ANVS is funded from the state budget. The Minister of I&W is obliged by law (KeW) to provide sufficient funding for the ANVS. The ANVS has the authority to decide how it uses its funding and resources. The ANVS is accountable to the Ministry of I&W for a legitimate and efficient use of its resources. Licensing fees (defined in KeW, Fees Decree) are paid to general funds of the Ministry, not directly to the ANVS.

The ANVS is the only regulatory authority responsible for authorisations. However, several other organisations perform inspections. For example, National Labour Authority and the IGJ perform inspection and enforcement in the field of occupational exposure and in medical exposure, respectively. In addition, SodM and IMG also perform inspections in the radiation protection sector.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The ANVS's position as an independent organisation is laid down in the KeW. In the governmental structure, the ANVS is an independent administrative body under the Ministry of I&W which has no role in energy policy. Furthermore, the KeW states that the regulatory body shall carry out its duties independently. The ANVS is separated from those governmental bodies that have a role in energy policy or that may promote the use of nuclear energy.

To avoid conflict of interest, the ANVS applies several measures. The ANVS has a procedure (ANVS Procedural Regulation on Conflict of Interest) that defines rules for staff originating from authorized parties, for non-civil servant staff and for advisory and support services. Furthermore, the general legislation concerning civil servants apply to ANVS staff, like the Integrity Code of Conduct or the Dutch Whistle-blower Protection Act published in January 2023. Each new staff member needs to make an oath of integrity in the beginning of the employment. In the training provided for new employees, the independency of an administrative body is discussed. If the new staff member comes from an authorised party, that staff cannot be involved in work related to that authorised party for two years. Exemptions are possible but then special arrangements must be made to avoid conflict of interest.

Each inspector of the ANVS has the authority to intervene if they detect unsafe activity. In practice, the inspector is advised to call and discuss the decision with his/her supervisor or other management. A procedure for intervention is included in the management system.

The ANVS has the mandate under Article 4 of the KeW to establish and publish regulations on technical or organisational matters that are designated by Decree or Ministerial regulation, for the sake of nuclear safety, security, and radiation protection.

The ANVS has the authority to decide independently on how it uses its budget and resources.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Number of staff at the ANVS has increased significantly in the recent years and is expected to continue increasing. The ANVS is in the process of recruiting new staff but has several existing vacancies. In general, ANVS has sufficient resources for carrying out most of its obligatory functions. However, in inspection of radiation sources facilities and activities, there have been some challenges noted. This issue is addressed in Recommendations R13 in Chapter 7.6.

It is often a challenge to find competent staff, as there are many job opportunities at the moment in the Netherlands and there is competition in the labour market. The ANVS has invested in recruiting and attracting new staff. The ANVS is also applying alternative approaches like recruiting or hiring staff with less experience and training them. Also, they are after recruiting or hiring staff from abroad. The latter is somewhat limited by the need-to-know Dutch language for carrying out most regulatory tasks. Consideration is also being given to evaluate what competences should be maintained in-house and where TSOs can be used. ANVS has a Strategic Personnel Plan and a Tactical Knowledge Plan.

Training new staff and integrating them to the ANVS's organisation demands resources itself.

In planning human resources, the ANVS considers the potential developments in the nuclear and radiation sector. Both annual and longer term (~2-5 years) planning is done. For some projects (like PALLAS Research Reactor) the whole duration of the project is taken into account.

The need for new staff has been discussed with the Ministry of I&W. The Ministry has not placed a limit to the ANVS's recruitments. The bottlenecks in human resources are mainly in availability of competent staff in the labour market, and to some extent also in the pace the organisation can accommodate new staff.

The ANVS has started in 2020 a knowledge management programme. The aim of the programme is to ensure that the ANVS continuously has the right expertise in its use. For recruitment and training, the ANVS has created knowledge profiles for the different tasks. Basic training is given to all new employees. Further training needs are determined based on the background and experience of the new employee, and on his/her task at the ANVS. Every year the competence and additional training needs are evaluated individually for each employee, and an individual training programme is prepared.

Both internal courses and external courses (e.g. Government Academy of the Netherlands, national universities and international courses for example by the IAEA and NEA) are used. Mentoring and learning by doing are important elements in training. Participation in international working groups can also be used to support competence building.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The ANVS has an Advisory Council. The Council gives advice to the ANVS either on topics the ANVS has requested, or by its own initiative. In practice, the ANVS Board and the Council jointly set the agenda for the next meeting. Meetings are held 3-4 times every year. Recent topics have been for example regulatory approach to an event in one facility, transparency, implications on the ANVS (organisation, competence) of long-term operation of Borssele NPP, and preparations for licensing of new NPPs. The Council has now six members with expertise from various fields, including nuclear safety, radiation protection, waste management and decommissioning, enforcement, communication, culture and behaviour and cybersecurity. The Council has a legal obligation to inform ANVS if any council member may have a conflict of interest.

The ANVS has several TSOs with which it has contracts. In addition, the ANVS can contract other TSOs when necessary. TSOs are used for different purposes. In strategic knowledge development, one considered aspect is that what capabilities the ANVS must have in-house, and where TSOs can be used. TSOs can also be used to help with temporary high workload. The work carried out by the TSOs is paid from the budget or, if a need for external support emerges during review of an application, the costs can be charged to the applicant. The ANVS has an adequate annual budget for technical support. Despite the use of TSOs, the ANVS is the responsible authority for the decision-making.

When using TSO's, the need to address conflict of interest is considered as part of contractual agreements. The general rules (like General Government Terms and Conditions for Public Service Contracts, General Government Purchasing Condition) apply.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The ANVS has both formal and informal communication channels established with the authorized parties.

The ANVS has regular management-level meetings with the licensees of the nuclear facilities. In day-to-day work, the staff members can be in direct contact with the staff of the facilities. ANVS has dedicated plant inspectors for the nuclear facilities, the plant inspectors are kept informed about communication between the experts. The plant inspectors coordinate the oversight of the facility in question, they are not resident inspectors. ANVS does not have resident inspectors in any of the facilities.

In the radiation protection sector, professional associations, like Dutch Association for Radiation Protection, are engaged for joint collaborations. The ANVS meets with such associations once or twice a year.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The regulatory requirements are the bases for consistent regulatory control. In the Dutch regulatory framework, requirements in some areas are very general, or not established. For that reason, it is typical to define more detailed requirements in licence conditions. For example, IAEA Safety Standards and/or WENRA reference levels that must be complied with are specified in the licence conditions. This issue is addressed in Recommendation R17 in Chapter 9.1.

To improve the predictability and transparency of regulatory expectations, ANVS has published and applies its strategic policies such as the Licensing Policy and Inspection and Enforcement Strategy to explain the regulatory approach and expectations. For nuclear reactors a guidance document, Dutch Safety Requirements for Nuclear Reactors (VOBK), has been published. The VOBK covers both water cooled nuclear power plants and water cooled Research Reactors.

Furthermore, a pre-licensing phase often precedes the actual licensing phase. In the pre-licensing phase, the expectations for the license application are discussed. In the pre-licensing phase, significant amount of review and assessment work can be carried out. However, the pre-licensing process is not a formal process and not described in the management system. The ANVS has identified the need to formalize the pre-licensing process. This issue is addressed in Suggestion S3 in Chapter 5.1.

The ANVS has started a project (WIDOCS) to update in a systematic way the IAEA Safety Standards and WENRA Safety Reference Levels in the policy rules and the licence conditions and improve the transparency of the process.

To avoid subjectivity, training of staff and "four-eye-principle" in drafting the decisions are important tools.

Guidance for review, assessment and inspections is also used to avoid subjectivity. The ANVS has internal procedures for its staff, but not for all review, assessment and inspection tasks. Regarding review, technical review plans can be prepared for specific needs, especially for nuclear facilities. For example, a technical review plan was prepared for the evaluation of the licence application of the PALLAS Research Reactor. Regarding inspections, for inspecting nuclear facilities, detailed, check-list type instructions are usually not used. For inspections of radiation practices, check-list type procedures are used for some inspections. The management system is still under development. This issue is addressed in Recommendation R3 in Chapter 4.5.

The ANVS is required to give justification for its decisions. The justification should include elements like assessment of associated risk, safety considerations, organizational aspects, explanation if (when applicable) dose limitations are met etc. In general, licence decisions for nuclear installations and major radiological activities are made available for the public for comment before they are finalised. A shorter procedure applies to applications for changes of licences for facilities or activities where there are none or minor detrimental consequences for the environment.

The ANVS has an internal review policy for revision of regulations. Draft regulations are made available for the public and to different stakeholders for commenting.

3.7. SAFETY RELATED RECORDS

The ANVS and other organisations keep safety related records

- ZAPP (a case management system) has records of sealed radioactive sources and radiation generators that need a license or registration.
- For occupational doses, a national register NDRIS exists. It is managed by the NRG, which is appointed by the Ministry of SZW.
- The ANVS keeps a record of events that must be reported. The record is in a document management system called “Content Manager”. The authorized parties keep records of other events.
- General inventory of radioactive waste and spent fuel in the Netherlands is kept and reported by COVRA together with RIVM. In addition, operators keep their own inventories.
- Information related to the safety of the facilities and for decommissioning is submitted to ANVS mainly through licence applications. ANVS records this information in the Content Manager. The legislation has some provisions for obliging the licensees to keep their own records.

Some other registers exist too, for example ANVS keeps a register of radiation protection experts.

The ANVS has access to all of the above records and utilises them in support of different regulatory tasks including reporting as appropriate.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The ANVS has in the Assessment and Advice Department a team for Communication and Public Information. The team size has been increased since 2015 from two persons to eight. In the team there are different specialists, like for example specialist on on-line communication.

The ANVS has a communication strategy which due to the recent developments it is being revised. In planning its communication, ANVS considers scientific research on communication related topics. The ANVS uses more detailed communication plans for separate topics and projects, like licensing the PALLAS research reactor. Sometimes communication plans are prepared together with neighbouring countries, for example, when Dutch waterways close to Belgium border were used for transferring steam generators of a French NPP, a communication plan for the transportation was prepared together with France and Belgium.

The ANVS uses different platforms for communication: website, social media, traditional media, and different meetings. For example, when the war in Ukraine started, the ANVS arranged workshops for media to share information. The ANVS did this with the RIVM, the Ministry of I&W and the Ministry of VWS.

On the website, basic information about radiation and nuclear facilities is given. Regulatory documents like reports, guidelines or decisions are published too. The ANVS publishes on the website and the licence database all authorizations it has given as well as all enforcement decisions. The most important licence decision (like licenses for nuclear facilities or their changes) are published already in drafting phase to give the public and any interested party the opportunity to comment the draft decision.

The ANVS publishes a public annual report. The annual report of the Advisory Council is attached to the ANVS’s report.

The ANVS organizes and participates in different meetings, e.g. meetings with population or municipal authorities in the vicinity of facilities.

The ANVS staff are given training in communication and in working with the media. The trainings have a broad scope; the ANVS staff has for example been given training on how to feel comfortable with the present-day phenomena, like being filmed by mobile phones when using cars with the ANVS logos.

The ANVS follows trends from the society to identify communication needs and interested parties. Information is also received from local governments and contact persons in the Safety Regions.

Other governmental organisations perform inspections including enforcement activities. The framework for the work is established in cooperation agreements between ANVS and the government agency. However, the full suite of existing working arrangements is not complete with some still under development. This issue is addressed in Suggestion S1 in Chapter 1.5.

The ANVS has contact persons in all Safety Regions. Lately the ANVS has organized a tour to all Safety Regions of the Netherlands to meet with the organisations that have a role in nuclear or radiological emergency.

The KeW requires the licence holders of nuclear facilities to provide information to the public of their facilities and the associated risks.

The ANVS has arrangements with the Belgium regulatory body for cross-border information exchange. In addition, the ANVS and the Belgium regulator cooperate in communication as similar questions are often raised in both countries. With Germany, the Netherlands has a formal agreement on exchanging information.

3.9. SUMMARY

The ANVS has an organizational structure that allows it to effectively carry out its regulatory responsibilities and it has implemented resource and knowledge developments plans. Advisory Council and technical support organizations support the ANVS in its functions.

ANVS carries out it tasks independently and communicates openly and frequently with the interested parties and general public. The ANVS has established ways to communicate with the authorized parties.

Some opportunities for improvement have been identified. For example, further development of the regulatory framework and the management system would support the consistency and stability of regulatory control, and providing sufficient resources remains essential. Related discussions are included in Chapters 1, 4, 5, 7 and 9.

4. MANAGEMENT OF THE REGULATORY BODY

The Bbs assigns regulatory responsibilities to the ANVS together with the Ministry of SZW (for protecting employees against dangers of ionizing radiation) and to the Ministry of VWS (for protecting patients against dangers of ionizing radiation).

For this IRRS mission, the Netherlands provided comprehensive information in the ARM on the management for the ANVS only, and for this reason only the management system of ANVS could be reviewed.

Article 16 of the Rnvk requires that the ANVS shall have a management system. The ANVS management system is called ANVS Integrated Management system (AIM). The ANVS has a management system software application called ANVS Centraal.

The ANVS is, through its Programme Plan AIM, seeking to improve its integrated management system to include all its activities. The ANVS indicated in their action plan for this mission the need to "Complete the implementation of the Action Plan for improving the ANVS Integral Management System".

The ANVS is developing its management systems in line with the goals they have stated in their high-level documents: the ANVS Vision Document 2022-2025, Organisational Decision 2.1 and Guidance to National Policy for nuclear safety and radiation protection 2022.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The management chain of responsibility outlined in Organizational Decision 2.1 consists of:

- Management Board consists of a Chair and Deputy which sets the long-term strategy for the organisation and has ultimate responsibility for the ANVS.
- Three ANVS departments (Competent Authority Department (DGB), Assessment and Advice Department (DBA) and Operational Management and Information Provision Department (DBI)), each of these has a director who is responsible for their department and creates departmental strategy based on the Management Board's long-term strategy
- The ANVS Management Team is composed of the Management Board and the three Directors.
- Departments are made up of between 3 to 5 teams, each team having a team leader who sets individual team objectives.

The ANVS vision and targets are documented in Vision Document 2022-2025; attaining these goals is organised through Organization Decision ANVS 2.1.

The stated Mission of the ANVS is: *ANVS is independent and professional; it continuously monitors and enhances nuclear safety, radiation protection and security for this and future generations.*

The ANVS guiding principles as stated in Vision document 2022-2025 are the following:

- Personal responsibility and justified trust;
- Continuous improvement;
- Operating in a risk-oriented way;
- Being connected to our environment;
- Cooperating at the international, national and regional levels.

On recruitment staff have to pledge that they will comply with the governmental general Code of Ethics.

The ANVS targets are translated into specified goals and actions by working groups. Team leaders and the Management team can set further priorities. These goals/actions form the ANVS annual plan, that is made publicly available.

Each year ANVS produces an accountability document for the Ministry of I&W. This document reports on the attainment of targets for the previous year, as well as the planned targets and risks for the upcoming year.

Feedback from staff to the management is achieved by:

- ANVS striving to have an open-door working environment which encourages staff to express their views
- Weekly information sessions regarding the senior management decisions
- Every fortnight team meetings are conducted to discuss the content of the work
- Monthly one-to-one meetings between staff and their line manager
- Annual employee review and
- Employee satisfaction surveys performed every two years.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The ultimate responsibility for the management system resides with the ANVS Board. The maintenance and development of the management system falls under the remit of the Director, Business Operations and Information Department. Development of the management system is coordinated by the Administrative Services and Control Team. This team has a web application specialist and a quality advisor.

Responsibility for the content and implementation of the processes is delegated to the directors and the team leaders.

The ANVS has shown commitment to developing its management system. This is evidenced by the decision made by the ANVS Management Team in November 2021 which resulted in the AIM 2.0 Plan of Action, which in turn led to the Programme Plan. The stated target date for the incorporation of all the documentation into the management system is the end of 2024.

The ANVS action plan for this mission includes a recommendation to: complete the implementation of the action plan for improving the AIM. This issue is addressed in Recommendation R3 in Chapter 4.5.

Goals are developed by working groups from targets that included in the Vision Document 2022-2025. These goals, along with priorities of the statutory duties set by the management team and team leaders are included in the ANVS annual plan. Progress against the targets in the annual plan is assessed twice a year, by the team of Directors.

The ANVS monitors a variety of performance (production) indicators, extracted from ZAPP (an ANVS management application), which the ANVS Board reviews every four months.

4.3. THE MANAGEMENT SYSTEM

The ANVS AIM has an associated software application called ANVS Centraal. Management system documentation is stored in the “Content Manager” which acts as a data repository.

In addition to AIM, there is the ZAPP application for authorisation, licencing, inspection and enforcement processes. Through ZAPP, information can be shared with other regulatory bodies with responsibilities for safety. Although, there is an absence of a complete set of documented working arrangements between ANVS and other governmental regulatory organisations.

For ANVS, not all the elements of an integrated management system are yet to be in place. This includes the interaction with other government regulatory organisations with responsibilities for safety. This issue is addressed in Recommendation R3 in Chapter 4.5.

AIM is aligned to the goals given in the Guidance to National Policy for Nuclear Safety and Radiation Protection 2022 and the Vision Document 2022-2025.

There is a handbook for the AIM which includes the organisational structure and the assignment of responsibilities for processes. Safety culture is referred to in the AIM handbook, but there is no specific document for individual commitment to safety. This issue is addressed in Suggestion S2 in Chapter 4.6.

All ANVS staff can access management system documentation either through ANVS Centraal or directly from their intranet. However, ANVS Centraal is not routinely used by all staff for all their regulatory activities. Staff can perform their administrative functions bypassing ANVS Centraal by using their intranet where they can access all the required documentation, and the content manager.

The general management system used by the Ministry of VWS was briefly observed. This system had a section that dealt with ionising radiation, however, from the review it was not possible to determine if it met the requirements of GSR Part 2 or otherwise.

4.4. MANAGEMENT OF RESOURCES

The required competencies and numbers of staff in each team are laid down in the "*organisatiebesluit"*. The training requirements for these staff are laid down in the Technical Knowledge Plan (TKP).

The ANVS uses the Civil Service Job description and Evaluation system (JDES) which describes a variety of managerial, coordinating/specialist advisor and inspector grades.

The ANVS is able to set the required competencies (knowledge and skill sets) for any particular post. The ANVS follows the governmental pay scale structure but can supplement the pay if justified.

Each Team Leader has responsibility to ensure that their team has sufficient competence or knowledge to discharge their duties. Each team has its own knowledge plan which is a living plan including: task evaluation; education needs and required level of experience.

Training and education are a mandatory in the yearly performance review of each staff member during which their competencies, knowledge, education, and training are discussed. Staff review and appraisal interviews are an important part of discussing existing knowledge and where more expertise is needed. As a consequence, they form the basis for personal training programmes. There is an onboarding and mentoring programme for new employees.

The ANVS is developing a business continuity plan (BCP). The BCP will outline how ANVS will continue to operate during and after an unforeseen event or disruption. The BCP will describe how the impact of unforeseen external events, such as the recent COVID-19 pandemic can be minimised and will ensure that ANVS core regulatory functions can be sustained.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The ANVS management system AIM has an associated software application called ANVS Centraal.

The management system documentation consists of:

- High level documentation (e.g. Vision document 2022-2025, Guidance to National Policy for Nuclear Safety and Radiation Protection 2022, Organisational Decision ANVS 2.1, ANVS Licensing Policy etc.)
- Handbook for the management system.
- Processes
- Procedures
- Work instructions

The ANVS Centraal system is not currently widely used by all staff for all of their regulatory activities; instead, staff use the information available through the ANVS intranet and the content manager. ANVS has plans for ANVS Centraal to be revised to bring in in line with the new AIM.

The ANVS is aware of the need to improve the AIM and has plans through the Programme Plan ANVS AIM to improve the consistency, clarity, efficiency, effectiveness, and user-friendliness of the management system. The Study of the ANVS management system in September 2022 proposed reorganisation of the existing AIM material documentation into a more logical structure. In the ANVS Action Plan, ANVS identified that it needed to "Complete the implementation of the action plan for improving the ANVS Integral Management System".

Whilst there is a stated commitment by ANVS to complete the management system by the end of 2024, it is noted that the follow up to the previous IRRS mission in November 2018 concluded that actions taken by ANVS showed that sufficient progress had been made and confidence in the effective completion of the management system.

The ANVS recognises the need to develop a complete set of processes and procedure and include these in its management system. When this happens, the ANVS management system will be fully integrated. In addition, there

is currently a lack of documentation regarding ANVS's interaction with other government regulatory organisations with responsibilities for safety. Given the pivotal role that ANVS play in managing regulatory issues should be looked at the earliest possible opportunity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS management system is incomplete and has inconsistencies in its structure, and as a result is not fully effective. ANVS Centraal is not consistently used across the organisation. This has been recognized in the ARM and is part of the Action Plan.	
(1)	**BASIS: GSR Part 2 Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organisation's goals without compromising safety".*
(2)	**BASIS: GSR Part 2 Requirement 10 para. 4.28 states that** *"Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation".*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 para 4.17 states that** "*The management system shall specify, in a coherent manner, the planned and systematic actions necessary to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled. Furthermore, regulatory requirements shall be considered in conjunction with the more general requirements under the management system of the regulatory body; this helps to prevent safety from being compromised".*
R3	**Recommendation: ANVS should implement the improvements of the ANVS Integral Management System, in order to identify and develop its processes and procedures in a coherent manner, integrate them in its management system, and ensure that the management system is consistently used throughout the organisation.**

4.6. CULTURE FOR SAFETY

With regard to promotion of a culture for safety, the ANVS high level documentation makes reference to Safety First, the implementation of which is elaborated in part in the handbook on the ANVS management system. The handbook gives the elements of safety culture within the organisation, but does not go into sufficient detail with regard to attitudes and behaviours that would support a strong safety culture (reference can be made to GSG-12 Para 3.7-3.9).

The ANVS informed the IRRS team that it is its intention for the handbook to be updated and it is the intention of ANVS to do so under the ongoing project "Programme Plan ANVS Integrated Management System".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In the ANVS management system there are insufficient measures for the fostering and sustaining of the safety culture.	
(1)	**BASIS: GSR Part 2 Requirement 12 states that** *"Individuals in the organization, from senior managers downwards, shall foster a strong safety culture".*
(2)	**BASIS: GSG-12 Para 3.4 states that** *"A strong safety culture does not grow by itself; it should be fostered and sustained. The behaviour and commitment of leaders to safety influences the attitudes and behaviours of individuals. Therefore, a strong safety culture needs the strong commitment and engagement of senior management, with the support of the integrated management system".*
(3)	**BASIS: GSG-12 Para 3.7 states that** *"These attributes should permeate the entire regulatory body and should be reflected in the integrated management system so that individuals demonstrate a questioning attitude, feel responsible and are supported in identifying safety concerns".*
S2	**Suggestion: The ANVS should consider including additional measures for fostering and sustaining of the safety culture in its AIM.**

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

There is an annual review of all processes within the AIM management system. The Quality Advisor within the administration Services and Control Team within Business Operations and Information Department independently audits the processes within the AIM.

The management receives input from employees through the employee survey and the integrity surveys which are performed on alternate years.

The ANVS performed a gap analysis of its Management System through the AIM 2.0. Plan of Action. This gap analysis led to the development of the Programme plan ANVS AIM. This plan has a stated completion date of the end of 2024. The review has been performed by ANVS staff who are and those who are not involved in the development of the management system.

The ANVS monitors a variety of performance (production) indicators, which the Board reviews every four months.

4.8. SUMMARY

This module review is limited to the management system of ANVS.

The ANVS has developed its management system in line with the organisation's goals. It was evident to the IRRS team, that ANVS gives the development of its management system high priority and has the full support of the Board.

Aware of the need to improve its management system, the ANVS has taken steps since the last IRRS follow-up mission to review its management system.

The ANVS Action Plan identified the need to develop the management system and to bring it in line with the requirements of GSR Part 2.

The IRRS team identified the following areas of improvement:

- Should complete the review of its management system, identifying processes and then developing a set of policies and procedures which can be included in its integrated management system., Finally they must ensure that the management system is consistently used throughout the organisation.
- Ensure that the planned revision of documentation of the management system includes the provisions for the fostering and sustaining of culture for safety.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Dutch legal framework for the authorization of facilities and activities is mainly established under the provisions of the KeW, which sets out requirements for the application of nuclear technology and materials, makes provisions for radiation protection, designates the competent authorities and outlines their responsibilities. In addition, based on KeW there is a body of legislation constituted by Governmental decrees, ministerial regulations and ANVS regulations. In addition to the KeW, several other regulations may apply to facilities and activities e.g. Environment Protection Act.

The ANVS is the sole authority with responsibilities for issuing authorizations for nuclear and radiation sources facilities and activities. However, there are often several authorities involved in the authorization process.

The ANVS Licensing Policy is the document governing the principles and procedures for the authorization process.

The graded approach is applied in the authorization process, taking into consideration the magnitude of the risks associated with the facilities or activities. According to this graded approach, ANVS can grant three types of authorization documents: licence (for medium to high risk activities), registration (for low to medium risk activities) and notification (for very low risk practices that cannot be exempted due to their nature).

The graded approach is also reflected in the number of the licensing stages in the authorization process. For nuclear installations, there are three stages: Construction; Commissioning and Operation; and Decommissioning. For radiation sources usually there is only one stage, however in some cases decommissioning licence is used.

The procedures to obtain a licence under the KeW follow the procedure specified in the Awb. This procedure allows for public involvement by which any stakeholder is entitled to express their views regarding a proposed activity. Stakeholders may submit comments on the content of the licence (including the licence conditions), within 6 weeks from the ANVS' initial invitation for public consultation. An objection may result in the licence being amended and the licensee having to cease certain activities. For activities with a lower risk a procedure is followed where no public consultation on a draft decision is done but where a final decision is published and opened to objection immediately.

In addition, in accordance with the provisions of this Act, the ANVS is required to issue a licence within a maximum of six months from the date the formal and amenable application was made. The IRRS team was informed that this time limit may not allow sufficient time for an effective review and assessment of a licence application for complex installation such as a nuclear facility. This term of six months can be extended by the ANVS after the applicant has had the opportunity to submit an objection. KeW licences are excepted from the Lex Silencio Positivo (LSP) principle. This means that they may not be deemed to have been granted tacitly if the statutory decision period is exceeded.

The licensing process is the principal means by which ANVS is able to apply the legal and regulatory framework and by which the responsibilities of the applicant or licensee are clearly connected to the legal framework. The ANVS discharges part of its responsibilities for facilitating that the authorisation process can be completed within six months through the organization of an informal pre-licensing step. During this step, ANVS and the applicants hold meetings with the purpose of allowing ANVS to communicate and explain the regulatory requirements and expectations that will form the basis for the regulatory review and assessment and the basis for decision making. This pre-licensing step is not required by law and is not legally binding, therefore no rights can be acquired from it by the applicant.

Pre-licensing activities became a regular practice at ANVS in preparation for each licensing phase of a nuclear facility as well as larger radiation activities, in order to allow sufficient time for the regulatory review and assessment process. A licence application must contain all the information necessary to be able to properly check and assess it. If the Authority concludes that insufficient information has been provided to be able to assess the application, it will ask the applicant to provide further details to supplement the application. If the application is still incomplete after supplementary details have been provided, the ANVS may decide not to process the application as it is deemed not amenable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In order to effectively carry out the licensing process of new facilities and activities, ANVS performs pre-licensing activities as an informal step in the process. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 22 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. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based".*
(2)	**BASIS: SSG-12 para 2.6 states that** *"The licensing process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the licensing process should be discrete and should follow a logical order. In developing a licensing process, consideration might be given to adoption or adaptation of 'pre-licensing' processes, for example, steps that provide for early approval of sites and advance certification of standardized plant designs for authorization for construction and operation of a nuclear installation. Such a licensing process may help to minimize duplication of effort through the different steps and may allow for some steps to be conducted in parallel…".*
S3	**Suggestion: The ANVS should consider formalizing the pre-licensing step of new facilities and activities in its management system.**

The ANVS issues indefinite licenses for the authorization of nuclear and radiation sources facilities and activities, with the exception of transport. The set of regulatory requirements that the licensee must meet are attached to the existing licence as licence conditions and become binding when the licence is issued.

To ensure licence requirements are based on the most up to date safety standard, ANVS currently makes use of provisions from IAEA safety standards and safety guides as well as WENRA reference levels through licence conditions. The ANVS carries out activities (with some periodicity) to assess and further confirm, whether that changes in the regulatory framework have been reflected (transport licences are an exception to this) in the licences. However, these activities are not part of a process by which the incorporation of changes in regulation and guides can be systematically ensured.

The Licensing Policy provides the process that allows licences to be amended or revised, with the purpose, to reflect any later modification to the facility, and to incorporate new regulations and guides. The process to modify a licence condition follows the so-called 'uniform public preparation (or 'long)' procedure'. According to this procedure draft decisions need to be published in the Dutch Government Gazette ('Staatscourant'), and in the national and/or local press. Documents provided with an application for a licence are to be made available to inform members of the public. A long process, as a result the ANVS has the practice of consolidating multiple updates and incorporating them to the licence when appropriate. Currently, the ANVS is working on the WIDOCS project to map current IAEA safety standard requirements against the current regulatory framework and licence conditions. This will allow ANVS to include new or revised regulatory requirements into its regulatory and licensing framework. This has been included in the Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS does not have a formal process to ensure periodic updates of the licensing conditions to assure that changes in regulations and guides for the continuous improvement of nuclear and radiation safety are incorporated into individual licences. This has been recognized in the ARM and is included in the action plan.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24 states that "***An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	activity concerned (e.g. as a result of a change in the conditions under which the authorization was granted). This would have to lead to a new regulatory decision which may require the amendment, renewal, suspension or revocation of the authorization".
(2)	**BASIS: GSR Part 3 Requirement 3 states that** "*The regulatory body shall establish or adopt regulations and guides for protection and safety and shall establish a system to ensure their implementation".*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained".*
(4)	**BASIS: GSG-13 para 3.11. states that** *"As part of its integrated management system, the regulatory body should establish a process for the development of regulations and guides. This process should ensure that the regulations and guides:* *(a) Provide the framework for regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization* *(b) …".*
(5)	**BASIS: GSG-13 para 3.93. states that** "*Principles for authorization should be established in the regulatory and legal framework. Examples of principles for authorization include the following:* *(b) The regulatory framework for dealing with requests for authorization should be clear, especially the process for applying for authorization.* *(c) The regulatory framework for the authorization process should be explicitly established by the regulatory body.*
S4	**Suggestion: The ANVS should consider establishing a process to update the conditions of individual licences to reflect changes in regulations and guides.**

Licence documents for similar facilities are different in format for each nuclear installation and do not have standardized conditions. Taking into consideration the graded approach, according to the IAEA Safety Standards, cases where the licence conditions may differ in format, could lead to inconsistent regulatory oversight between the different licences. The ANVS is developing a systematic approach to keep the licence conditions in line with the IAEA requirements and for consistency of regulatory oversight for nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The licence granted by the ANVS for nuclear facilities can be different between licensees, this can lead to inconsistent regulatory oversight of different licensees.	
(1)	**BASIS: GSG-13 para. 3.114 states that** *"While authorization conditions may differ in format, they should exhibit certain basic qualities and characteristics to make them understandable and effective. Each authorization condition should be consistent with all other authorization conditions in that the fulfilment of one should not conflict with the fulfilment of another or with any other legal requirement".*
(2)	**BASIS: GSR Part 1 (Rev.1) para 4.28 states that** *there shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties".*
S5	**Suggestion: The ANVS should consider standardizing the licence conditions for nuclear facilities taking into account a graded approach to ensure that the fulfilment of the regulatory requirements is consistent to build confidence among interested parties.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

In the Netherlands, there is only one NPP under operation since 1973, Borssele NPP (450 MWe, KWU - German design). Currently this NPP is under the first long-term operation licence.

The licensing process for a nuclear power plant follows the rules and procedures for authorization of nuclear facilities as described in Chapter 5.1 of this report.

In accordance with the current regulatory framework, the licensing process of a new NPP is a three-step process, starting with the stage of construction licence. There is no separate licensing stage for site evaluation or design, these are considered as part of the construction licensing stage.

For new builds, ANVS has developed a document ("Dutch Safety Requirements on the Safe Design and Operation of Nuclear Reactors"-VOBK) containing requirements for design and operation, which is an integral part of the basis for decision making and regulatory process for granting the construction licence. The VOBK is publicly available and periodically updated. In the pre-licensing it plays a key role in describing the safety expectations of a new reactor and the review and assessment of a new project.

Design modifications including improvements of the plant may arise from the periodic safety review, or reactive to any lessons learned from ageing management and events. These may require authorization from ANVS before being implemented and commissioned, depending on their safety significance and following a graded approach. The IRRS team was informed that licensee has a procedure to categorize design modifications according to their safety significance. This procedure has been approved by ANVS.

Currently, the end of operation of the Borssele NPP is 31 December 2033 as stated in the Nuclear Energy Act. The licence will be revoked with respect to the activity to produce energy; the licence conditions will remain in force. However, according to the national nuclear programme there are plans to extend the period for long-term operating of Borssele NPP, with due regard for safety.

Regarding the authorization of personnel, ANVS has a process for the licensing of personnel with critical duties before they are appointed. In the licence of the Borssele NPP reference is made to NVR NS-G-2.8 (Dutch application of IAEA NS-G-2.8) and the specific Safety Guide NVR 3.2.1 for licensed control room personnel.

The operator licence is valid for two years. To renew their licence, operators must undergo a retraining programme. The annual retraining programme for the control room operators is developed corresponding to a 5-year training plan.

5.3. AUTHORIZATION OF RESEARCH REACTORS

Research reactors are subject to authorization in accordance with the ANVS Licensing Policy and it follows the same regulatory licensing process applicable for all nuclear facilities including the general requirements and arrangements, which are described in Chapters 5.1 and 5.2.

The IRRS team observed that there are pre-licensing activities performed (i.e. the activities taking place before a formal application is made) as an informal stage in the process for research reactors and this process is not described in the integrated management system. This issue is addressed in Suggestion S3 in Chapter 5.1.

Regarding the authorization of personnel, ANVS has a process for the licensing of personnel with critical duties before they are appointed based on ANVS regulation (Rnvk), technical specifications and relevant IAEA safety standards.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

Fuel cycle facilities are subject to authorization in accordance with the ANVS Licensing Policy and follow the same regulatory licensing process applicable for all nuclear facilities including the general requirements and arrangements, which are described in Chapters 5.1 and 5.2.

The IRRS team observed that there are pre-licensing activities performed (i.e. the activities taking place before a formal application is made) as an informal stage in the process for the fuel cycle facilities and this process is not described in the integrated management system. This issue is addressed in Suggestion S3 in Chapter 5.1.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Each radioactive waste (RAW) producer in the Netherlands is authorised for practices with radioactive substances. Depending on the authorisation process, the applicant has to submit to the ANVS, among others, "a description of the management of radioactive waste and of the facilities for storing that waste." RAW producers need this authorisation also for a short time storage of RAW, before it is transferred to COVRA.

COVRA is the national RAW management facility authorized by the ANVS for the processing and storage of radioactive waste and for the storage of spent fuel from research reactors. The licensing process for COVRA facility follows the rules and procedures for authorization as described in Chapters 5.1 and 5.2 of this report.

In addition to COVRA, there are three landfill disposal facilities for hazardous waste that also accept certain types of NORM radioactive waste in operation, and another site that previously accepted certain types of NORM radioactive waste has been closed. Licences for these landfill disposal facilities are issued by provinces which are the regulatory authorities for licensing of the landfill. These licensing and supervising responsibilities are not regulated under the KeW but are regulated by general acts and decrees. However, any landfill disposal facility seeking to dispose of certain types of NORM radioactive waste needs an authorization from the ANVS. These authorization procedures are generic and are regulated in the KeW and related decrees.

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The ANVS has established a graded approach for authorisation of radiation sources facilities and activities under the KeW. Authorization via licences is applied for medium to (very) high risk facilities and activities of a complex nature where radiation safety depends to a large extent on human behaviour and "performance", for example radiotherapy and industrial radiography. Authorisation by registration is intended for low to medium risk activities such as dental/veterinary and subject to fewer regulatory requirements.

The application process for a licence includes grounds for refusal. A licence is only granted if all of the required information is satisfactorily addressed which includes justification of the practice, optimization of protection of workers, environment and patients, compliance with dose limits to workers and the population and qualifications of radiation protection personnel. There is also a need to prepare a security plan, emergency-response plan and decommissioning plan for high risk radiation sources facilities and activities.

Clarification is needed whether the KeW provides for authorization of different stages in the lifetime of radiation sources facilities and activities such as site evaluation, design, construction, commissioning, operation, shutdown and decommissioning. Therefore, consistency with IAEA Safety Standards which requires that different types of authorization apply to different stages in the lifetime of the facility is not entirely clear.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current legal framework does not have provision for authorization of all different stages in the lifetime of radiation sources facilities such as site evaluation, design, construction, commissioning, operation, shutdown and decommissioning.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para. 4.29. states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure)…".*
R4	**Recommendation: The government should review the legal framework with respect to different types of authorization for all different stages in the lifetime of a radiation sources facility in accordance with a graded approach.**

Licences for radiation sources facilities and activities are granted for an indefinite period of time. This may require the regulator to impose licence conditions to require that licensees verify safety requirements at specific hold points prior to progressing to the next stage in the lifetime of a facility or the duration of an activity.

The regulations provide general requirements for the safety and security of category 1 to 3 sources including at the end of their useful lives. There are also requirements for radiation generators and radioactive sources to ensure protection and safety including engineering, performance and functional specifications. For High Activity Sealed Sources (HASS) additional requirements are applied, e.g. financial security (e.g. bank guarantee), agreement with the manufacturer or supplier regarding the return of the source when the source is no longer required.

All licensees and registrants are required to appoint a Qualified Expert (QE) and radiation protection officer/s (RPO) to ensure appropriate radiation safety expertise to ensure safety and protection. QE's are responsible for establishing safety requirements consistent with the KeW including providing annual reports on safety and protection to licensees. RPO's are responsible for supporting day to day safety requirements within authorised parties.

The ANVS requires holders of complex licences to implement a system of radiation protection and safety provided by QE's and RPO's including for internal supervision of workers. QEs may also issue internal approvals on the basis of independent safety assessments.

QE(s) and radiation protection officers are required to hold qualifications in accordance with requirements specified in the regulation. Workers are also required to have specific knowledge and skills in both radiation protection and safety including competency in carryout the activity involving the radiation source. This information is required as part of the authorisation of the licence holder.

All licensees are required to have a management system including a Nuclear Energy File prepared by their QE. The QE(s) provide an annual report to the licensees, on the outcome of their risk assessment and safety and protection measures. Such reports are however, not required to be provided to ANVS other than by licensees with a complex licences or licensees in oil and gas industry.

The Government has submitted a written commitment to work towards the full implementation of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (CoC). The import and export of category 1 and 2 sources between Netherlands and another EU country is governed by the Euratom Regulation 1493/93 which is consistent with the CoC. The import and export of category 1, 2 or 3 sources countries outside of EU require a transport licence.

The ANVS maintains a national registry of HASS sources as specified under the regulation. The licensees are required to annually report the current inventory of their HASS sources via the ZAPP, the ANVS online portal. This includes transfer to another authorised party. Licensees who do not comply in a timely manner with HASS annual reporting requirements may be targeted for inspection by ANVS.

The ANVS has commenced a project for accurate and timely reporting and recording of HASS sources to its Register under ZAPP. This project is however, in its initial stages and yet to be finalised by ANVS. The IRRS notes that ANVS should give priority to finalising this project to ensure accurate timely reporting, recording and tracking of HASS sources in the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS has commenced a project to ensure accuracy and timely reporting of HASS sources to its HASS Register. This project is still in its initial stages and yet to be finalised. This has been identified in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 3 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:* *— Registers of sealed radioactive sources and radiation generators;…".*
S6	**Suggestion: The ANVS should consider finalizing an accurate register of HASS.**

HASS can only be transferred to another authorised party. However, there is no similar requirement that a radiation generator or non-HASS radioactive sources should only be transferred to a recipient that has an appropriate

authorisation. This is not consistent with IAEA Safety Standards which requires non-exempt sources to be under the control of an authorised party.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Other than the transfer of HASS sources, the KeW does not have a requirement that a radiation generator or radioactive source can only be transferred to an authorised party. This has been identified in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 3 Requirement 17, para. 3.55 (c) states that** *"A radiation generator or radioactive source is transferred only if the recipient possesses the necessary authorization."*
R5	**Recommendation: The Government should establish provisions in the legal framework that a radiation generator or a radioactive source (not being HASS) is transferred only if the recipient possesses the necessary authorization.**

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Decommissioning facilities and activities are subject to authorization in accordance with the ANVS Licensing Policy and it follows the same regulatory licensing process applicable for all nuclear facilities including the general requirements and arrangements, which are described in Chapters 5.1 and 5.2.

In addition, the Dutch legal framework (Bkse) and Shutdown and Decommissioning Regulations include detailed provisions on decommissioning licensing for nuclear installations. For non-nuclear installations decommissioning is executed under an amended operational licence. However, the ANVS is empowered to issue a separate decommissioning licence. This issue is addressed in Recommendation R4 in Chapter 5.6.

5.8. AUTHORIZATION OF TRANSPORT

The ANVS is the Competent Authority for the transport of radioactive material as recognized in the KeW. The modal agreements and regulations (ADR, RID, ADN, ICAO TI, and IMDG Code) are transposition of the IAEA Transport Regulations SSR-6 (Rev.1) for each mode of transport and therefore all the provisions in SSR-6 (Rev.1) are to be addressed in the authorization process. However, it was noted that some misalignment between the national regulations and the modal regulations exists due to the early structure of the national regulations and Council directive 2013/59/EURATOM.

According to a graded approach, licenses are requested for all modes of transport, for shipments into/from Dutch territory, within the Netherlands for transit of fissionable material, radiopharmaceuticals, consumer products containing radioactive substances and HASS. A notification, three weeks before the transport, is requested for transport of radiopharmaceutical within the Netherlands and for transport, into/from Dutch territory, within the Netherlands, or transit of other radioactive substances. Under specific conditions an annual notification can be submitted instead of the three weeks notification. For example, for transport of radiopharmaceuticals an annual notification can be submitted because of the high volume and orders on short notice.

Licenses may be issued to the consignor, the carrier or the consignee and any one of these licensed parties is required to be the licensee of record for a particular shipment taking sole responsibility for ensuring that the transportation of radioactive material is accomplished safe and in compliance with applicable regulatory requirements. A transport license is also requested for shipments by special arrangements and Surface Contaminated Objects (SCO-III). All aspects relevant for safety and the data of the shipment must be included in the documents submitted in the application form according to the Transport Decree.

Licenses for transport of fissionable and radioactive material are granted for three years for an existing transporter already known to ANVS and one year for new applicant.

Package design approvals, design approvals for special form radioactive material, are issued by ANVS. When they are used for transport in the Netherlands only, the approvals are issued in Dutch. For international transports they are issued in English. It was noted that the Human Environment and Transport Inspectorate (ILT), in addition to other

tasks, is the main partner on supervision on the transport of dangerous goods including Class 7 (radioactive material). For transport by air ILT issues a recognition to the operators, based on the "Dutch Aviation Law" and the "Dutch decree on transport of Dangerous goods by air". To avoid potential undue duplication in the assessment and conflicting requirements to the authorized parties the coordination between the ILT and ANVS, based on a formal agreement, is essential. This issue is addressed in Suggestion S1 in Chapter 1.5.

A web system is available on the ANVS web site to apply for a license, to submit a notification or to request a design approval. Applications for transport licences are processed in accordance with the Netherlands Awb and made public on the ANVS website.

5.9. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Protection of workers against the risks of ionizing radiation is addressed in the Bbs. This Decree establishes responsibilities for protection of workers both in nuclear and radioactive facilities.

Occupational exposure is reviewed and assessed as part of the authorisation process by ANVS including whether the activity is justified. The Rbs provides a list of justified and non-justified practices. The regulation also includes guidance on how to justify the practice from the occupational exposure point of view.

The ANVS applies a graded approach to the licensing process of radioactive facilities, by requesting a Risk Inventory and Evaluation (RI&E) for low risk applications, and on top of that a more detailed Radiation Protection Programme for high risk applications.

For nuclear facilities, a radiation protection programme is required in order to demonstrate compliance with the Bbs. Nuclear facilities and complex license activities are required to have an independent radiation protection unit directed by a QE with sufficient support personnel.

The Bbs establishes dose limits in accordance with Schedule III of GSR Part 3 Requirement 12. The Bbs also establishes the obligation for the licensee to establish dose constraints for planned exposure situations.

The Bbs contains the requirements and responsibilities for all involved parties in the protection of workers in planned and existing exposure situations, including organizational, procedural and technical requirements for the control of occupational exposures, including designation of supervised and controlled areas, classification of workers, cooperation between employers, registrants and licensees and requirements to assess and register the worker's doses.

The use of protective equipment, information on the risks and training is addressed by the Working Conditions Act, which is applicable to radiation exposure in the workplace. QE(s) and RPO's are responsible for monitoring occupational exposures to ensure that are maintained under the respective dose constraints.

Dosimetry services are authorized by ANVS with the criteria established by the Ministry of SZW in the Regulation on Radiation Protection for Occupational Exposure. During the authorisation process for a dosimetry service, ANVS consults with the Ministry of SZW, but these consultations are not formalized. The NDRIS is managed by Nuclear Research Group (NRG), an independent organization appointed by the Ministry of SZW. Currently, there are two dosimetry services authorized in the Netherlands. The NRG, as NDRIS manager, holds technical meetings twice a year with the authorized dosimetry services.

The Bbs establish specific provisions for the protection of pregnant and breastfeeding workers, as well as for persons under 18, consistent with IAEA Safety Standards.

The Netherlands has a National Radon Action Programme that establishes reference levels for recording the radon concentration in air at the workplace. Additional requirements for data recording are laid in the Ministry of SZW's Regulations on Radiation Protection for Occupational Exposure.

The Regulations on Radiation Protection for Occupational Exposure issued by the Ministry of SZW establish the accepted methods to assess the doses of aircraft crews.

5.10. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The authorization function for the activities involving ionizing radiation in the medical field is performed by the ANVS. Different types of authorization are issued, according to the Bbs, such as registration, licence and complex licences (hospitals that have more than 100 applications).

The authorizations of medical practices contain in the annexes different conditions, including conditions from other authorities. References to the national or international guidelines that should be followed are also listed in the annex, thus effectively becoming legally binding when incorporated into the licence. At present there is no formal process for meetings between the Ministry of Health and the ANVS for the assessment or justification of new practices or new technology, however, in practice informal meetings occur.

Generic justification of practices is published in Annex 2.1 of the Regulation on Basic Safety Standards for radiation protection (Rbs). It consists of a list of justified and unjustified practices. The IRRS team was informed that the list is planned to be reviewed by the end of the year.

The Bbs requires Minister of VWS to ensure that DRLs exist and are regularly reviewed. There are DRLs for diagnostic x-ray procedures but these were produced in 2012, there are no DRLs for nuclear medicine procedures. As a consequence, current DRLs do not exist for all procedures and the existing DRLs need to be reviewed.

The Regulation on Basic Safety Standards empowers the Minister of Health, Welfare and Sport to set dose constraints for carers and for persons involved in research. However, to date, no dose constraints have been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no diagnostic reference levels for diagnostic nuclear medicine procedures. There are no dose constraints for carers and comforters or for volunteers participating in a programme of biomedical research. This has been recognized in the ARM. Furthermore, the current diagnostic reference levels have not been reviewed since 2012.	
(1)	**BASIS: GSR Part 3 Requirement 34 states that** *"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established".*
(2)	**BASIS: GSR Part 3 Requirement 34, para. 3.149 states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:* *(a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for:* *(i) Exposures of carers and comforters;* *(ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research".*
R6	**Recommendation: The Ministry of VWS should ensure that Diagnostic reference levels for medical exposure, dose constraints for carers and comforters and for volunteers participating in a programme of biomedical research are established.**

The Bbs establishes that the justification of individual medical exposure is assessed by the referrer and the medical expert in advance. But the use of referral guidelines is not stated in the regulations.

The Federation of Medical Specialists published on its website more than 350 general medical guidelines, however these are not legally binding. Some of these guidelines includes direction for clinical indication of medical exposure.

The Dutch Society for Radiology together with the Dutch Association of General Practitioners has issued referral guidelines for general practitioners for X-ray investigations. There are no similar guidelines for diagnostic nuclear medicine.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The referral guidelines available for the justification of the individual medical exposures are limited to general practitioners for X-Rays.	
(1)	**BASIS: GSR 3, para 3.158 states that:** *"Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure".*
(2)	**BASIS: GSR 3, para 1.14 states that:** *"…For the final level of justification, the application of the radiological procedure to a given individual has to be considered. The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account by means of referral guidelines developed by professional bodies and the health authority".*
S7	**Suggestion: The Ministry of VWS should consider ensuring the completion of referral guidelines for individual medical exposures.**

The requirement for calibration of dosimeters used for dosimetry for patients are not defined in the regulations, including the requirement for traceability to standards dosimetry laboratory.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no requirements for the calibration of dosimeters used for dosimetry of patients being traceable to a standard dosimetry laboratory.	
(1)	**BASIS: GSR Part 3 Para 3.167 states that** *"in accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standard dosimetry laboratory".*
R7	**Recommendation: The Government should ensure that there are regulatory provisions for calibration of dosimeters and other equipment including the traceability to a standard dosimetry laboratory.**

There are no legal requirements to have advisory signs for pregnant or breast feeding women in public places, waiting rooms for patients, cubicles and other appropriate places. During the site visit the IRRS team noticed that no such warnings were displayed in the nuclear medicine department.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulatory requirements for registrants and licensees to ensure that advisory signs for pregnant or breast-feeding women in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places.	
(1)	**BASIS: GSR Part 3, para 3.175 states that** *"Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that: (a) She is or might be pregnant; (b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical".*
R8	**Recommendation: The Ministry of VWS should establish requirements to ensure that advisory signs for pregnant or breast-feeding women in appropriate languages are placed in public places,**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	waiting rooms for patients, cubicles and other appropriate places.

However, the Bbs regulation is entirely in line with the EU-BSS with regards to the requirements for dosimetry by the medical physicist, and the notification of pregnant or breastfeeding women before a radiological procedure. On these aspects there are (subtle) differences between the GSR Part 3 requirements and those depicted in the EU-BSS.

According to the Decree on Basic Safety Standards for radiation protection, medical applications can only be performed by properly trained personnel. In the law on individual healthcare providers (Individual Healthcare Professions Act (IHPA)) it is described that only registered doctors, dentist and medical technologists can perform radiological procedures on patients.

The IRRS team noted that the profession of the clinical physicist is recognized only by the Dutch Society for Medical Physics (DSMP).

5.11. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The KeW applies to both nuclear and radioactive sources and is the primary control of the authorisation process. Various guides are also available to support the process, but these are not legally binding. The ANVS, as the competent authority, can attach requirements for the protection of people under the KeW. The ANVS is the sole authority which can authorise discharges that may impact members of the public.

On application, the ANVS checks whether the principles of radiation protection (justification, optimization and dose constraints) are met on the basis of the information in the application supplied by the applicant. Dose limits are the final step and provide the public protection levels. Article 3.2 ANVS Regulation requires that applicants provide an estimate of the ambient annual dose to members of the public as result of the operation of a facility or conduct of an activity. Thus, the public exposure is assessed as part of the authorisation process. During the site visit to the Reinier de Graaf hospital in Delft, it was noted by the ANVS inspector that the assessment of the public dose made by the operator as part of its annual assessment had some errors in the dose calculation. As there is no requirement for periodic reporting to ANVS this error was missed and not corrected until the inspection.

For offshore oil and gas licences some of which are almost twenty years old and predate ANVS. The assessment of doses to the public are based on a generic assessment which is conservative and can be scaled according to actual proposed discharges. In addition, the licence also specifies that a public dose limit of 10 micro Sv per year from all pathways cannot be exceeded.

Authorisation of nuclear sites discharges is monitored and assessed consistently with the requirements of Euratom. However, releases from non-nuclear sites (oil and gas together with Hospitals) to the environment which are authorised are not subject to the same rigour as nuclear sites, nor is there an established monitoring programme in place to retrospectively assess the discharges. As a result, ANVS cannot, independently verify the impact on the representative person. Optimization for public exposure is undertaken by making comparisons to current best practice and consideration of cost with an intention to, wherever practicable, lower the potential doses towards 10 micro Sv per year.

Transposition of the latest Euratom Directive included transposition into Dutch law on consumer goods (raised in the 2018 IRRS follow-up mission) prohibits the deliberate addition of radioactive substances to toys and jewellery and can only be added to other products if justified and below exemption values (10 µSv per year). A licence is always required for import, production and export of consumer products with radioactive material. Some justified products are being phased out e.g. smoke detectors following a reassessment and subsequent changes to the building regulations in 2002 for new buildings and a change to justification of new detectors in 2013.

Some consumer products which are no longer justified have been detected in the Netherlands. Following the detection of the importation of thorium welding electrodes which were no longer justified in the Netherlands an awareness programme was undertaken by Inspectorate Social Affairs and Employment (now known as the NLA). Similarly, in response to the selling of unjustified ‘negative ion’ products ANVS raised awareness that such items are not safe for use.

The list of currently justified consumer products is available in Annex 2.1 Rbs. Annex 2.1 Part B of the same document provides "Categories or types of non-justified practices and measures". This regulation was updated following the latest Basic Safety Standards although there is no formal periodicity to the review period.

The Netherlands made provisions for existing exposure situations when it implemented the EU-BSS (2013/59/EURATOM), the Decree on Basic Safety Standards for Radiation Protection contains provisions for identification and management of existing exposure situations (6.15 -6.19). The same decree details a national action plan for radon, in home 6.20 and gamma radiation from building materials 6.21. Reference levels for existing exposure situations and radon in homes are detailed in 9.10 and in 6.21 for gamma radiation from building materials.

Clearance and exemption levels were updated following the new European Basic Safety Standards, in addition further clearance and exemption can be introduced for specific practices or items such as consumer products, in most cases such further exemptions/clearances have a specific condition associated with granting that exemption/clearance.

5.12. SUMMARY

The Dutch legal and regulatory framework for the authorisation of nuclear and non-nuclear facilities and activities is mainly established under the provisions of the KeW. The ANVS has in place a comprehensive licensing policy and associated procedures governing the authorization process.

However, areas for improvement in the authorisation process were identified. These include to:

- Formalise the pre-licensing step of new facilities and activities and standardise the contents of the licences for nuclear facilities and activities under the AIM.
- Strengthening requirements to ensure that authorization are issued for the different stages in the lifetime of a radiation sources facilities and establishing a register for recording, tracking and reporting of HASS.
- Strengthen protection and safety in medical exposures to ensure appropriate diagnostic reference values, referral guidelines including requirements for calibration of dosimeters.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The ANVS is empowered to perform review and assessment of applications for authorisation of facilities and activities in accordance with a graded approach.

The ANVS performs review and assessment of applications and modifications of authorisations including periodic safety reviews in order to determine whether the applicant or the authorised party complies with applicable regulatory requirements.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The review and assessment process interacts with the tasks of authorisation, inspection and enforcement. This requires personnel working within these respective areas of the ANVS to work collective to form a single view. Results of the review and assessment process are recorded in the ANVS document management system (Content Manager (CM)) and used for feedback.

The main focus for the review and assessment for a nuclear installation is on both the level of the PSAR, and the Safety Report. To respect the authorisation timeframe of six months which has been established by the General Administrative Law, a system of pre-licensing engagement is used to support applicants, which is especially important for complex facilities and activities.

The AIM also incorporates a risk-based planning and prioritisation process for the review and assessment for nuclear facilities and activities. For example, for normal review and assessment task such as modifications allowed within the licence, the Quickscan form is used by the plant inspector and/or technical specialist to evaluate the acceptability of the application/information, and to determine the scope and planning of the review and assessment. For more complex review and assessment tasks such as periodic safety reviews or large licence applications a review team is assembled and a planning/priority decided.

All relevant documentation and quality control processes are managed via the AIM, except for documentation that is classified. All quality control steps are documented in CM using the "rondzendmap" process, where each participant is required to sign off on the quality control task. The decisions based on the review and reviews itself are also separated with the QA process.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The IRRS team was informed that ANVS is capable of carrying out review and assessment responsibilities independently; this is one of the key factors that support its effective regulatory independence. This was observed for the Hospital inspection to Reinier de Graaf hospital. However, some particular analyses may require the use of TSOs.

The review and assessment activities for nuclear facilities are typically carried out with professionals belonging to the groups of "Technical and Organisational Expertise" and "Radiation protection, waste & decommissioning" (ONT and SAO). The practice is to create "technical task groups" (TTG) with professionals belonging to these groups in order to secure the knowledge, skills and attitudes needed for the specific review and assessment activities. In general, a TTG consists of at least three or four specialists with different levels of seniority and experience.

For review and assessment activities of radiation sources facilities and activities including transport, the "Competent Authority Department" is supported by the department of Assessment & Advice for any specialized review and assessment tasks both of these are within ANVS.

In the case of complex review and assessment activities, like in-depth evaluation or confirmatory analysis, the ANVS can use external TSOs. In these cases, an assignment form is completed which ensures ANVS's own personnel always participate in the evaluation. The IRRS team finds that this arrangement is adequate to enable ANVS to discharge its

responsibility and supports decision making process. In this regard, the ANVS has shown itself to be an "intelligent customer".

The IRRS team was informed that the ANVS has a dedicated education plan for building up competences of the personnel belonging to each function group. The ANVS staff can also be QEs.

A graded approach is used in prioritising the planning and resources for review and assessment. The technical specialists within the department of Assessment and Advice are responsible for review and assessment tasks of non-nuclear facilities and activities including transport.

The ANVS has a competence matrix; however, the ARM has acknowledged that it is challenging to maintain the minimum Knowledge, Skills and Abilities (KSA) necessary to perform all review and assessment tasks within the allocated time due to resource constraints. However, external resources are available through TSO contracts, with specialists available from the RIVM and the Ministry of Health and universities in the Netherlands and where necessary from different countries. The current TSO contract provides support in review and assessment tasks and inspection tasks. The ANVS technical specialists guide the TSOs to achieve the outcomes of review and assessment tasks.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The bases for review and assessment are established in the regulations, regulatory requirements and guidelines. For all facilities and activities, the bases in regulation and guidance for review and assessment are described under the corresponding sections of this report.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The first stage in the review and assessment process is the evaluation of completeness and quality of submissions. This is done by the technical task group in charge of the review and assessment, with regard to the licensing stage and by applying a graded approach. When TSO's are involved in the activity, both the ANVS and the TSO can perform the review in parallel, but using different levels of details, in order to have an independent review. As described in Chapter 6.1.1, scope of the tasks is determined through the quick scan process.

The ANVS performs several activities on a regular basis focused on the integration of outcomes from review and assessment, and inspections activities. For example, for nuclear facilities under article 15(b) of the KeW, every three months ANVS conducts meetings between the personnel in charge of a topical review and inspections, to discuss results from their activities and integrate the outcomes from these activities. During these meetings common topics under discussion may include: incidents and feedback to the annual inspection plan, etc.

The IRRS team notes that the integrated assessment is a key activity for the decision making during the authorization process or for judging whether it is acceptable for the facility to continue operation. Performing integrated assessments by reviewing outcome from all regulatory activities in an integrated manner enables an assessment of the overall safety performance, trends and conclusions to be made in order to identify areas for improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS has in place different arrangements for performing integrated assessments by reviewing outcome from all regulatory activities in an integrated and comprehensive manner. However, there is no formal process for conducting such integrated assessment, which may lead to inconsistencies in review and assessment.	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.46 states that** *"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. 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…. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach".*
R9	**Recommendation: The ANVS should include a process for the regulatory integrated safety**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	assessment activities in the AIM.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

Review and assessment of licence applications and for modifications of licences for nuclear power plants follows the general approach described for other nuclear facilities in Chapter 6.1.

The submissions that are subject to the review and assessment are related to licence applications, modifications of licences, periodic safety reviews and to those documents necessary to ensure that the licensing basis remains valid as established in the licence conditions. In addition, the ANVS evaluates the operational performance every two years by integrating review and assessment and inspections results.

The ANVS has developed the following documentation governing the review and assessment of the relevant submissions in connection with the authorization process:

- "Technical Review Report", guiding the review of the Safety Analysis Report for nuclear reactors during all stages of the lifetime.
- "Guidelines for the ten-yearly Periodic Safety Review of nuclear facilities", describing the process, the steps and the responsibilities for the review and assessment of periodic safety review of nuclear installations.

Regarding safety assessment for nuclear installations, Dutch Safety Requirements details the requirements for the review and assessment. For probabilistic safety analyses, ANVS has published the "ANVS Guide on level 3 PSA" as a supplement to level 1 PSA and level 2 PSA. Relevant IAEA safety standards and/or WENRA RL for nuclear facilities are listed in the licence of each facility.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The review and assessment of licence applications and modification of licences for research reactors follows the general approach described for other nuclear facilities in Chapter 6.1.

For the review and assessment of licencing application of new research reactors, ANVS uses the TRP and the DSR - Annex 6, as both documents provide the basis and the criteria for the review and assessment.

In the Netherlands all research reactors must have a full scope level 3 PSA, enabling them not only to show compliance with legal limits but also to gain a fundamental overview of the risk contribution of SSC's. To enable a clear PSA acceptance process, the ANVS developed and recently updated its own comprehensive Level 3 PSA guide, to complement the level 1 and 2 guidance from the IAEA. For non-reactors, a quantitative risk assessment is performed, in which postulated initiating events (PIE's) and hazards are identified, the installation response is determined, source terms are calculated for scenarios leading to radiological release and dispersion models are used to derive the individual and societal risk.

The use of risk metrics in the Bkse approach leads to a very thorough risk assessment for all nuclear installations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Dutch legal framework (Bkse Decree) prescribes how risk analyses for specific types of nuclear facilities have to be performed. This risk analysis is carried out in the form of a full Probabilistic Safety Assessment, PSA. The ANVS has developed a guide for the use of Level 3 PSA which has been successfully used during the licensing of PALLAS research reactor.	
(1)	**BASIS: GSR Part 4, Requirement 6, para. 4.19 states that** *"The possible radiation risks associated with the facility or activity include the level and likelihood of radiation exposure of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	workers and the public, and of the possible release of radioactive material to the environment, that are associated with anticipated operational occurrences or with accidents that lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation".
GP1	**Good Practice: The ANVS has developed the guide on use of the PSA level 3 and implemented it for the licensing process of research reactors.**

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The review and assessment of license applications and modification of licences for fuel cycle facilities follows the general approach described for other nuclear facilities in Chapter 6.1 and 6.2. In addition to the assessment of licensing applications and changes in licence, review and assessments are performed on supporting documents which are listed in their licence conditions and need to be approved by ANVS. In cases where ANVS performs reviews of documents not listed in the licence conditions for approval, the normal supervision process that is described in Chapter 7 is used where they are considered as an inspection and this process is used.

Periodic Safety Review is performed every ten years for fuel cycle facilities following the Article 11 (3 and 4) of the Rnvk. The Guidelines for the ten-yearly Periodic Safety Review of nuclear facilities is applied for fuel cycle facilities with specific safety factors is specified in the guidelines.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The review and assessment of activities related to radioactive waste management follow the general review and assessment processes at ANVS in Chapter 6.1. Within the licensing process, the safety cases and the supporting safety assessments are reviewed and assessed by the ANVS. Once the licence is issued the safety is reviewed and re-assessed every ten years.

In recent years, the ANVS reviewed and assessed the PSR of the COVRA licensee and the facilities on this site, the safety of the extension of the HABOG (high-level, heat producing waste), VOG2 (U3O8 storage) and recently MOG (intermediate level waste storage facility) installations operated by COVRA. COVRA licence contains a condition for a ten-year cycle for the PSR.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Review and assessment of applications for a licence or registration for radiation sources, facilities and activities depends on the degree of complexity and risk of a facility or activity. This means that the higher the risk of a facility or activity, a more thorough and detailed review and assessment is performed. A key part of the assessment depends on whether the principles (justification, optimization and dose limits) of radiation protection including competence, security, emergency planning and financial requirements have been satisfied.

A standardised and automated process is used for making applications for registration of sources through the ANVS online portal (ZAPP). Authorisation by registration is subject to generic conditions stated in laws and regulations and not specifically stated on the registration. Any change to details of registration including the authorised parties triggers the need for submitting an amendment application. The IRRS team was advised that ANVS receives over 1000 applications per year with a total of around 7000 registrants at present.

The ANVS issues three types of licences, i.e. single, combined or complex licence depending upon the number, complexity and diversity of facilities and activities. The ANVS applies a flexible approach to the type of licence issued and any changes to the existing situation may lead to changes in the type of licence issued. The IRRS team was informed that there are 2500 licensees in Netherlands at present.

The ANVS authorises two levels of QEs, one for complex licences and nuclear facilities which require a higher level of training and competency including on-going structured professional development which is specified under the regulation. The training and competency for the second level of QE is less stringent. There are more than 350 QEs currently authorised in Netherlands. The QEs are required to be re-certified every five years. Radiation Protection Officers are not registered by ANVS but are required to satisfy specific training and competency requirements specified under the regulations.

The IRRS team was informed that ANVS undertakes a review and assessment of the management system of all licensees.

The ANVS cooperates with other inspectorates such as the NLA, IGJ, SodM to review the licence applications when appropriate, to assess enforceability of imposed conditions by the respective inspectorates. However, there is no formalised procedures to support sharing of information or collaboration between the inspectorates and ANVS.

There is a general process under the AIM to describe how the review and assessment process of submitted documents is to be handled. The ANVS has also prepared standardised templates and licence conditions to ensure consistency and accuracy in the issuing authorisations. The ANVS has some internal guidance on the procedures which are to be followed in the review and assessment of radiation sources facilities and activities, these procedures are not adequately incorporated under the AIM. The IRRS team was informed that there are projects underway to develop and finalise the AIM, which are addressed in Chapter 4.

The IRRS team was informed that there is no formal internal guidance or prioritisation processes for review and assessment using a graded approach to ensure a systematic and risk based approach. The granting of authorisations requires a number of internal checks prior to being approved by the Team leader.

To ensure that ANVS can determine an application within the legal timeframe (six months) ANVS uses a pre-authorisation period to hold informal consultation with the applicants in order to achieve an acceptable and complete application. A draft licence is subject to a six-week public consultation process prior to finalisation. Any issues raised by the members of public must be considered prior to issuing of the licence by ANVS. Such decisions may be appealed and resolved through the judicial process.

The licences are issued for an indefinite period with no hold points for specific stages in the lifetime of a facility. The review and assessment does not account for feedback from the previous stages in the operation of a facility prior to authorisation. The ANVS however, issues licence conditions which may require licensees to undertake safety assessments at specific hold points, as appropriate. The IRRS team was informed that non-compliance with safety assessments at specific hold points will trigger an inspection seeking rectification of the non-compliance. Licensees are not authorised to commence activities with sources or operate a facility pending restoration of compliance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS has some internal guidance on the procedures to be followed in the review and assessment of radiation sources facilities and activities, these processes are not adequately captured under the AIM. There are projects underway to develop and finalise the full suite of procedures for review and assessment including processes for consistent implementation and updating of procedures.	
(1)	**BASIS: GSG-13 para 3.191. states that** *"The regulatory body should provide internal guidance for its own staff on the procedures to be followed in the review and assessment process and on the safety objectives to be met. Internal guidance on specific topics for review and assessment should also be provided, as necessary".*
(1)	**BASIS: GSG-13 para 3.192**. *"The regulatory body should develop internal guidance on reporting on its review and assessment activities and on how it reaches its regulatory decisions...".*
S8	**Suggestion: The ANVS should consider further developing internal guidance procedures and processes for the review and assessment of radiation source facilities and activities using a graded approach under the AIM.**

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

According to the Bkse the final decommissioning plan is a part of the documentation the applicant must submit to the ANVS. This plan is reviewed by the ANVS using the established review and assessment process. After this review, the decommissioning activity is licensed, and the final decommissioning plan becomes part of the licence. If the licensee proposes a substantial change to the final decommissioning plan, the decommissioning licence will require to be amended.

The Bkse also requires the licensee to update a preliminary decommissioning plan during the operational phase every five years or whenever the ANVS deems necessary and submit it to the ANVS for review and assessment.

Once the decommissioning is completed, the ANVS decides on the cancellation of the decommissioning licence.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of transport activities in the Netherlands are performed considering the requirements established in the IAEA SSR-6 (Rev.1) and implemented by the modal agreement and regulations (ADR, RID, ADN, ICAO TI and IMDG).

Most of the packages used in the Netherlands, that need competent authority approval, are designed, manufactured, and approved by the Competent Authority of the countries of origin. For packages approved in non-ADR countries, ANVS issues a validation of the approval certificate by a limited review and assessment, or, by a more comprehensive analysis of the Package Design Safety Report (PDSR), according to the experience of the competent authority of the state of origin of the package.

In the 2018, the package approval certificate NL/0244/B(M)-96 (Rev.1), for transport of radioactive waste, was issued by ANVS based on the application of the company Robatel NL. The package was designed and manufactured in France for the use in the Netherlands. Internal ANVS staff competences were available for shielding and leaking assessment, while mechanical and thermal assessments were performed by a TSO (the Netherlands organization for Applied Scientific Research (TNO)) and supervised by ANVS. Tests on a 1:2 scale prototype and some constructing phases of the package were witnessed by ANVS as part of its compliance assurance programme. Review and assessment of compliance with the SSR-6 (Rev.1) of none approved packages are performed during the inspections at the premises of the consignors.

Para. 308 of IAEA SSR-6 (Rev.1) establishes that periodic assessment of doses to the workers and to the member of the public, due to the transport of radioactive material, shall be arranged by the relevant competent authority. This action is part of the compliance assurance activities of the competent authority and may be used to evaluate the effectiveness of the Transport Regulations. Another important aspect is the assessment of whether there is effective optimization of protection and safety. This may also help in achieving and maintaining public confidence. The occupational doses of the exposed workers involved in transport of radioactive material are collected and assessed by NDRIS, the existing system for dose registration, for which the Minister of SZW is responsible.

For doses to the members of the public no specific periodic assessment is required by ANVS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Periodic assessment of doses to the workers and members of the public due to the transport of radioactive material, is not required by the ANVS.	
(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.*"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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: The ANVS should require periodic assessment of the dose to members of the public, due to the transport of radioactive material, and verify that the dose remains below the dose limits.**

6.9. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Review and assessment of occupational exposure is performed by ANVS as part of the authorisation process for radiation sources, facilities and activities (refer to Chapter 6.6). The process involves assessing the RI&E submitted by the applicant. For nuclear facilities and complex licences, a radiation protection programme is requested and assessed as a part of the authorisation process.

The RI&E contents for radiation facilities is laid down in the Ministry of SZW's regulations on radiation protection for occupational exposure and includes all relevant aspects from GSR Part 3 related to exposure optimization, limitation and protection measures.

The radiation protection programme shall provide enough information to demonstrate compliance with the Bbs regarding justification, optimization, and limitation including radiation protection expertise to operate the facility or conduct the activity, in accordance with the requirements in the Bbs. The ANVS also uses GSG Part 7 as a reference in the assessment process for specific aspects of occupational exposure.

Nuclear facilities, complex licence holders, and oil and gas companies are required to send annual reports to ANVS. These reports are reviewed by ANVS during the preparation of the inspections to these licensees.

The results of the individual monitoring are reported to: the NLA for radioactive facilities; to the ANVS for nuclear facilities and activities; and to SodM, for mining operations. Individual monitoring data are recorded in the NDRIS and the annual report is made public available.

Documents related to occupational radiation protection are reviewed in case of a modification of the licence that has an impact on the RI&E or the radiation protection programme.

The ANVS reviews various documents related to occupational exposure, such as annual reports, dose estimations, dose evaluations as well as the radiation protection programme.

6.10. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The ANVS does not perform review and assessment of medical exposures as part of the licensing process. However, medical exposures to patients are reviewed and optimised as part of radiological reviews under the quality control measures implemented by radiological facilities.

Medical societies and professional bodies regularly (one peer review every 5 years) audit the radiological performs review for radiological facilities. Such reviews include all aspects of patient care, compliance with justification and optimisation requirements. The availability and appropriateness of procedures for quality control of sources and equipment and the regular performance of required quality control tests are also evaluated.

Radiological facilities record doses both therapeutic and diagnostic medical exposures.

6.11. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

The maximum annual exposure to members of the public is prescribed in the Decree on Basic Safety Standards for Radiation Protection is less than 1 mSv. To ensure compliance with this limit, the regulatory body has established facility or practice specific constraint of less than 0.1 mSv/yr; and requires optimisation of releases below this value. Lower limits for constraint of the optimisation have also been specified and are: – 0.001 mSv per year in the case of gaseous or liquid discharges – 0.01 mSv per year in the case of external radiation.

The Ministry of I&W has the responsibility for independent monitoring programmes to verify the public dose from authorised releases of radioactivity into the environment.

RIVM, the Dutch National Institute for Public Health and the Environment reports annually on the level of radioactivity that occurs under normal circumstances in the environment and food. However, such data relate to environmental concentration values rather than intakes and do not routinely include external dose rates. As such the total dose to the representative person is not assessed by RIVM. Although it is expected that the total dose to the public representative person is well within the 1 mSv limit, ANVS cannot, at present, verify this is the case.

This has been identified by the Netherlands self-assessment and the IRRS team encourage completion of this using a graded approach as soon as practicable. The monitoring programme and its subsequent assessment should provide confirmation that the public dose limit has not been exceeded.

Article 9.6 of the Decree on Basic Safety Standards for Radiation Protection obliges licensees are to provide appropriate monitoring equipment, programmes and methods for assessing public exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS does not verify that the doses to the public are within the public dose limit. This has been recognized in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 3 Requirement 32, para.3.135 states that** *"The regulatory body shall be responsible, as appropriate for:…(a) (ii) assessing doses to the public; and; (d) Assessment of the total public exposure due to authorised sources and practices in the state on the basis of monitoring data provided by registrants and licensees and with the use of independent monitoring data and assessments".*
R11	**Recommendation: The ANVS should independently verify that the dose to the public from authorised releases remains below the dose limits.**

Although the regulator does not undertake its own monitoring assessment for oil and gas production, the generic assessment provided by the oil and gas sector, which can be scaled according to specific limits or discharges provides conservative assessment. This assessment shows that the doses from such releases are negligible. In addition, as part of the obligations on the Netherlands under OSPAR, the dose to members of the public from such discharges into the North Sea have been assessed as being below the legislated dose limit.

The provisions for the assessment of consumer products are addressed in the licensing provisions (Chapter 5).

The Netherlands Action Plan states that "*The HASS directive (aimed at preventing unregulated sources) has been implemented in the Decree on Basic Safety Standards for Radiation protection"*. This Decree allows the Minister to intervene in case of contamination from past activities or events and grants the ANVS oversight in such situations. Specific regulations (the Radioactively Contaminated Scrap Metal Detection decree and the Radioactively Contaminated Scrap Metal Detection Regulation) are in place for detection and management of radioactive contaminated scrap metal.

Article 6.15 of the Bbs states that "*The Authority, in agreement with Our Minister concerned, is tasked with drawing up an inventory of possible existing exposure situations involving an exposure that is non negligible from the perspective of radiation protection, as well as determining that exposure. In so doing it can use the monitoring programme referred to in Article 6.24*."

The RIVM undertook a review of potential existing exposure situations in the Netherlands. This review reported that "no existing situations have been identified that are of concern from a radiation protection point of view". This assessment does not verify that the dose is consistent with the IAEA Safety Standards. Further, this review may have been limited in scope, for example, it did not consider the historic use of radium for luminescing and therapeutic uses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS does not consider all potential existing exposure situations in its review.	
(1)	**BASIS: GSR Part 3 Requirement 47, para. 5.3 a** *"Shall specify the exposure situations that are included in the scope of existing exposure situations".*
S9	**Suggestion: The ANVS should consider periodically updating its review of potential existing exposure situations in the Netherlands.**

6.12. SUMMARY

The review and assessment process of ANVS is quite comprehensive in accordance with the legislative framework and aligned to the ANVS Licensing Policy. However, areas for improvement in the review and assessment process were identified in order to:

- Formalize in AIM management system, the integrated safety assessment that is done periodically and by which, the overall performance of a facility is verified;
- Supplement the internal guidance for the review and assessment by developing the one corresponding to radiation source facilities and activities using a graded approach.
- Require periodic assessment of the doses to members of the public, due to the transport of radioactive material, to ensure that the system of protection is complete.
- Assessment of dose to the public from authorised releases and revise it whenever circumstances change
- Review of potential existing exposure situations in the Netherlands.

In the Netherlands all research reactors must have a full scope level 3 PSA, enabling them not only to show compliance with legal limits but also to gain a fundamental overview of the risk contribution of SSC's. The ANVS has developed and used in the licensing of PALLAS reactor, a state-of-the-art guide for the development of a level 3 assessment. This is acknowledged by the IRRS team as a good practice.

7. INSPECTION

7.1. GENERIC ISSUES

The inspections of nuclear and radiation facilities and activities are performed based on the Awb. Inspections of nuclear safety are conducted by the ANVS. Inspections in the field of occupational exposure, except nuclear installations (conducted by ANVS) and mining works (conducted by SodM), are conducted by NLA and IGJ is responsible for the inspections of patient protection in medical exposure.

Planned inspections are undertaken following the annual inspection plans. The IRRS team was informed however that the IGJ does not have a plan for inspections for medical exposures. For nuclear installations and for radiation sources and activities, the most used inspection method are interviews with the licensee and review of documents. Other inspection methods, such as surveillance, walk downs, observation of activities, etc. are also used. For nuclear installations, radiation sources and activities, announced inspections are usually performed. Unannounced inspections are typically performed during outages of facilities or in situations where an announcement could lead to undue bias of the inspection.

A training programme is developed for each newly appointed inspector based on their training needs. All inspectors are strongly recommended to complete a National Academy for Oversight that teaches the basics of inspection conduct and enforcement. Newly appointed inspectors then undergo on-the-job training until their manager deems them suitable to perform inspections independently.

A plant inspector is assigned to coordinate inspections at each nuclear facility. The plant inspectors rotate every five years.

The ANVS has a process for preparation, review, and approval of inspection reports. Inspection results are reported to the licensees or registrants via a letter which may attach the inspection report.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

Annual inspection plans are made based on experiences using risk assessment by technical task group and plant inspectors for each nuclear facility. EPR can be included as a point of attention in these inspections. The annual inspection plans and the different areas/topics to be covered during the inspections are discussed within a small group of inspectors together with the plant inspector.

The IRRS team observed that there is no inspection programme for nuclear facilities in place which describes the different areas for inspections in a systematic way. Facility specific indicators are not used when planning and evaluating inspections. An inspection agenda is prepared before each inspection in compliance with the annual inspection plan of the facility. The inspections are guided by an internal procedure, which includes the use of several templates for the inspection report. The ANVS uses plant inspectors for nuclear power plant and performs about 40 inspections per year.

The IRRS team was informed, that a project for developing an inspection programme for nuclear facilities just started. The aim of this new programme is to formalize and ensure systematic inspection planning e.g. to use proper frequency for performing different inspections in a systematic way. This approach emphasizes the use of multidisciplinary teams and the use of risk data when available. The inspection programme will be the part of the ANVS management system. The project is expected to be completed by the end of 2024.

The main parts of the project are:

- determination of goals for different inspection types,
- overview the inspection strategy, harmonized with the legal requirements,
- development an inspection table, based on a graded approach,
- development of detailed guides and supporting documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Currently, inspection plans for each nuclear facility are prepared annually, based only on their experience. The ANVS is developing an inspection programme for nuclear facilities, including both long-term and annual inspection plans. This is expected to be completed by 2024.	
(1)	**BASIS: GSR Part 1, Requirement 29, 4.50, states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach".*
R12	**Recommendation: The ANVS should continue the development and implementation of a multi-annual inspection programme for nuclear facilities.**

Inspections are supported by external experts from TSOs or another organization with relevant knowledge. The ANVS also conducts inspections together with regulatory bodies from other countries providing a forum to benchmark inspection practices.

Site visit to Borssele NPP

The IRRS team visited Borssele NPP site and observed an on-site inspection of fatigue monitoring concept of the NPP conducted by ANVS inspectors. The team was accompanied by ANVS counterparts. The ANVS inspection team was comprised of two inspectors and an external expert. The inspection was carried out by means of interviews of the licensees and review of documents. In their preparation, the inspectors specifically discussed the inspection objectives and specific items which had been previously identified. The inspection was carried out in accordance with the inspection agenda. The inspectors were found to be well prepared and competent during the inspection and showed a professional and cordial attitude, which facilitated a productive interview. Inspection results were documented and discussed with licensee staff.

The IRRS team also met the Borssele NPP management staff, who stated that the work of ANVS provides mainly valuable feedback on the performance of the facility. Clarity of regulatory requirements and expectations should in their opinion be improved. The ANVS is open to detailed discussion of safety issues, and this is an effective tool to clarify regulatory expectations. Managing certain changes poses challenges to the licensees, such as the changes of regulatory system and involvement of new inspectors or new TSOs.

7.3. INSPECTION OF RESEARCH REACTORS

The inspection process for research reactors follows the general approach described for nuclear facilities in Chapter 7.1 and 7.2.

The ANVS uses a plant inspector for the research reactor and performs about 10-15 inspections to the High-Flux Reactor per year, and approximately 10 inspections to the Reactor Institute Delft per year. These inspections focus on reactor safety and radiation protection according to a facility specific approach, which is used to determine topics and frequency of the inspections. The IRRS team observed that there is no inspection programme in place which describes the different areas for inspections with the frequency in a systematic way. This issue is addressed in Recommendation R12 in Chapter 7.2.

The IRRS team was informed, that a new oversight practice has been developed before the construction licence for the PALLAS RR was issued. A new oversight strategy and a long-term inspection plan was developed considering the best international practices for monitoring of the facility construction. Based on these, the first annual inspection plan for PALLAS RR was prepared.

The resources necessary for oversight are provided by the ANVS and with involvement of TSOs.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

The inspection process for fuel cycle facilities follows the general approach described for other nuclear facilities in Chapters 7.1 and 7.2.

The ANVS uses a plant inspector for fuel cycle facilities and performed 5 to 10 inspections at each of the FCF during the last year and the same volume of inspections is in the annual plan for 2023. The IRRS team observed that there is no inspection programme in place which describes the different areas for inspections with the frequency in a systematic way. This issue is addressed in Recommendation R12 in Chapter 7.2.

Site visit to COVRA

The IRRS team visited COVRA (the central organisation for radioactive waste) in Nieuwdorp to observe an inspection related to discharges into water and air during normal operation. The licensee was provided with an inspection agenda according to the ANVS inspection procedures. The two inspectors performing the inspection acted professionally in the interacting well with the licensee. The inspections started with an entrance meeting, followed by the planned activity. Findings of inspections were presented orally at the end of the inspection. The inspection report and letter are sent at a later stage.

IRRS team members also interviewed the representatives of the licensee and were informed that the number of changes that had taken place at ANVS since it was established as one issue of concern. Further, they pointed out that it is challenging to follow the specific roles and responsibilities of the various authorities that exist. Finally, they mentioned the generation exchange, which is not only an issue for the ANVS and other authorities, but it is relevant for all the actors within nuclear sector.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspection of waste management facilities is accomplished using the same general approach as described in sub-Chapter 7.1 above and for nuclear installation operated by COVRA as described also in Chapter 7.2.

Site visit to the research reactor at TU DELFT

Two members of the IRRS team visited the research reactor in Delft operated by the Technology University of Delft (TUD). TUD is a licensee for R&D activities performed on the site of the university campus. Within the visit, the members of the team witnessed a planned RAW management inspection conducted by the ANVS staff. The usual frequency of this kind of inspection is once a year. The objective of the inspection was to gain an overview of RAW management, specifically by inspecting the management system of TUD, quantities of RAW in storage installations, controls performed by the licensee and licensee's procedures and instructions. The inspection was a jointly co-ordinated inspection undertaken by the ANVS plant inspector and specialist inspector. The IRRS team noted that both inspectors were highly competent and professional in their interactions with each other and the licensee. Their actions demonstrated a good understanding of the inspection agenda and ANVS inspection procedures. The inspection included interviews with facility managers and operating staff on site and visit of RAW management installations. Then the ANVS inspectors summarised their conclusions and at the debriefing, they effectively communicated their findings to the licensee in a clear and straightforward manner. As an outcome from the inspection the licensee will receive an inspection report and an inspection letter summarising the findings from the inspection.

During the separate discussion with TUD - Reactor Institute Delft (RID) management, the members of the IRRS team were informed that communication with ANVS has been open, frank and transparent. There was a total of approximately 10 ANVS inspections performed annually, mainly oriented on the operational safety processes. From the perspective of TUD-RID the inspection effort of the ANVS could be optimized by focusing on the overall management system implemented by the licensee such as effectiveness of licensee's safety policy rather than specific operational safety factors. This may be discussed at the next TUD-RID and ANVS management level meeting which occurs once or twice a year.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The ANVS Department of Competent Authority, Regulatory Inspection & Enforcement Radiation Applications is responsible for the inspection of radiation sources facilities and activities. In addition to the scope of the ANVS inspections, other inspectorates undertake inspections of facilities and activities involving exposure to workers (NLA, SodM) and patients (IGJ).

The ANVS has both a long-term inspection and an annual plan which incorporates a graded approach. The criteria to determine the type of inspection are described in the ANVS Inspection and Enforcement Strategy. ANVS inspectors and specialists contribute to the development of the yearly programme.

The ANVS inspection programme incorporates announced, unannounced, planned, and reactive inspections. The inspection programme is underpinned by the document "Monitoring of Medical and Industrial Applications of Ionising Radiation" (dated 2 May 2019) which provides the framework for risk informed inspection programme for radiation sources facilities and activities involved in medical or industrial applications. This includes the frequency of inspections and the areas to be inspected. Examples of risk prioritisation measures include the potential for loss/discovery of sources; activities being performed in open spaces or at third-party locations; activities involving high-activity sources; etc. The results of the risk analysis are used to inform risk classification (A (high) to D (low)) of medical or industrial radiation sources facilities or activities and used to risk prioritise inspections. Another feature of ANVS inspection programme also includes research into blind spots, i.e. potential risks about which there is limited or no information available. Research into blind spots is used to determine whether significant safety risks, systematic violation of legal requirements or non-authorised applications occur or could occur within particular facilities or activities.

ANVS's robust risk informed inspection planning which targets potential vulnerabilities in the operation of a facility or performance of an activity as well as objectively researching areas of its own lack of knowledge or potential blind spots to further optimise its regulatory inspection programme of radiation sources and facilities is considered as good performance by the IRRS team.

The IRRS team was however, informed that NLA, IGJ or SodM inspectorates responsible for occupational and patient exposures do not apply the ANVS risk assessment process or strategy documents in the planning or conduct of their inspections. The IRRS team was informed that other inspectorates may have their own risk assessment processes, however this could only be verified for the NLA.

For inspections of radiation sources facilities and activities the ANVS has established procedures and checklists for inspections. There are 7 inspectors responsible for radiation sources facilities and activities, with one inspector being on call 24/7 to deal with incidents and accidents. ANVS inspectors are qualified experts and empowered under the KeW as inspectors. Inspections may be performed by a team of inspectors or a single inspector. The NLA, IGJ and SodM have 3, 2 and 1 inspectors respectively.

Due to resource constraints, the ANVS was not able to complete the full suite of planned annual inspections in 2022. The IRRS team was informed that approx. 150 inspections (a high proportion of re-inspections) were undertaken in 2022, of which 40 were reactive in response to notifications regarding issues or incidents. The IRRS team notes that the number of ANVS inspectors is not sufficient to perform all of its planned inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The number of inspectors in the area of radiation sources and facilities is insufficient to perform all of the planned inspections.	
(1)	**BASIS: GSG Part 1 (Rev. 1) Requirement 18, states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
R13	**Recommendation: The Regulatory Body should ensure it has a sufficient number of inspectors to effectively perform all of its planned inspections.**

The IRRS team was informed that a web-based platform (PUC) is used as a publication platform for authorisations issued by the ANVS. This platform is used also by the other inspectorates to secure information about licences issues for inspection planning purposes. ZAPP is also used by the other inspectorates to access information from ANVS documentation regarding each authorisation, for example application, review and assessment, etc. There is, however, limited collaboration to optimise safety and protection in the conducts of inspections. The effectiveness of the regulatory bodies' inspection programmes may be enhanced through more formal mechanisms to coordinate and ensure consistency in inspection activities by the four agencies. This may include joint planning and risk prioritisation including proactive sharing of inspection finding and resources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Whilst there is some collaboration between the ANVS and the inspectorates responsible for occupational and patient exposures, the effectiveness of their respective inspection programmes may be significantly enhanced through more effective mechanisms to coordinate inspection planning and timely sharing of inspection findings between the inspectorates and ANVS.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 7, para. 2.18. states that** *"…This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience…".*
R14	**Recommendation: The ANVS should lead the establishment of effective mechanisms to coordinate inspection planning and timely sharing of inspection findings between the inspectorates and the ANVS.**

This observation has been validated by the 2022 State of Radiation Protection Report which evaluated the level of compliance of facilities and activities using results of inspections undertaken by ANVS and other inspectorates. The report noted that 49% of medical facilities and 65% of research facilities were assessed as being compliant. The report also estimated that there was 41% compliance with patient protection requirements within dental facilities and 13% compliance with worker protection within industrial radiography facilities. Likewise, NORM related activities where radiation sources are a by-product of the activity, the level of compliance is low. The ANVS team acknowledged the need for further work to more adequately evaluate the outcomes of the inspection programmes. The IRRS team commends the efforts in evaluating and reporting of inspection findings.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

There is only one nuclear installation in the Netherlands, which reached the decommissioning phase – according to the IAEA definitions, NPP Dodewaard. After shutdown in 1997 the facility started in 2005 its 40 years long safe enclosure period.

Inspection of decommissioning facilities is accomplished using the same general approach as described in sub-Chapter 7.1 and 7.2 above.

The ANVS performs inspections at the NPP Dodewaard at least once a year. The most recent planned inspection took place in May 2023 and was focussed on radiation protection.

7.8. INSPECTION OF TRANSPORT

Inspections are performed based on an annual inspection plan of authorized parties involved in the transport of radioactive material according to a graded approach. According to the ANVS inspection and enforcement strategy different types of inspections are performed to verify compliance of authorized parties in terms of radiation protection programme, records of safety training undertaken to the personnel, management system, maintenance of packages, arrangements for emergency preparedness and response.

Shipments licensed by ANVS are regularly inspected based on the provisions attached to the licence. Specific inspections are performed in the premises of stowage and handling of packages and on foreign packages in transit. The ANVS has two, plus one vacancy, Full-Time Equivalent dedicated to transport inspectors, that will spend around 50% of their time performing inspections. The annual inspection plan is mainly capacity driven, it may be of benefit to introduce a risk-based approach (e.g. using a system of risk categories 'high', 'medium' and 'low' risk). It was noted that additional human resources to inspect transport activities should be recruited and trained considering the number of operators involved, the large number of shipments annually performed and the transit of packages of foreign origin.

In case of road transport inspections, the drivers receive a summary of the results of the inspection, as required by "European directive 2022/1999 on uniform procedures for checks on the transport of dangerous goods by road". In the foreseen formal agreement between the ANVS and the Human Environment and Transport Inspectorate (ILT) the role and responsibilities of the two authorities should be clearly defined to fulfil the provision of the "Directive 2022/1999". This issue is addressed in Suggestion S1 in Chapter 1.5.

As part of the compliance assurance programme the competent authority should establish an inspection programme to verify by audits that the authorized parties' management system covers all the operations and conditions associated with, and involved, in the movement of radioactive material. Inspection of the operators' management system is an action of the competent authority compliance assurance programme to verify its implementation and application.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: An auditing programme, to inspect and verify if the transport organization's management system is adequate, is not implemented.	
(1)	**BASIS: TS-G-1.5, para. 4.58 states that** *"The competent authority should put in place an auditing programme to verify that the user's management system is implemented and followed correctly. The management systems used by designers and manufacturers, and by users of special form radioactive material, low dispersible radioactive material, Type B(U) packages, Type B(M) packages, Type C packages and packages containing fissile material, will be of particular interest to the competent authority. However, the competent authority should also ensure by means of an ongoing audit or inspection programme that suitable management systems are implemented in the transport of packages of other types. In determining the auditing programme, the continuity of the activity in question should also be taken into account; that is, the auditing programme for the manufacture of a single package may be different from that for the manufacture of packages in a continuous manner".*
S10	**Suggestion: The ANVS should consider establishing an auditing programme to inspect the authorized parties' management system involved in transport activities.**

7.9. INSPECTION OF OCCUPATIONAL EXPOSURE

The ANVS is the competent authority to perform inspections on occupational exposure in nuclear facilities, while NLA is the competent authority to perform inspections on occupational exposure for most non-nuclear facilities.

The ANVS inspects an average of four nuclear facilities per year, usually with a broad scope of activities regarding occupational exposure of workers. The ANVS has written procedures for performing the inspections. The ANVS has a yearly inspection plan as discussed in Chapter 7.1.

The NLA also performs inspections on nuclear facilities, regarding aspects regulated in the Working Conditions Act, such as the existence and use of adequate protective equipment as well as confirmation that no benefits are offered as substitutes for protection measures.

As part of the working agreement between NLA and ANVS, meetings are held every three months to discuss the results and findings of inspections. Minutes are kept of these meetings.

The NLA has inspected approximately 100 radiation sources and facilities per year in 2021 and 2022. NLA has a four-year programme with the objective to inspect all sectors in which occupational exposure applies. Due to the fact that NLA has three inspectors dedicating 50% of their time to occupational exposure, the facilities to be inspected are prioritized using a risk matrix that considers the risk of the facility along with the potential consequences of an incident in the facility.

The NLA prepares and conducts the occupational exposure inspections in accordance with written procedures and using standardized checklists.

The NLA frequently performs inspection campaigns on specific topics, such as industrial radiography and density and moisture measurements in roadworks. The results of these inspections are compiled into factsheets.

Under the Cooperation Agreement for radiological protection, ANVS and NLA have signed a working agreement that among other provisions allows NLA to consult the facilities' licenses from the ANVS ZAPP system and establishes the obligation for NLA to send the inspection reports of the occupational exposure inspections to ANVS.

7.10. INSPECTION OF MEDICAL EXPOSURE

The IGJ has general responsibilities for inspection of medical exposure and is administratively part of the Ministry of the Ministry of VWS.

The IRRS team was informed that medical exposures were not considered a priority for the IGJ as it is categorized as lower risk than other risk factors. As a result, there are no provisions for the regular inspection of medical exposures. The annual plan of IGJ includes other types of inspections, unrelated to medical exposures.

During the site visit to the Reinier de Graaf hospital the IRRS team was informed that in the last 8 years there were no inspections by IGJ for medical exposures in the nuclear medicine departments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regular inspections of medical exposure facilities by IGJ.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 29, 4.50, states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization".*
R15	**Recommendation: The IGJ should develop a regulatory inspection programme for medical exposures and implement it through the annual inspection plans following a graded approach.**

A training programme for IGJ inspectors is in place, based on the annual evaluation of training needs.

7.11. INSPECTION OF PUBLIC EXPOSURE

The IRRS team was informed that "The RIVM is commissioned by the ANVS to perform this assessment (of public exposure)". However, it should be emphasized that this assessment is not performed in a systematic way, using all data provided by licensees. These data are presented on the RIVM-website. These data report average doses to the population not the dose to the most exposed person. No information has been provided to demonstrate how the dose to the most exposed person is assessed or verified, that it is below the annual 1mSv limit. This issue is addressed in Recommendation R11 in Chapter 6.11.

The reports on the results of the independent monitoring programme are published by the National Institute on Public Health and the Environment (RIVM) on its website, including the results of the environmental monitoring programme in the vicinity of NPP Borssele. This report contains measurements of external exposure rather than a full assessment of the doses to the representative person from all pathways of exposure.

Site Visit: Reinier de Graaf Hospital

Three members of the IRRS team visited the Reinier de Graaf hospital in Delft. The team members oversaw an inspection of the hospital performed by two members of the ANVS. One inspector from the NLA was also present. The inspection was undertaken using the same format as the 25 hospital inspections performed last year.

The Reinier de Graaf Hospital has two SPECT CT and one PET CT scanners together with a dedicated laboratory, with a DEXA/DXA scanner and two radionuclide therapy rooms. The hospital routinely administers radiation for diagnostic purposes and provides treatments to patients. The hospital holds a permit from the ANVS to discharge radioactive material into the environment in liquid and gaseous form.

A site inspection was undertaken using a check list approach where the licensee was asked a series of questions about their activities. This inspection was prepared in advance by assessment of documents that were supplied by the hospital. A small number of clarifications were provided by the licensee on the assessment of the annual public dose.

A physical inspection of all the diagnostic and nuclear medicine facilities was undertaken by the ANVS. Following the inspection initial feedback was given to the licensee on the inspection findings.

Regarding medical exposure, it was noted that this hospital has never been inspected for the purposes of radiation protection of the patient by the IGJ.

The team observed the performance of inspection activities and discussed the effectiveness of the inspections with the licensee.

The licensee was asked if the effects if the COVID pandemic had impacted the activities in any way. The licensee noted that for nuclear medicine the pandemic had reduced the workload of the staff.

7.12. SUMMARY

Inspections are performed in planned manner; results are communicated to licensees and follow up of non-compliances is done, providing feedback to the regulatory inspection process in line with IAEA requirements.

Regarding inspections of radiation sources facilities and activities, the IRRS team identify as a good performance that the

- ANVS has developed a robust risk informed inspection planning. It targets potential vulnerabilities in the operation of a facility or performance of an activity as well as objectively researches areas of ANVS own lack of knowledge or potential blind spots to further optimise its regulatory inspection programme of radiation sources and facilities.

The IRRS team identified some areas for improvement, including:

- The need to develop and implementation of inspection programme for medical exposure,
- The establishment of an effective mechanism for coordination of inspection and sharing results between the responsible inspectorates for patient and occupational exposure,
- The requirement for the provision of adequate resources to be in place to ensure the effective inspection of radiation sources facilities, activities and oversight of transportation could be enhanced by auditing programme.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Legislation provides ANVS with the mandate and the authority to implement the enforcement of regulatory requirements on nuclear and radiation source facilities and activities. The legal bases are laid down in Chapter VIII of the KeW, general requirements for enforcement are laid down in, among others, the Awb, Environmental Law General Provisions Act and on the Economic Offenses Act.

In line with these powers and responsibilities, ANVS has established an enforcement policy (Inspection and Enforcement Strategy). The policy covers corrective measures in accordance with a graded approach and describes appropriate corrective action according to the importance of the regulatory findings including conditional fines, threat that the activity will be temporary or permanently suspended or limited and the threat that the necessary work is done at the cost of the neglectful organization etc. A new version of the Inspection and Enforcement Strategy have been developed by ANVS to better support practical application and extend it to minor deviations that are not formally non-compliances, providing a unified approach for enforcement.

As stated in Chapter 7.9, occupational exposure is inspected by ANVS for the nuclear facilities, and by NLA in non-nuclear facilities. The IRRS team noted that while ANVS can issue warnings, impose administrative sanctions, and prosecute as criminal offences non-compliances in the field of occupational exposure; NLA is not entitled to impose administrative sanctions in response to non-compliances related to occupational exposure.

The above stated fact impairs the application of a graded approach in the enforcement of occupational exposure requirements for radioactive facilities and could lead to different enforcement actions for the same non-compliance between nuclear and radioactive facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The NLA is not authorized to impose an administrative sanction in response to non-compliances with regulatory requirements or conditions of the license for radioactive facilities.	
(1)	**BASIS: GSR Part 1 Requirement 31, para. 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach".*
R16	**Recommendation: The Government should authorize the NLA to use the administrative law for enforcing compliance with regulatory requirements and license conditions related to occupational exposure.**

In matters related to the ANVS competence, communication with the licensees is done by a formal letter (if necessary substantiated by an inspection report) signed by a mandated person within the ANVS.

8.2. ENFORCEMENT IMPLEMENTATIONS

The decision-making process for the enforcement is well established, and the nature of the non-conformance to be solved is clearly indicated. Inspectors identify non-conformances (see the module 7 on inspection) and are equally responsible for determining and documenting the corresponding enforcement actions, and communicating them to the authorized party, firstly verbally on-site but always made official by a formal letter.

A detailed description of the actions related to the enforcement are included in specific process descriptions and work instructions. In short: after noticing a deviation from general regulations or, for authorized parties, conditions in the licence, the inspector first determines the safety impact of the non-compliance (graded approach), then the attitude of the offender, and whether any aggravating or alleviatory circumstances apply. Then, finding the corresponding cell in the so-called 'enforcement matrix', (one of) the pre-established enforcement actions for this level is determined.

The findings and corrective action are recorded by plant inspectors, but there is no a systematic approach to evaluate and confirm the effective implementation of a corrective action.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The ANVS does not have a systematic approach to analyse and follow-up on inspection findings and corrective measures at nuclear facilities. This has been recognized in the ARM and is part of the action plan.	
(1)	***BASIS:*** **GSR Part 1 (Rev. 1), Requirement 31 states that** *„In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties".*
(2)	***BASIS*****: GSR Part 1 (Rev. 1), Requirement 4.60. states that** *"Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions".*
(3)	***BASIS:*** **GSG-13, 3.294. states that** *"A programme to systematically analyse and follow-up on inspection findings should also be established. The programme should include provisions for periodic review and surveillance of the follow-up actions to verify that the authorized party is taking the necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the inspection findings should be formally closed and necessary documents and records should be maintained".*
S11	**Suggestion: The ANVS should consider developing and implementing a structured approach to monitor implementation of corrective actions related to nuclear facilities.**

8.3. SUMMARY

The existing legal framework provides adequate enforcement powers to regulators. The ANVS has developed and implemented a robust enforcement policy. This policy includes and describes graded actions for coping with non-compliances ranging from those of minor safety significance to those requiring strong enforcement measures.

The IRRS team identified some areas for improvement, like

- harmonization needs in the administrative law for enforcing compliance with regulatory requirements and license conditions related with occupational exposure.
- improving the evaluation of effective implementation of corrective actions.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Government and the ANVS have established a regulatory framework for nuclear and radiation safety. The legislation on nuclear activities and radiation protection is contained in the KeW and underlying Decrees, Ministerial Regulations and ANVS regulation. The regulations specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.

Nuclear regulation has been developed from the KeW into the Bkse and into the Ministerial regulation on Safety of Nuclear Facilities (RNV).

Radiation protection regulation is implemented through the Bbs which transposes the Council Directive 2013/59/Euratom. Additionally, the requirements for radiation protection are included in the ANVS Regulation on Basic Safety Standards, which is the only regulation issued by the ANVS to date.

In addition, the ANVS has developed Nuclear Safety Rules (NVRs), which are based on the IAEA Safety Standards. The NVRs only become legally binding when included in the licence conditions.

The Netherlands has an established system of stakeholder and public participation in all regulatory processes which is covered by different ANVS internal procedures. The IRRS team was informed that ANVS places significant emphasis on consultation with relevant stakeholders during the review of regulations and guidelines, which commence during the initial drafting stage of the regulations and guides. Ministry of I&W and ANVS are responsible for engaging with stakeholders, licensees, NGOs, and the public.

Contemporary consultation approaches such as the use of web-based platforms and forums, face to face meetings with licensees, relevant stakeholder and members of public are used. As part of the process of drafting legislation, ANVS assesses the practicability, enforceability and susceptibility to fraud of the proposed regulations/requirements. All legislations are published in the Official Journal (Laws and Decrees) or the Official (Government) Gazette (Ministerial Regulations) and are also made available on the internet.

The concept of graded approach has been adopted and is considered in the regulations and guides and depending on the risk it is expressed in the authorization process: exemptions, notification requirements and license requirements.

ANVS has an internal procedure for development and updating ANVS regulations and guides. The ANVS has the legal authority to participate in the preparation of regulations on nuclear safety as referred to in the Nuclear Safety Directive (governmental responsibility) and has the option of issuing guidelines and policy rules. One of the relevant guides is the VOBK for reactors.

Currently there is no systematic process for the revision of regulations to reflect development in nuclear safety. As a result, requirements may not reflect the most up to date IAEA Safety Standards. However, current practice at ANVS is to add new conditions to licences to reflect the current IAEA safety requirements when an applicant requires a new licence, the licence is modified or updated.

The ANVS has started the WIDOCS project which is aimed to ensure that IAEA safety requirements are updated and consistently applied in a systematic approach through the licence conditions. Furthermore, a policy rule is being prepared for new licence applicants. This issue is addressed in Suggestion S4 in Chapter 5.1.

As requirements in some areas of the regulatory framework are very general, or not established, the Dutch approach is to supplement the current framework that is strongly based on licence conditions. According to the IAEA Safety Standards, the consistency of the framework should be based on regulations and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In the Dutch regulatory framework, requirements in some areas are very general, or not established. For that reason, the ANVS defines more detailed requirements in licence conditions.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associate criteria for safety upon which its regulatory judgements, decisions and actions are based".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 34 para 4.62 states that** "*The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach".*
(3)	**BASIS: SSG-12 para 2.14 states that** *"Licence conditions are additional specific obligations with the force of law. Licence conditions should be incorporated into the licence, to supplement general requirements or to make them more precise, if necessary. Licences should state explicitly, or should include by reference or attachment, all conditions imposed by the regulatory body".*
R17	**Recommendation: The ANVS should further develop regulations and guides to be consistent with current IAEA safety standards.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The legal framework for nuclear power plants for constructions, operation and commissioning, and decommissioning are the KeW, the Bkse, the RNV and the NVRs.

The ANVS provides applicants with Dutch Safety Requirements for nuclear reactors, for the preconditions of nuclear installations and, for the continuous improvement of nuclear safety. The "Dutch Safety Requirements for Nuclear Reactors: Fundamental Safety Requirements" VOBK includes the IAEA Safety Standards that apply to all phases of the lifetime of a nuclear reactor.

The IRRS team was informed that the Netherlands is considering a lifetime extension of Borssele NPP beyond the current 2033 closure date. In addition, the Netherlands is planning for the construction of two new Nuclear Power Plants.

The IAEA Specific Safety Requirements in the existing licence for the Borssele NPP refer to the now obsolete versions of SSR-2/1 and SSR-2/2. As a result, the legal regulatory framework of regulations and guides, including the licence document, will have to be updated in respect with the new versions of SSR-2/1 and SSR-2/2. This issue was acknowledged by the ANVS and is included in the ANVS action plan. The IRRS team was informed that the WIDOCS project will include the development of a procedure to assure the regular updating of the licences to stay in line with the IAEA requirements.

Regarding the SSR-2/1, the required update of the regulation should carefully consider, among other requirements, the design basis accident and the internal and external hazards affecting the safety of the nuclear power plant. In relation to SSR-2/2, the update of the regulation should carefully consider the periodic safety review, accident management programme and long-term operation requirements.

For the new nuclear power plants, the new publication of SSR-1 Site Evaluation for Nuclear Installations should also be incorporate during the licence process. This issue is addressed in Recommendation R17 in Chapter 9.1.

The Government plans for the extension of operational lifetime of the Borssele Nuclear Power Plant beyond 60 years, which will require the Government to amend the KeW.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The Netherlands currently has two research reactors, High Flux Reactor (HFR) in Petten and Higher Education Reactor (HOR) in Delft and plans to build the new PALLAS research reactor in 2028.

The new PALLAS research reactor was granted a construction licence in 2023 by the ANVS. For the licensing process, ANVS has applied an internal procedure ("Technical Review Plan") that gives the basis for the site evaluation and the reactor design for the construction licence for the research reactor. The new Specific Safety Requirements SSR-1 Site evaluation for Nuclear Installations and SSR-3 Safety of Research Reactors are included in the updated version of this internal procedure. Per licence change on 19 May 2020 the IAEA SSR-3 is legally

binding for HFR through a licence condition. This procedure is sent to licensees as a regulator's guide for applying to obtain a construction licence.

The ANVS considers the recent licensing process of the PALLAS reactor as a model for future NPP´s construction licences. In this sense, the IRRS team was informed that the first lessons of the PALLAS licensing process are the following: pre-licensing is time-consuming, so regulatory efforts should concentrate on later stages; coordination between different disciplines offer opportunities for improvement; completeness and comprehensiveness of the documentation which is to be published provides a process of transparency for the public.

The existing licences of HOR and HFR research reactors are not fully consistent with the new IAEA SSR-3 Safety of Research Reactors. This has been recognized in the ARM and is part of the action plan. When updating the standard conditions for all licences these should be both consistent across similar licences and with the IAEA safety standards. This issue is addressed in Suggestion S5 in Chapter 5.1.

The ANVS issued the "Dutch Safety Requirements for Nuclear Reactors: Fundamental Safety Requirements" VOBK that includes the IAEA Safety Standards which apply to all lifetime phases of a research reactor: site evaluation; design; construction; commissioning; operation; and decommissioning. The graded approach has been adopted in the regulations and guides for research reactors. Specific safety requirements for research reactors are included in the VOBK guidance (Annex 6).

All research reactors in the Netherlands are required to have a full scope Level 3 PSA. The IRRS team identified the ANVS development and issue of the Guide on Level 3 PSA as a good practice. This is addressed in Good Practice GP1 in Chapter 6.3.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The generic regulatory requirements regarding nuclear facilities (e.g. the KeW and Decree on Nuclear Installation, Fissile Material and Ores) also apply to fuel cycle facilities, but the existing NVRs are not applicable to fuel cycle facilities. ANVS has not developed specific regulations for fuel cycle facilities. Rather, in addition to regulatory requirements, specific requirements for fuel cycle facility are included in the licence as licence conditions. The IRRS team observed that the licence conditions for the fuel cycle facilities include details that could appear in regulations based on IAEA Safety Standards. This issue is addressed in Recommendation R17 in Chapter 9.1.

The IRRS team also observed that the licence for fuel cycle facilities has not been updated to reflect SSR-4. This has been recognized in the ARM and is part of the action plan. The IRRS team was informed that the WIDOCS project aims to make the licence conditions more systematic and standardized and to be capable of update when new safety standards are issued. This issue is addressed in Suggestion S4 in Chapter 5.1.

The IRRS team identified that there are no regulatory requirements in the regulations for fuel cycle facilities for the establishment of an independent safety committee or when an independent safety assessment by the licensee has to be performed of documentation prior to submission to ANVS. The IRRS observed that there are no licence conditions regarding an independent safety committee in the license for the existing fuel cycle facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For fuel cycle facilities there are no requirements in the regulation relating to an independent safety committee or the performance of independent safety assessment by the licensee of the documentation before they are sent to ANVS.	
(1)	**BASIS: SSR-4 Requirement 6, states that** *"An independent safety committee (or an advisory group) shall be established to advise the management of the operating organization on all safety aspects of the nuclear fuel cycle facility".*
(2)	**BASIS: SSR-4 Requirement 6, para. 4.29 states that** *"The operating organization shall establish one or more internal safety committees (or advisory groups) to advise the operating organization on safety issues relating to the commissioning, operation and modification of the facility. The safety committee shall have among its membership experts with the necessary breadth of knowledge and experience to provide appropriate advice. The committee shall be independent of the regulatory body*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and its membership shall, to the extent practicable, be independent of the operations management".
R18	**Recommendation: The ANVS should establish regulatory requirement for the fuel cycle facilities regarding an independent safety committee or an advisory group to advise the management of the operating organization on all safety aspects of the nuclear fuel cycle facility.**

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

There is no specific decree or regulations related to radioactive waste management in the Netherlands. However, provisions on radioactive waste management are contained in the KeW; Nuclear Facilities, Fissionable Materials and Ores Decree; Ministerial Rnvk and the Bbs. More detailed requirements of radioactive waste predisposal activities are set in site specific licence conditions.

The national radioactive waste management policy states that the operation of a deep geological repository (DGR), which will accommodate all the radioactive waste stored in COVRA, is expected to start in 2130. Currently there are no detailed regulatory requirements for the disposal of radioactive waste in the Netherlands and a complete set of legal requirements needs to be developed. This issue was identified by ANVS and is reflected in the Action Plan.

Regarding the consistency of the National Radioactive Waste Management Policy with the fundamental safety principle in SF-1 that radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations, the IRRS team was informed that:

- the storage of radioactive waste and spent fuel in the COVRA facility is assumed until a DGR is available,
- funding for radioactive waste management is collected, and
- COVRA performs a research and development programme and is responsible for radioactive waste management in the country, including disposal.

The Ministry of I&W has started working on a roadmap to prepare for an operational geological facility in 2130. The roadmap will be comprehensive and regularly updated together with the National programme. It will include among others a research programme and necessary developments of the legal framework.

The IRRS team recommends to further investigate this area during the forthcoming ARTEMIS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no specific regulatory requirements supporting the development of planned deep geological repository in the Netherlands, which is intended to be operational in 2130. This has been also identified in the national Action Plan. Furthermore, additional requirements on radioactive waste disposal are needed for operational and closed landfill disposal facilities for NORM radioactive waste.	
(1)	**BASIS: SSR 5 Requirement 1 states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility".*
(2)	**BASIS: SSR 5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met".
R19	**Recommendation: The Government should provide for improved legal and regulatory framework for the operation of landfill disposal facilities.**
R20	**Recommendation: The Government should establish regulatory requirements well before a deep geological repository is established.**

In support of a licence application to ANVS for management of radioactive waste, the applicant needs to submit a safety case, and supporting safety assessment (safety report), to demonstrate safety. The safety assessment (safety report) is made prior to the application for a licence, as specified in the Nuclear Facilities, Fissionable Materials and Ores Decree. The list of documents to be submitted in support of the application for authorization, in addition to a safety assessment (safety report), is contained within two ANVS guides:

- Guidelines for the ten-yearly Periodic Safety Review of nuclear facilities,
- Guideline for submitting licence applications for activities under sections 15(a), 29 and 34 of the KeW.

These guides contain provisions of information to be submitted to support a PSR for nuclear installations and for licensing for non-nuclear installations.

Areas for improvement and clarification of the legal framework identified during the review of ARM and discussions with counterparts include:

- the interdependencies between the steps in predisposal management of radioactive waste and the impacts on the anticipated disposal option,
- the requirements on processing of RAW that ensure there is appropriate consideration of the RAW characteristics and of the demands imposed by the different steps in its management (this has been identified in the ARM and is part of the Action Plan),
- the requirements that ensure storage conditions take into account of the planned storage periods; the use of passive safety features; prevention of the waste containment degradation and; provisions for radioactive waste inspection, monitoring, retrievability and preservation (this been identified in the ARM and is part of the Action Plan),
- specific requirements for location and design of predisposal facilities,
- conditions for the procedures for the operation of predisposal waste management facilities and their documentation, incl. their maintenance.

This issue is addressed in Recommendation R17 in Chapter 9.1.

There are no regulatory requirements on definition, derivation, use and revision of waste acceptance criteria (WAC). The safety case is not identified as a source of the WAC for the radioactive waste.

COVRA does not have an established WAC. In the absence of the WAC at CORVA, radioactive waste specifications are used. Radioactive waste packages that fail to meet the COVRA specifications are not accepted for storage or are managed in COVRA at additional cost to the radioactive waste producer. The ANVS is informed of any radioactive waste transferred to COVRA which does not meet its specifications. As part of the construction and commissioning of a new storage facility at COVRA, the WAC are expected to be developed by this operator.

The IRRS team recommends to further investigate this area during the forthcoming ARTEMIS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Waste acceptance criteria are not considered in the Dutch legal framework. Safety case is not identified as a source of the WAC for the RAW packages and unpackaged RAW. This has been also identified in the national Action Plan submitted to the IRRS team.	
(1)	**BASIS: GSR Part 5 Requirement 12 states that** *"Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case".*
(2)	**BASIS: GSR Part 5 Requirement 12, para 4.24 states that** *"Waste acceptance criteria have to be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging".*
(3)	**BASIS: GSR Part 5 Requirement 12, para 4.25 states that** *"Adherence to the waste acceptance criteria is essential for the safe handling and storage of waste packages and unpackaged waste during normal operation, for safety during possible accident conditions and for the long term safety of the subsequent disposal of the waste".*
(4)	**BASIS: GSR Part 5 Requirement 12, para 4.26 states that** *"The operators' procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste".*
(5)	**BASIS: SSG 23 para. 4.72 states that** *"The safety case should be used to assist in the establishment of limits, controls and conditions to be applied to all work and activities that have an influence on the safety of the facility and to be applied to the waste that will be disposed of in the facility".*
R21	**Recommendation: The ANVS should develop regulatory requirements on Waste Acceptance Criteria. The safety case should be identified as the main source of criteria for accepting radioactive waste packages and unpacked radioactive waste for processing, storage and disposal.**

The radioactive waste classification scheme, as proposed in the IAEA GSG-1, is not fully implemented in the legal framework of the Netherlands. Elements of the IAEA radioactive waste classification system can be found in KeW and Decree on Basic Safety Standards for Radiation Protection (waste containing fissile material or ore), Decree on Basic Safety Standards for Radiation Protection (definition of RAW, short-lived waste, exempt waste) and in Waste (landfill ban) Decree (NORM waste).

The national radioactive waste management policy considers three categories of radioactive waste: short-lived waste; low and intermediate level waste (LILW) and; high level waste (HLW). For operational purposes, the operator of COVRA facility developed a site specific RAW classification scheme, which splits the category of LILW defined by the national radioactive waste management policy into four sub-categories.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The radioactive waste classification scheme does not consider some classes of radioactive waste proposed in GSG-1. Heat-generating HLW is not currently separately categorised in the legal framework.	
(1)	**BASIS: GSR Part 5 Req. 3, para. 3.8 states *that*** *"To facilitate compliance with regulatory requirements, the regulatory body has to do the following:* *..." - Establish an appropriate definition and/or classification of radioactive waste".*
(2)	**BASIS: GSG 1, para 2.2 states that** *"... six classes of waste are derived and used as the basis for the classification scheme:* *(1) Exempt waste (EW): ...* *(2) Very short lived waste (VSLW): ...* *(3) Very low level waste (VLLW): ...* *(4) Low level waste (LLW): ...*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(5) Intermediate level waste (ILW): ... *(6) High level waste (HLW): Waste with levels of activity concentration high enough to generate significant quantities of heat by the radioactive decay process or waste with large amounts of long lived radionuclides".*
S12	**Suggestion: The ANVS should consider enhancing the radioactive waste classification scheme, including heat generating HLW, in the regulatory framework.**

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The ANVS has prepared regulation and guides for radiation sources facilities and activities under the KeW. The requirements include fundamental principles of radiation protection concerning justification, optimisation and dose limitations which encompasses all exposure situations including the fostering of a graded approach to prioritise safety significant issues. The ANVS adopts IAEA Safety Guides with regard to the conduct of regulatory activities, e.g. specific authorisation or inspection topics and activities for radiation sources facilities and activities.

The IRRS team notes that there are some gaps in the required suite of regulations and guides to consistently and effectively perform the regulatory functions, for example guides for performing review and assessment of radiation sources and facilities. ANVS may therefore benefit by undertaking a gap analysis and implementing a process to systematically reviewing and updating regulations and guides to ensure they are adequate and current. This issue is addressed in Recommendation R17 in Chapter 9.1.

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The responsible ministries, through the legislative framework, have established:

- administrative criteria for decommissioning, such as timeframe for the decommissioning authorization and for the review of decommissioning plans, requirements on licensee's financial assurance for decommissioning, and
- criteria related to the protection of workers and the public, protection of the environment during the decommissioning, including criteria for clearance and termination of the authorization for decommissioning.

The Bkse and Shutdown and Decommissioning Regulation include detailed provisions on decommissioning and financial assurances for the decommissioning of nuclear installations. Nuclear safety and radiation protection during decommissioning of nuclear installations is regulated by the ANVS. Any application for a decommissioning licence is required to be supported by a safety assessment. In granting a decommissioning licence the ANVS has to approve the final decommissioning plan. If changes to the final decommissioning plan are required, these are regulated in Bkse as changes of a licence.

For non-nuclear installations, the Bbs contains a provision on the decommissioning plan called termination plan. Conditions for the refusal of the licence are listed in the Decree, but, unlike for nuclear installations, there is no requirement to support the plan with a safety assessment.

It can be concluded that the legal framework does not specify documents to be submitted in support of the application for authorization other than e.g. safety assessment for nuclear installations. The IRRS team recommends to further investigate this area during the forthcoming ARTEMIS mission.

The Bkse considers, that decommissioning starts immediately after the final shutdown of a nuclear facility with no transitional period. In accordance with the regulations, deferred decommissioning is currently applicable only for NPP Dodewaard, as it was shut down before the current regulation came into effect. It is not expected that other installations will be decommissioned in this way. Any application to accommodate a transitional period under "special circumstances" would need to be authorized by ANVS based on the requirements of Bkse.

NPP Dodewaard has a licence to operate a nuclear facility in safe enclosure issued under the previous legislation. NPP Dodewaard is exempted from the obligation of immediate dismantling when the new regulation was introduced. Under the current regulatory framework neither an operational nor a decommissioning licence has been issued. During the safe enclosure period the licensee of NPP Dodewaard has not performed a periodic safety review at regular intervals. The requirement of the PSR was incorporated in Rnvk and this regulation is also applicable to NPP Dodewaard since 2018.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: NPP Dodewaard has a licence to operate a nuclear facility in safe enclosure according to the previous legislation. In special circumstances, which can lead to an exception of the immediate dismantling, there are no legal requirements established.	
(1)	**BASIS: GSR Part 6 Requirement 11 para 7.14 states that** *"If deferred dismantling has been selected as a decommissioning strategy, the licensee shall demonstrate in the final decommissioning plan and supporting documents that such an option will be implemented safely."*
(2)	**BASIS: SSG-47 para 7.41 states that** "*A surveillance and maintenance plan for the safe enclosure period should be developed on the basis of the outcomes of the safety assessment. The safety assessment for the deferred dismantling strategy should be the basis of identification of the safety functions and the safety parameters (e.g. confinement, shielding, temperature, humidity, level of discharges to the environment) that should be provided and maintained by the means described in the surveillance and maintenance plan. The possibility of corrosion and brittle fracture of materials, as well as ageing and obsolescence of materials (spare parts) should be considered carefully. During the safe enclosure period the licensee should perform a review of the safety of the facility as a whole at regular intervals, to demonstrate that it continues to be in its expected condition".*
S13	**Suggestion: The Government should consider enhancing the regulatory requirements for deferred decommissioning under special circumstances.**

The preliminary decommissioning plans of operating facilities have to consider immediate dismantling and release of the site from regulatory control without restrictions (green field).

The Nuclear Facilities Shutdown and Decommissioning Regulation contains the obligation to provide in the decommissioning plan a description of how the licensee intends to remove the fissile material present in the facility and manage radioactive waste, including a description of treatment and conditioning.

The Nuclear Facilities Shutdown and Decommissioning Regulation requires that preliminary decommissioning plans contain provisions for description of the measures for the retention of knowledge and information. This area is regularly inspected by the ANVS and next planned inspection to NPP Dodewaard will be focused on this subject.

There are no criteria for the release of the site from a regulatory control with or without conditions after the completion of decommissioning activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no regulatory framework to define criteria to release the site from regulatory control with and without restrictions after the completion of decommissioning activities. Therefore, the licensee cannot demonstrate that the end state of the facility has been reached. This has been also identified in the ARM and is part of the action plan.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 2 para 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(17) The criteria for release from regulatory control".*
(2)	**BASIS: GSR Part 6 Requirement 15 states that** *"On the completion of decommissioning actions, the licensee shall demonstrate that the end state criteria as specified in the final decommissioning*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	plan and any additional regulatory requirements have been met...".
(3)	**BASIS: GSG-13 para 3.137 states that** *"Before release from regulatory control, the authorized party should be required to demonstrate to the regulatory body that the site meets the release criteria. The regulatory body should review the evidence submitted by the authorized party, should confirm compliance with the criteria and only then should the site be released from regulatory control. Guidance on the release of sites from regulatory control is provided in WS-G-5.1".*
(4)	**BASIS: WS-G-5.1, para 3.7 states that** *"The regulatory body should establish safety requirements and guidelines for the planning, approval and conduct of clean-up activities, for the management of contaminated material and the waste that arises from this process, and for the release of land, buildings and structures from regulatory control. The responsibilities of the regulatory body should also include:* *a) Establishing, promoting and adopting criteria and guidance for the clean-up and release of sites as a part of decommissioning activities".*
(5)	**BASIS: SSG 47 para 3.24 states that** *"The responsibilities of the licensee for decommissioning end with the termination of the authorization for decommissioning by the regulatory body when the end state of decommissioning is achieved. However, for sites released with restrictions on their future use, the responsibility for institutional controls should be assigned to the licensee or to another organization".*
R22	**Recommendation: The Government should develop regulatory requirements for the release of sites from regulatory control with and without restrictions.**

9.8. REGULATIONS AND GUIDES FOR TRANSPORT

The regulatory framework for the transport of fissionable and radioactive material is based on the KeW and on the Fissionable Materials, Ores and Radioactive Materials Transport Decree. These require that the transport activities shall comply with the provisions laid down in the international agreements and regulation governing the transport of dangerous for all the modes of transport (road, rail, in-land waterway, sea and air). The modality agreements and regulations (ADR, RID, ADN, ICAO TI, and IMDG Code) are transposition of the IAEA Transport Regulations SSR-6 (Rev.1) for each mode of transport and therefore all the provisions in SSR-6 (Rev.1) are addressed in the authorization process.

The international regulations governing the transport of dangerous goods, including Class 7, are implemented by the Transport Decree for all modes of transport (road, rail, in-land waterway, sea and air). Although specific national guides have not been issued, direct reference is made to the IAEA Specific Safety Guides that cover the:

- preparedness and response for a nuclear or radiological emergency involving the transport of radioactive material;
- radiation protection programme;
- management system and the package design safety report.

These IAEA safety guides are considered mandatory when specified in the licence. The requirements for the license to the transport of fissionable and radioactive materials are specified in the Transport Decree. The radiation protection provisions are considered in the Transport Decree making reference to the applicable articles of the Radiation Protection Decree.

9.9. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

Responsibilities of the employers and authorised persons, along with requirements regarding information on the risks and training, are established in the Working Conditions Act from the Ministry of SZW.

Regarding occupational exposure, the requirements on responsibilities of the parties involved with regards to occupational exposure are established in the Bbs, which transposes the 2013/59/Euratom Directive.

Additional regulations have been issued to provide information to the licensees and applicants for occupation exposure on particular aspects of the regulations.

Rbs contains additional information on justification of practices, requirements on radiation protection experts and radiation protection officers, as well as an explanation of Bbs articles.

Regulation on Radiation Protection for Occupational Exposure includes information on the contents of the RI&E for radioactive facilities, the accepted method for assessing the doses of aircraft crew, requirements on dosimeters and dosimetry services, instructions on recording exposure to radon in workplaces as well as radiation and radon warning signs.

Additional information for applicants is also provided in the document "Guideline for submitting licence applications for activities 15, 29, 34", where the regulatory body specifies the information that shall be included in the licence applications.

9.10. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The regulatory framework for medical exposure control in the Netherlands is based on General Health Care legislation. The IHPA defines the policy for the use of radiation in medicine by medical professionals, whereas the Healthcare Quality, Complaints and Disputes Act obliges healthcare institutions to deliver responsible, quality-system-based care to patients.

The Healthcare, Complaints and Disputes Act stipulates that safe care must be delivered. Based on the same legislation, any incidents in which patients are seriously injured or die must be reported to the IGJ. The licence also includes a condition that, in the event of incidents involving ionising radiation, it must be reported to either the IGJ, the ANVS and/or the NLA depending on the situation. Information provided to the IRRS team states that ANVS does not have a definition of "events" as they do not consider medical exposure. The only guidance provide to the IRRS team was "Report disasters under Wkkgz to IGJ" which is for general care.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Bbs has requirements for accidental and unintended exposures and significant events. However, there is no definition of what constitutes significant unintended and accidental medical exposures.	
(1)	**BASIS: GSR Part 3, para 3.180 states that** *"Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:* *(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;* *(b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;* *(c) Any exposure for diagnostic purposes that is substantially greater than was intended;* *(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;* *(e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;* *(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended".*
(2)	**BASIS: GSR Part 3, Requirement 41 states that** "*Unintended and accidental medical exposures Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R23	**Recommendation: The Ministry of VWS should ensure the practical measures are in place to define what constitutes significant unintended and accidental medical exposures.**

The IHPA establishes that the use of ionising radiation is included in the list of reserved activities. These activities may only be carried out under the responsibility of a physician, dentist or clinical technologist who must be qualified and skilled.

The Directive "Responsibility Structure for Radiation Protection in Institutions for Specialist Medical Care" states the required radiation protection training for persons that bear joint responsibility for the radiation protection of patients.

The clinical physicist is authorized in accordance with the Clinical Physicists (Training and Field of Expertise) Decree. The training requirements for medical physicists have been established by the Minister of Health, Welfare and Sport in 2005. The IRRS team suggest that it should be evaluated whether these training and accreditation requirements for medical radiation protection remain adequate.

Justification of medical exposure of new practices and individual justification, together with optimization of all medical exposures are addressed in the Decree on Basic Safety Standards for Radiation Protection.

The Government has not provided for the establishment of criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures. A guideline and calculation tool for therapeutic use of radionuclides was published on the Federation of Medical Specialists website. It includes release criteria for all radioisotopes in use.

Special provisions on medical exposure of pregnant and breast-feeding patients are in place.

9.11. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The authorization process includes an "environmental review (for medical and industrial applications, for example) including a calculation of the radiation exposure of people outside the boundary of the location". How to undertake this calculation has been laid down in annex 10 of the ANVS Regulation on Basic Safety Standards on Radiation Protection (Vbs).

The calculation can be performed at three tiers with the first being a high-level conservative screening assessment and the last being a detailed site-specific assessment, which provides a graded approach to the authorisation process. The maximum exposure for persons outside the location (the representative person) is 10 microsievert per year with any higher values must be justified. The statutory upper limit is 100 microsievert per year (see also subsection 5.2.4). For nuclear facilities, the environmental review is part of the safety report that must be submitted with the application. Thus, all the responsibility of assessing the impact of any discharge on the public lies with the applicant, and in assessing that impact they must follow the process laid down in Annex 10 of the VBS (referred to in ANVS licensing policy 2019 Towards a joint vision).

9.12. SUMMARY

The Government of the Netherlands established a regulatory framework for nuclear and radiation safety. However, the IRRS team identified some areas for improvement, such as further development of the regulations and guides as a clear framework to make regulatory requirements and conditions consistent with IAEA safety requirements. The ANVS should establish and implement a systematic approach to update the safety requirements included in the licence conditions.

For landfills, improvements of their legal and regulatory framework can enhance safety. For deep geological repositories the establishment of regulatory requirements will allow expectations to be understood. The regulatory framework should include requirements on radioactive waste acceptance criteria. Furthermore, the regulatory framework should consider enhancing the classification of radioactive waste to address all classes. The regulatory requirements for deferred decommissioning should be established.

For medical exposures a better definition of unintended and accidental medical exposures or events is required.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The legal framework for Emergency Preparedness and Response (EPR) in the Netherlands is largely based on the KeW and on the Bbs. Other legal documents complete the EPR framework in the Netherlands including: Environmental Management Act; Awb; Regulation on Basic Safety Standards for Radiation Protection (Rbs); ANVS Regulation on Basic Safety Standards for Radiation Protection (Vbs) and Bkse.

Several ministries are jointly responsible for the legal framework and the specific legislation on nuclear safety and radiation protection. The coordinating ministry for the overall EPR framework is the Ministry of I&W.

The Dutch government has given powers to the ANVS to regulate on-site EPR arrangements of the authorized parties for regulated facilities and activities.

The ANVS is the sole licensing authority under the KeW and assesses the EPR arrangements of the authorized parties as part of the licence application. The ANVS is also responsible for publishing technical regulations and guides, together with inspection and enforcement. The ANVS monitors any events reported by the licensee (incidents, accidents and radiological emergencies).

The authorization process for facilities and activities includes an obligation that on-site emergency response arrangements need to be established and approved by the ANVS before the authorization is issued. Based on a graded approach, nuclear facilities and facilities and activities with category 1, 2 and 3 sources are required to have a binding decision on their emergency arrangements from the ANVS. If, following authorisation substantive amendments from the point of view of radiation protection are made to the emergency response plan or to the facility, the ANVS can require any necessary adjustments to be made to the amended plan.

There is an obligation in Dutch legislation that each applicant must provide ANVS with "a description of their quality assurance system", which is captured in the Bbs and Rbs and forms a general requirement of part of the licence application process, including the EPR arrangements.

The required content of the on-site emergency response arrangements is established in the Annex 6 of the Bbs. The detailed requirements are defined by ANVS on a case-by-case basis using a graded approach.

Authorizations for facilities and activities are for an indefinite period of time, except for transport. For nuclear installations there are periodic safety reviews and the EPR arrangements are part of that review. Nevertheless, for radioactive applications there is no procedure which would include periodic evaluation of the EPR arrangements by the ANVS.

In addition, there is no legal disposition for the authorized parties to establish a frequency for review the on-site emergency response plan of the facility or activity. In the absence of any legal requirement the IRRS team was informed that during the authorization process the ANVS impose a review frequency for EPR based on a graded approach.

The Bbs requires that the on-site emergency response plans from the authorized parties should be coordinated with the relevant off-site emergency arrangements of the response organizations and arrangements are in place ensuring coordination with the competent off-site emergency response organizations.

The ANVS applies a graded approach in regulating the EPR arrangements based on source category and potential events. Nevertheless, the country lacks a comprehensive, robust, cross sector hazard assessment for facilities or activities classified in the EPC (Emergency Preparedness Categories) III, IV and V, to provide a sound basis for a graded approach and for the development of a protection strategy. For a justified and optimized response, hazards should be identified, and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. This issue is addressed in Recommendation R27 in Chapter 10.3.

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

The preparedness for radiological and nuclear emergencies encompasses facilities or activities classified in EPC I, II, III, IV and V, as per IAEA categorization.

According to the KeW, the authorized party should maintain the arrangements for EPR up to date.

In the National Emergency Radiation Plan, it is stated that the Safety Region has responsibilities related to the emergency workers. Part of this responsibility is issuing instructions to emergency workers to carry out specific tasks. However, there is an absence of more detailed provisions to provide instructions on how to perform the duties under emergency conditions ('just in time' training) to emergency workers not designated in advance and helpers in an emergency, immediately before the conduct of their specified duties.

A Safety Region is a public body whose task is to facilitate regional cooperation in dealing with crises, disasters and disruptions of public order. Each municipality belongs to one of the 25 safety regions. Together they are responsible for drawing up joint regulations for crisis management and for administering the emergency services in their respective region.

The Bbs defines clear legal basis for the protection of Emergency Workers for all facilities and activities and establishes dose limits and reference levels for emergency occupational exposure. Nevertheless, the IRRS team noted that there is no definition for Helpers in an emergency (per IAEA definition) and no arrangements are in place for the protection of Helpers in a nuclear or radiological emergency. Also, the IRRS team was informed that are no legal disposition(s) preventing that Helpers may assist in an emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Arrangements for the protection of Helpers in a nuclear and radiological emergency are absent from the legal framework.	
(1)	**BASIS: GSR Part 7 Requirement 11 states that** *"The government shall ensure that arrangements are in place to protect emergency workers and to protect helpers in a nuclear or radiological emergency".*
(2)	**BASIS: GSR Part 7 Requirement 11, para. 5.50 states that** *"Arrangements shall be made to register and to integrate into operations in an emergency response those emergency workers who were not designated as such in advance of a nuclear or radiological emergency and helpers in an emergency. This shall include designation of the response organization(s) responsible for ensuring protection of emergency workers and protection of helpers in an emergency".*
R24	**Recommendation: The Government should ensure appropriate arrangements are put in place to protect Helpers in a nuclear and radiological emergency.**

Criteria for the termination of an on the site and off the site emergency is absent in the current framework together with legal dispositions requiring the authorized party to develop criteria for the termination of on the site emergencies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The emergency preparedness and response arrangements for radiological and nuclear emergencies lack criteria for the termination of an on-site or off-site emergency and legal dispositions to require the authorized party to develop on-site termination criteria.	
(1)	**BASIS: GSR Part 7 Requirement 18 states that** *"The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity".*
(2)	**BASIS: GSR Part 7 Requirement 18, para 5.97 states that** *"The termination of a nuclear or radiological emergency shall be based on a formal decision that is made public and shall include prior consultation with interested parties, as appropriate".*
R25	**Recommendation: The Government should revise the framework of emergency preparedness and response to establish criteria for the termination of on-site and off-site nuclear and radiological emergencies.**

Pursuant to the obligations on EPR, authorized parties in the event of an emergency with significance from the point of view of radiation protection and safety are required to immediately contact the 24/7 Expert Service at the ANVS or the authorities of the Safety Region for notification and advice.

The ANVS has developed a number of guides to support the implementation of safety measures for specific practices and emergency exposure situations to be used by authorized parties and other stakeholders with a role in safety, namely:

- Guideline for submitting licence applications for activities under sections 15(a), 29 and 34 of the KeW;
- Guidelines for the ten-yearly Periodic Safety Review of nuclear facilities;
- ANVS multi-year plan for Instruction, Training and Drills (OTO) for the emergency response organization 2022-2025;
- Assessment framework for licensors for the purpose of a uniform assessment of the company emergency response plan;
- Crisis Expert Team (radiation and nuclear) Manual.

Nevertheless, it is recognized in the ARM and is part of the Action Plan that there is no guidance for licence holders of radiation sources Cat 1, 2 and 3, on the expected content of emergency plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no guidance for licence holders of radiation sources Cat 1, 2 and 3, on the expected content of emergency response plans, this is recognized in the ARM and is part of the Action Plan.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 32, states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based".*
(2)	**BASIS: GSR Part 7 Requirement 2, para 4.12 states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization".*
S14	**Suggestion: The ANVS should consider completing the development of regulations and guides relevant to support the implementation of emergency plans guidance for licence holders of radiation sources Cat 1, 2 and 3.**

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

The National Emergency Radiation Plan states that radiation accidents are classified based on category A or category B facilities, a distinction made in the KeW. A radiation accident at a category A facility can have supra-regional or even cross-border consequences.

A radiation accident involving a category A facility has a more than local relevance, and as a consequence requires administrative coordination by national government in line with the National Manual on Decision-making in Crisis Situations. A radiation accident involving a category B facility generally has only local effects and therefore requires local coordination.

The legal framework establishes that the authorized party should provide training to their employees for emergency situations and conduct periodic exercises on emergency response on-site. The ANVS has the competence to evaluate and observe exercises conducted by the authorized parties.

The ANVS is the authority responsible for inspecting the compliance of operating organizations with EPR arrangements.

Procedures state that the ANVS has competence to perform inspections to the facilities or activities after an emergency has occurred. The IRRS team was informed that if a radiological incident is reported, the inspection of

the ANVS makes a risk assessment based on the type of incident, the circumstances and additional information that is given by the license holder and acts accordingly.

The IRRS team observed that some arrangements for EPR in the Netherlands are not in full compliance with the GSR Part 7, this includes the requirements for: a comprehensive protection strategy; a comprehensive, robust, cross sector hazard assessment for facilities or activities classified in the emergency preparedness categories III, IV and V; a policy for the waste management generated during an emergency; and guidance on how to mitigate the non-radiological consequences of a radiological and nuclear emergency. Nevertheless, the IRRS team noted that under the responsibility of the Ministry of I&W the Steering Committee responsible for EPR for nuclear and radiological emergencies approved a Strategic Agenda with milestones and timelines to develop and implement a Protection Strategy for a Nuclear or Radiological Emergency that will encompass these arrangements and, once complete this will bring them in line with IAEA Safety Standard GSR Part 7**.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The emergency preparedness and response arrangements for radiological and nuclear emergencies lacks a comprehensive protection strategy encompassing a cross sector hazard assessment, waste management and non-radiological consequences, inter alia.	
(1)	**BASIS: GSR Part 7 Requirement 5 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency".*
(2)	**BASIS: GSR Part 7 Requirement 4 states that** *"The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency".*
(3)	**BASIS: GSR Part 7 Requirement 4, para 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency".*
(4)	**BASIS: GSR Part 7 Requirement 15, para 5.84 (a) states that** *"The national policy and strategy for radioactive waste management shall apply for radioactive waste generated in a nuclear or radiological emergency…".*
(5)	**BASIS: GSR Part 7 Requirement 16, states that** *"The government shall ensure that arrangements are in place for mitigation of non-radiological consequences of a nuclear or radiological emergency and of an emergency response".*
R26	**Recommendation: The Government should complete the protection strategy, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency, consistent with the IAEA Safety Standards.**

The IRRS team also noted that the Strategic Agenda expresses the willingness for requesting an Emergency Preparedness and Response Review Service (EPREV) to IAEA.

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

The national emergency response system in the Netherlands for radiological and nuclear emergencies is detailed in the National Emergency Radiation Plan (2021). The National Emergency Radiation Plan (LCP-s) replaces the National Emergency Plan for Radiation Incidents (NCS) (2016), the NCS Response Plan 2017 and the NCS Crisis Communication Plan (2017).

Emergency response in the Netherlands is based on the Dutch generic system for crisis control. The Minister of Justice and Security has a coordinating role for national crisis control and coordinated decision making with regard to general measures. The Minister of I&W is responsible for the coordination of the preparations for radiation accidents involving category A facilities during the preparedness and response phases and the decision making on radiation protection crisis measures and their implementation.

The Minister of I&W performs these duties alongside other ministers involved in the radiation protection crisis measures such as the Ministers of VWS and Agriculture, Nature and Food Quality (LNV), as detailed in the National Emergency Radiation Plan.

The Board of the Safety Region is responsible for preparation for radiation accidents involving category B facilities. The municipality is responsible for coordinating the effective response to accidents involving category B in these facilities.

In the event of an emergency the ANVS has duties as an emergency preparedness and response organisation, for this the ANVS has organised and is responsible for the Crisis Expert Team – radiation and nuclear (CETsn). The CETsn is the knowledge and advice network that brings together the knowledge and expertise in the field of nuclear safety and radiation protection via experts from various institutes. The ANVS chairs the CETsn.

The National Emergency Radiation Plan details the relationship between national and regional, with the knowledge and advice network (CETsn), and other important stakeholders.

The ANVS has assigned competences on EPR, including:

- To be involved in maintaining and implementing the National Emergency Radiation Plan;
- To coordinate with the Ministries of I&W (coordinator for nuclear accident control), J&V (national crisis coordinator, Safety and Security regions), and the Ministry of VWS (health care, distribution of iodine prophylaxis);
- To set standards for the preparation of nuclear accidents and crises in close consultation with neighbouring countries;
- To ensure the uninterrupted availability (24/7) and training of experts who can be deployed as advisors in the nuclear emergency organisation;
- To maintain an expertise and monitoring system, including the National Radiological Monitoring Network (NMR);
- To provide continuous contribution to emergency response decision-making.

The IRRS team was informed that during a nuclear or radiological emergency as detailed in the framework of the CETsn the ANVS is responsible for the dose assessment of the emergency workers and the public.

The ANVS operate its own dedicated emergency support centre, with staff members that ensure duty officer functions 24/7 hours. The ANVS has a comprehensive set of radiation measurement instruments and personal protective equipment; communication systems and computers and facilities that can be used in an emergency response.

The RIVM, under contract with the ANVS, has capabilities in place for operational use in case of a nuclear or radiological emergency, including the real-time NMR, mobile measurement teams, decisions support systems, laboratory facilities etc.

The Netherlands is a Party to the IAEA "Convention on Early Notification of a Nuclear Accident", and "Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency". The ANVS has the competency of being the National Warning Point, Competent Authority for Emergencies Abroad and Competent Authority for Domestic Emergencies for these conventions and has the role of INES National Officer.

The ANVS ensures the Dutch representation on the Emergency Preparedness and Response Standards Committee (EPReSC) of the IAEA. The Netherlands also reports monitoring data to the International Radiation Monitoring Information System (IRMIS) of IAEA.

The Netherlands has established bilateral agreements related to the EPR, namely with: Germany, Belgium, Norway, UK and USA.

Staff competence for EPR in the ANVS is achieved through in-house training and attendance of international training courses, workshops and conferences, all the staff involved in EPR undergoes a minimum of 40h of training each year.

The ANVS regularly participates in emergency response exercises such as the IAEA ConvEx and ECUREX exercises to test their emergency response capabilities. Staff from the ANVS helps to organise and participates in national exercises and in the training of other entities such as the safety regions, first responders, the safety and security forces and others.

The IRRS team noted that the Netherlands has developed a web-based information system named CalNET where relevant information and communication during response to a radiological or nuclear emergency is exchanged. All the response organizations including the 25 Safety Regions, as well as the authorities responsible for public safety and security have access to the information at all times via this system. The IRRS team considered this as a Good Practice. This system forms a robust basis for a coordinated emergency response at national and an online, real time, cross-border coordination of protective actions during the early phase of a nuclear accident.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Netherlands have developed a web-based information system named CalNET where relevant information, and communication during response to a radiological or nuclear emergency is exchanged. All the response organizations including the 25 Safety Regions, as well as the authorities responsible for public safety and security have access to the information at all times via this system. The online, real time, participation in CalNET is also available to the authorities of neighbouring countries, namely Belgium.	
(1)	**BASIS: GSR Part 7, Requirement 22, para. 6.13 states that** *"When several different organizations of the State or of other States are expected to have or to develop tools, procedures or criteria for use in the response to an emergency, arrangements for coordination shall be put in place to improve the consistency of the assessments of the situation, including assessments of contamination, doses and radiation induced health effects and any other relevant assessments made in a nuclear or radiological emergency, so as not to give rise to confusion".*
(2)	**BASIS: GSR Part 7 Requirement 6, para 5.10 states that** *"Arrangements shall be made with other States, as appropriate, for coordinated response to a radiological emergency".*
GP2	**Good Practice: The CalNET information system forms a robust basis for a coordinated emergency response for national and cross-border coordination of protective actions during the early phase of a nuclear accident.**

10.5. SUMMARY

The existing regulatory framework provides a basis for implementing the IAEA requirements to achieve a harmonized graded approach in establishing arrangements for preparedness and response to radiological emergencies, and the regulatory framework assigns to the authorized party the responsibility for the on-site Emergency Preparedness and Response.

The IRRS team observed that some requirements for emergency preparedness and response are not in full compliance with the IAEA safety standards. For example, the development of a comprehensive protection strategy, a policy for the waste management generated during an emergency, the need to have in place arrangements for the protection of helpers in a nuclear and radiological emergency and criteria for the termination of an emergency.

The IRRS team considers the creation of the CalNET as a Good Practice of the Netherlands on complying with the Standards.

The Netherlands has put in place an adequate operational emergency preparedness and response capability for radiological and nuclear emergencies and established a comprehensive bilateral and multilateral exchange with the neighbouring countries.

11. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

As agreed by the Netherlands, the scope of the IRRS mission covered the national regulatory implications of the COVID-19 pandemic with a focus on business continuity to maintain the 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 in the course of the mission, to identify ways to strengthen governmental, legal and regulatory frameworks for safety.

11.1. GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

In evaluating the measures undertaken during the pandemic account was taken of the importance that the Netherlands gives to nuclear safety and radiation protection.

From the beginning of COVID pandemic, measures were taken by the Government to limit the spreading of infection, like working from home, when possible, social distancing, banning overseas travel.

The Ministry of I&W had a steering group named “Continuity of Ministry of I&W”, in which ANVS participated. The Ministry of I&W issued additional guidelines for the ANVS to be followed in fulfilling its regulatory functions.

To allow vital functions to remain available during a full lockdown, the Public Health Act includes provisions for exempting the necessary staff to keep the vital functions.

11.2. REGULATORY FRAMEWORK

At the ANVS, a working group was set-up to advise the management about the implementation of measures and to monitor how the regulatory tasks were fulfilled. The ANVS staff were informed about changes to the government guidelines and their implementation by the Ministry of I&W and the ANVS.

The ANVS identified as vital personnel the designated safety inspectors (nuclear and radiological); all designated members of the emergency preparedness and response organisation; cybersecurity inspectors and employees in essential functions for business continuity (financial, etc.). The ANVS prepared letters of authority to allow travelling to sites and responding to any radiological incident.

In March 2019 work has started on a specific ANVS business continuity plan, even though analysis showed this was not (legally) obligatory. At the time of the IRRS mission, some risks have already been assessed, such as the lack of cell phone service for more than one hour, lack of electrical power, water, and other commodities that would make it impossible to work safely at the ANVS premises. During COVID several measures were taken to ensure the continuity of the work of the ANVS, as described in the ARM. Recently the work on the business continuity plan has restarted, with a first focus on IT continuity.

During the pandemic, the ANVS asked for support from the Ministry of I&W in terms of logistics, such as: office chairs and IT resources for the home office, various accommodation issues.

The ANVS’s approach was to maintain the critical infrastructure to enable it to perform the essential regulatory activities.

The prevention measures included strict rules concerning coming to the office, restricting physical meeting of staff members involved in same functions, supporting working from home and of course following the general rules set by the Government. Daily management meetings were held to assess the situation and to decide on additional measures if needed.

The transition to teleworking was smooth, as the ANVS was prepared for remote working already before the pandemic. For example, digital signing of documents was already in use. The main challenge in teleworking was virtual meetings, since there was no previous experience, and the tools were not standardized. However, the challenges were overcome relatively soon.

With authorized parties, a major part of communication (emails, phone communication, databases, websites etc.) remained unaffected. Virtual meetings soon became a routine.

The TSOs were able to shift to teleworking smoothly and no significant problems were met in getting services during the pandemic.

Like in many other regulatory authorities, the COVID pandemic changed the approaches to be followed in preserving nuclear safety. The experience gained by the ANVS during the COVID pandemic can be a valuable asset for the ANVS' future activities, (e.g. updating the BCP) and could be shared with other organisations, both at national and international level.

The ANVS supported the wellbeing of its staff by providing equipment (ergonomic chairs etc.) for arranging proper home offices. Members of staff, for whom working from home was not possible, were allowed to work from the office (as their number was low). The ANVS also paid attention to maintaining social (even if virtual) contacts between the staff so that no one would feel left alone in the exceptional conditions during the pandemic. New staff was given priority for working at the office to help their incorporation into the ANVS organization and culture.

Even after the pandemic, the ANVS recommends that its staff works at the office two days per week to preserve the ability for teleworking if some future crisis would again make it necessary.

11.3. REGULATORY FUNCTIONS

The ANVS took measures to limit the effect of the pandemic on their operations, this included:

Some flexibility in regulatory control was introduced during the pandemic:

- An increase in the number of X-ray and CT scanners in hospitals meant that hospitals could had exceeded their licence limits. A fast authorisation process was established which allowed hospitals to extend their licence limits without impacting the hospitals COVID response.
- Radiation Protection Experts (RPE)s were not able to undertake the necessary training required to renew their certificates of competence. As a result, the ANVS established provisional rules to allow RPE's to retain certification.

With regard to inspections:

- Several of scheduled physical inspections were not possible during the Covid pandemic and to protect the hospitals no physical inspections of these premises were undertaken. However, physical inspections of non-destructive testing facilities continued throughout the pandemic.
- Online inspections of non-nuclear sites were developed which were mandatory for some sectors such as dentistry.
- The inspections that took place at nuclear facilities during the pandemic were performed by the minimum necessary number of inspectors and with observance of health measures like social distancing.
- Inspections at nuclear sites were only performed if the inspection was critical or the inspection could not be conducted at a later date. However, most planned inspections were undertaken.

In addition to the measures exposed in Chapters 11.1 and 11.2., the following practices were also in place:

- Security sensitive work was performed at the office.
- There was extensive use of video calls to maintain team communication.
- Staff had access to the management system documentation whilst performing their duties.

11.4. EMERGENCY PREPAREDNESS AND RESPONSE

Throughout the pandemic the ANVS maintained close coordination with the Crisis Centre of the Ministry for I&W which in turn coordinates to the National Crisis Centre. During the pandemic the ANVS maintained the capability to activate its own crisis response organization. Also, inspections on location were made when feasible.

The IRRS team was informed that the ANVS emergency response organisation, and the national CETsn, were able to discharge their competences without disruptions. Its 24/7 roster schedule was in some cases tight when personnel had to go into COVID-19 isolation, but in all cases it could be filled. The EPR response personnel from the ANVS were considered “vital workers” by the Government and granted a special discharge from lockdown to be able to comply with any duties related to EPR matters.

The ANVS developed a plan for avoiding gatherings of personnel and cross contamination of persons with the same functions so that redundancy could be maintained. Nevertheless, the pandemic never reached the stage where it was deemed necessary to completely isolate the members of the EPR from each other to guarantee business continuity.

The IRRS team was informed that the RIVM, was also able to maintain an operational status and assure the maintenance of the NMR.

The personnel of the ANVS EPR team still undergone training and exercises throughout the pandemic. Education and training was organized online as much as possible. Emergency exercises were deemed to be vital work and continued to be physical, except for the acute months of the pandemic.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
CIUREA-ERCAU Cantemir	National Commission for Nuclear Activities Control (CNCAN)	cantemir.ciurea@cncan.ro
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LIAISON OFFICER		
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VAN LONKHUYZEN Wouter	Ministry of Infrastructure and Water Management	wouter.van.lonkhuyzen@minienw.nl

GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

FIRST WEEK											
Time	**SAT**	**SUN**	**MON**	**TUE**	**WED**		**THU**	**FRI**	**SAT**	**SUN**	**Time**
08:00-09:00	Arrival of IRRS Team members					Site Visits	Briefing from the site visits			IRRS Team rest day	**08:00-09:00**
09:00-12:00			Entrance Meeting	Interviews	Interviews		Follow-up interviews	FU Interviews and report preparation; DTC writes introductory parts	IRRS Team members draft the report. Finalization of recommendations, suggestions and good practices		**09:00-12:00**
12:00-13:00			Standing lunch	Standing lunch	Standing lunch		Standing lunch	Standing lunch			**12:00-13:00**
13:00-14:00		Initial Team Meeting • TL Opening remarks • IAEA Introduction • Self-introduction of all attendees • IRRS Process, IAEA • Schedule (TL, IAEA) • Presentations of the first impressions • Administrative arrangements: Liaison Officer, IAEA	Interviews (parallel discussions)	Interviews; TBD, Visit Ministry: TL DTL, TC, M1, 2, 3 IRRS Reviewers	Writing first draft of preliminary findings R/S/GP; Site Visit		Report preparation	Policy issues discussion			**13:00-14:00**
14:00-15:00											**14:00-15:00**
15:00-16:00											**15:00 -16:00**
16:00-17:00					**Written preliminary findings delivered**			Daily Team Meeting for report preparation: finalization of			**16:00-17:00**
17:00-18:00			Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: Discussion of findings		Daily Team Meeting: Discussion of findings				**17:00- 18:00**
18:00-20:00	Dinner	Dinner (D)	D	D	D		D	D	D		**18:00-19:00**
20:00-24:00			Report Writing (RW)	R W; NPP group departs to NPP site	RW		RW	RW	TL, DTL, TC edit the report		**20:00-24:00**

<table>
<tr><th colspan="8">SECOND WEEK</th></tr>
<tr><th>Time</th><th>MON</th><th>TUE</th><th>WED</th><th>THU</th><th>FRI</th><th>Time</th></tr>
<tr><td>08:00-09:00</td><td colspan="2"></td><td>Finalization of the draft Report
Submission of the Draft Report to the Host</td><td colspan="2"></td><td></td><td>08:00-09:00</td></tr>
<tr><td>09:00-10:00</td><td rowspan="3">Individual discussions of report sections with counterparts</td><td rowspan="3">Report writing</td><td rowspan="2">TL, DTL, TC draft Executive Summary</td><td rowspan="2">Hosts reviews the Report Draft</td><td rowspan="3">Hosts review the Report Draft
Written Host's comments are submitted to the Team</td><td rowspan="3">TL, DTL, TC finalize Executive Summary
TL finalises exit presentation
TC and AF draft the press release</td><td rowspan="3">Discussion with Host on findings</td><td rowspan="3">Exit Meeting</td><td>09:00-10:00</td></tr>
<tr><td>10:00-11:00</td><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td><td>11:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td colspan="2">Standing lunch</td><td colspan="2">Standing lunch</td><td>Standing Lunch</td><td>Lunch</td><td>12:00-13:00</td></tr>
<tr><td>13:00-15:00</td><td colspan="2" rowspan="2">Draft Report
cross-reading</td><td rowspan="3">TL, DTL, TC prepare exit presentation</td><td rowspan="3">Host reviews the Report Draft</td><td colspan="2" rowspan="3">IRRS Team members
Host's comments</td><td>Team meeting for finalisation of the Report
Submission of the Final Draft Report to the Hosts</td><td rowspan="5">IRRS Team Members Departure</td><td>13:00-15:00</td></tr>
<tr><td>15:00-17:00</td><td>15:00-17:00</td></tr>
<tr><td>17:00-18:00</td><td colspan="2">TL, DTL, TC and DTC finalise the report text</td><td>Briefing of the IAEA official
Finalisation of the press release</td><td>17:00-18:00</td></tr>
<tr><td>18:00-20:00</td><td colspan="2">Dinner</td><td colspan="2">Dinner</td><td colspan="2" rowspan="2"></td><td rowspan="2"></td><td>18:00-20:00</td></tr>
<tr><td>20:00-24:00</td><td colspan="2">TL, DTL, TC and DTC finalise the report text</td><td colspan="2">TL, DTL, TC and „editors" finalise the report text</td><td>20:00-24:00</td></tr>
</table>

APPENDIX III – SITE VISITS

COVRA - central organization for radioactive waste
EPZ/KCB Nuclear Power plant, Borssele
Reinier de Graaf hospital
RID - Reactor Institute Delft, Research Reactor

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**R1**	**Recommendation: The Government should develop a national strategy for safety that sets out the mechanisms for implementing the national policy for radiation protection and nuclear safety, considering a graded approach, in line with the IAEA Safety Fundamentals.**
	R2	**Recommendation: The Government should evaluate and improve, as required, the regulatory framework and ensure that there are provisions for sufficient resources to regulate future facilities and activities, in line with national priorities.**
	S1	**Suggestion: The Government should consider ensuring the establishment of formal working agreements between all authorities responsible for assuring the regulatory framework for safety.**
2. THE GLOBAL SAFETY REGIME	**n/a**	n/a
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**n/a**	n/a
4. MANAGEMENT OF THE REGULATORY BODY	**R3**	**Recommendation: ANVS should implement the improvements of the ANVS Integral Management System, in order to identify and develop its processes and procedures in a coherent manner, integrate them in its management system, and ensure that the management system is consistently used throughout the organisation.**
	S2	**Suggestion: The ANVS should consider including additional measures for fostering and sustaining of the safety culture in its AIM.**
5. AUTHORIZATION	**S3**	**Suggestion: The ANVS should consider formalizing the pre-licensing step of new facilities and activities in its management system.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S4	**Suggestion: The ANVS should consider establishing a process to update the conditions of individual licences to reflect changes in regulations and guides.**
	S5	**Suggestion: The ANVS should consider standardizing the licence conditions for nuclear facilities taking into account a graded approach to ensure that the fulfilment of the regulatory requirements is consistent to build confidence among interested parties.**
	R4	**Recommendation: The government should review the legal framework with respect to different types of authorization for all different stages in the lifetime of a radiation sources facility in accordance with a graded approach.**
	S6	**Suggestion: The ANVS should consider finalizing an accurate register of HASS.**
	R5	**Recommendation: The Government should establish provisions in the legal framework that a radiation generator or a radioactive source (not being HASS) is transferred only if the recipient possesses the necessary authorization.**
	R6	**Recommendation: The Ministry of VWS should ensure that Diagnostic reference levels for medical exposure, dose constraints for carers and comforters and for volunteers participating in a programme of biomedical research are established.**
	S7	**Suggestion: The Ministry of VWS should consider ensuring the completion of referral guidelines for individual medical exposures.**
	R7	**Recommendation: The Government should ensure that there are regulatory provisions for calibration of dosimeters and other equipment including the traceability to a standard dosimetry laboratory.**
	R8	**Recommendation: The Ministry of VWS should establish requirements to ensure that advisory signs for pregnant or breast-feeding women in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
6. REVIEW AND ASSESSMENT	R9	Recommendation: The ANVS should include a process for the regulatory integrated safety assessment activities in the AIM.
	GP1	Good Practice: The ANVS has developed the guide on use of the PSA level 3 and implemented it for the licensing process of research reactors.
	S8	Suggestion: The ANVS should consider further developing internal guidance procedures and processes for the review and assessment of radiation source facilities and activities using a graded approach under the AIM.
	R10	Recommendation: The ANVS should require periodic assessment of the dose to members of the public, due to the transport of radioactive material, and verify that the dose remains below the dose limits.
	R11	Recommendation: The ANVS should independently verify that the dose to the public from authorised releases remains below the dose limits.
	S9	Suggestion: The ANVS should consider periodically updating its review of potential existing exposure situations in the Netherlands.
7. INSPECTION	R12	Recommendation: The ANVS should continue the development and implementation of a multi-annual inspection programme for nuclear facilities.
	R13	Recommendation: The Regulatory Body should ensure it has a sufficient number of inspectors to effectively perform all of its planned inspections.
	R14	Recommendation: The ANVS should lead the establishment of effective mechanisms to coordinate inspection planning and timely sharing of inspection findings between the inspectorates and the ANVS.
	S10	Suggestion: The ANVS should consider establishing an auditing programme to inspect the authorized parties' management system involved in transport activities.
	R15	Recommendation: The IGJ should develop a regulatory inspection programme for medical exposures and implement it through the annual inspection plans following a graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
8. ENFORCEMENT	R16	Recommendation: The Government should authorize the NLA to use the administrative law for enforcing compliance with regulatory requirements and license conditions related to occupational exposure.
	S11	Suggestion: The ANVS should consider developing and implementing a structured approach to monitor implementation of corrective actions related to nuclear facilities.
9. REGULATIONS AND GUIDES	R17	Recommendation: The ANVS should further develop regulations and guides to be consistent with current IAEA safety standards.
	R18	Recommendation: The ANVS should establish regulatory requirement for the fuel cycle facilities regarding an independent safety committee or an advisory group to advise the management of the operating organization on all safety aspects of the nuclear fuel cycle facility.
	R19	Recommendation: The Government should provide for improved legal and regulatory framework for the operation of landfill disposal facilities.
	R20	Recommendation: The Government should establish regulatory requirements well before a deep geological repository is established.
	R21	Recommendation: The ANVS should develop regulatory requirements on Waste Acceptance Criteria. The safety case should be identified as the main source of criteria for accepting radioactive waste packages and unpacked radioactive waste for processing, storage and disposal.
	S12	Suggestion: The ANVS should consider enhancing the radioactive waste classification scheme, including heat generating HLW, in the regulatory framework.
	S13	Suggestion: The Government should consider enhancing the regulatory requirements for deferred decommissioning under special circumstances.
	R22	Recommendation: The Government should develop regulatory requirements for the release of sites from regulatory control with and without restrictions.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R23	**Recommendation: The Ministry of VWS should ensure the practical measures are in place to define what constitutes significant unintended and accidental medical exposures.**
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R24**	**Recommendation: The Government should ensure appropriate arrangements are put in place to protect Helpers in a nuclear and radiological emergency.**
	R25	**Recommendation: The Government should revise the framework of emergency preparedness and response to establish criteria for the termination of on-site and off-site nuclear and radiological emergencies.**
	S14	**Suggestion: The ANVS should consider completing the development of regulations and guides relevant to support the implementation of emergency plans guidance for licence holders of radiation sources Cat 1, 2 and 3.**
	R26	**Recommendation: The Government should complete the protection strategy, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency, consistent with the IAEA Safety Standards.**
	GP2	**Good Practice: The CalNET information system forms a robust basis for a coordinated emergency response for national and cross-border coordination of protective actions during the early phase of a nuclear accident.**
11. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS	**n/a**	n/a

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

9th and 8th CNS National presentation-NL final
Administrative Regulations of the ANVS
ANVS 2022 Starting and Accountability document
ANVS Annual Report 2022
ANVS Arbo Jaarplan 2023 (ENG version)
ANVS Inspection and Enforcement Strategy
ANVS Integrated Management System 2.0 PvA
ANVS Licensing Policy
ANVS Multi-Year Plan for Instruction, Training and Drills (OTO) for the Emergency Response Organization 2022-2025
ANVS Regulation on Basic Safety Standards for Radiation Protection-Articles v2 (ANVS-verordening)
ANVS Response and Plans for following the Recommendations
ANVS Vision document 2022-2025
Appointment of Inspectors and Fullfilment of Duties (Nuclear Energy Act) Decree 2013
Arrangements regarding International Representation in the field of Nuclear Safety and Radiation Protection
Article 16 and 18 Transport License ANVS-2022 8122
Assessment Framework for Company Emergency Response plan
Assessment Framework Tab 1 General
Assessment Framework Tab 2 App 6,B
Assessment Framework Tab 3 LCP-s
Assessment Report for the Certification of the Robatel R79 transport container
Autonomous Administrative Bodies Enabling Act
BRAS Guidelines
Brochure for Care Providers; Reporting calamities to the Health and Youth Care Inspectorate
CCP Phase 3 procedure
Coalition Agreement 2022- sentence
Code of conduct on Research Reactors
Code of conduct on Safety and Security of Radiation Sources
Covenant ANVS-Tax and Customs Administration
Convention on Physical Protection of Nuclear Material and Nuclear Facilities
Cooperation Agreement for Radiation Protection 2017
Covenant SZW-VWS-ANVS
Crisis Expert Team (radiation and nuclear) Manual
Decision Lloyds Register Nederland B.V.
Decree on Basic Safety Standards for Radiation Protection-Annexes
Decree on Basic Safety Standards for Radiation Protection (Bbs)
Decree on Basic Safety Standards for Radiation Protection-Transposition and Concordance Tables
Directive Responsibility Structure for Radiation Protection in Institutions for Specialist Medical Care
Directive Working with Therapeutic Doses of Radionuclides - Dutch Federation of Medical Specialists
Disposal Radioactive Waste policy in the Netherlands
Drinking Water Decree Annex A
Dutch Safety Requirements (DSR) (VOBK)
Dutch Federation of Medical Specialists: Directive Working with therapeutic doses of radionuclides

Exemptions Decree Ministry of Defence Nuclear Energy Act
Fissionable Materials and Ores - Recording - Decree
Fissionable Materials Ores and Radioactive materials Transport Decree
General Administrative Law Act
General Conditions COVRA 2022
General Government Purchasing Conditions 2018 (ARIV-2018)
General Government Terms and Conditions for Public Service Contract 2018
Guidance to National Policy for Nuclear Safety and Radiation Protection 2022
Guideline for submitting Licence Applications for Activities under section 15(1), 29, 34 Nuclear Energy Act
Guidelines for Funeral Companies
Guidelines for the ten-yearly Periodic Safety Review of nuclear facilities
Guidelines on Metal and Scrap Metal containing Radioactive Materials
HRM Cycle and Personnel Review
Import and Transit Decree re Implementation of Waste Directive
Letter to Parliament Conditions for new build
Licensing on ANVS Website
List of decisions Management Team ANVS dated 11 December 2018
List of decisions Management Team ANVS dated 3 November 2021
List of decisions Management Team dated 5 January 2016
Mandate and Submandate, Power of Attorney and Authorization Decree 2020
Manual- Changing processes in ANVS Centraal
Manual- Describing processes in ANVS Centraal
Manual Mavim Manager conventions and ANVS Centraal
Memorandum Rad. Waste Policy
Ministerial Nuclear Safety Regulation for nuclear installations (Rnvk)
Model for requirement for annual report regarding complex licence
Monitoring of medical and industrial applications of inonising radiation
Motion by member Lansink 1-11-1979
National Emergency Plan Radiation 2021
National Radon Action Programme
National Report for the Convention on Nuclear Safety (CNS)
National Report for the Council Directive 2011 70 Euratom
National report for the Joint Convention of the Safety of Spent Fuel Management
Notification Criteria Guidelines for Nuclear Facilities
Nuclear Accidents Liability Act
Nuclear Energy Act
Nuclear Energy Act - Confidentiality Decree
Nuclear Energy Act - Fees Decree
Nuclear Facilities Fissionable Materials and Ores Decree (Bkse)
Nuclear Facilities Fissionable Materials Security Regulation
Nuclear Pressure Equipment Regulation
Offer Letter Recommendations Advisory Board about role of the ANVS irt final disposal of radioactive waste
Organizational chart ANVS 2.1
Organizational Decision ANVS 2.020
Organizational Decision ANVS 2.1

Oversight and Enforcement Strategy 2023
Programme Plan ANVS (AIM)
Protocol Additional Agreement EU-countries IAEA of the Treaty Non-proliferation of Nuclear weapons
Radioactivity Contaminated Scrap Detection - Regulation
Radioactivity Contaminated Scrap Detection Decree
Recital from ECLI
Recommendations by the Advisory Board about the role of the ANVS in relation to the final disposal of radioactive waste
Regulation on Basic Safety Standards for Radiation Protection v1 (Rbs)
Regulation on Radiation Protection for Medical Exposure
Regulation on Radiation Protection for Occupational Exposure
Report of the Kingdom of the Netherlands for the combined 8th and 9th review meeting in 2023
Response by the ANVS to the recommendations by the Advisory Board concerning radioactive waste
Revision Decision of COVRA 7 Jan 2015
Safety Culture ANVS
Script for ANVS Centraal – Managing your work!
Security Regions Act
Shutdown and Decommissioning Regulation
State of Nuclear Safety and Radiation Proctection Report 2019
State of Nuclear Safety and Radiation Proctection Report 2022
Statutory evaluation 2018 - paragraphs
Study of ANVS Integrated Management System (AIM) by De Raadgever
Supervisory Vision of Ministry IenW-ANVS
The National Programme for the management of radioactive waste and spent fuel - June 2016
The Orange Booklet
Towards a Nuclear Technology and Radiation Agenda and Platform
Transport License COVRA
Transport License to TAM International 18-7-2022
Transposition Table
Vbs Section 3.16
Vision document 2022-2025
Warning letter to Fast Forward Freight 19-1-2022
Waste (landfill ban) Decree (section 11k)
Web text Applying for a licence
Web text Ten-yearly Periodic Safety Reviews of nuclear facilities
WET BIG Health Care Professions Act-section 35-36
Wet KKGZ Healthcare Quality, Complaints and Disputes Act Ch.1-4
WMO Medical Research Involving Human Subjects Act
Working Conditions Act section 11
Working Conditions Act section 3
Working Conditions Act section 5
Working Conditions Act section 8
Working Conditions Decree Div. 1, section 8.1
Working instructions for assessing the loss of a transport
Working instructions for damaged transport

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

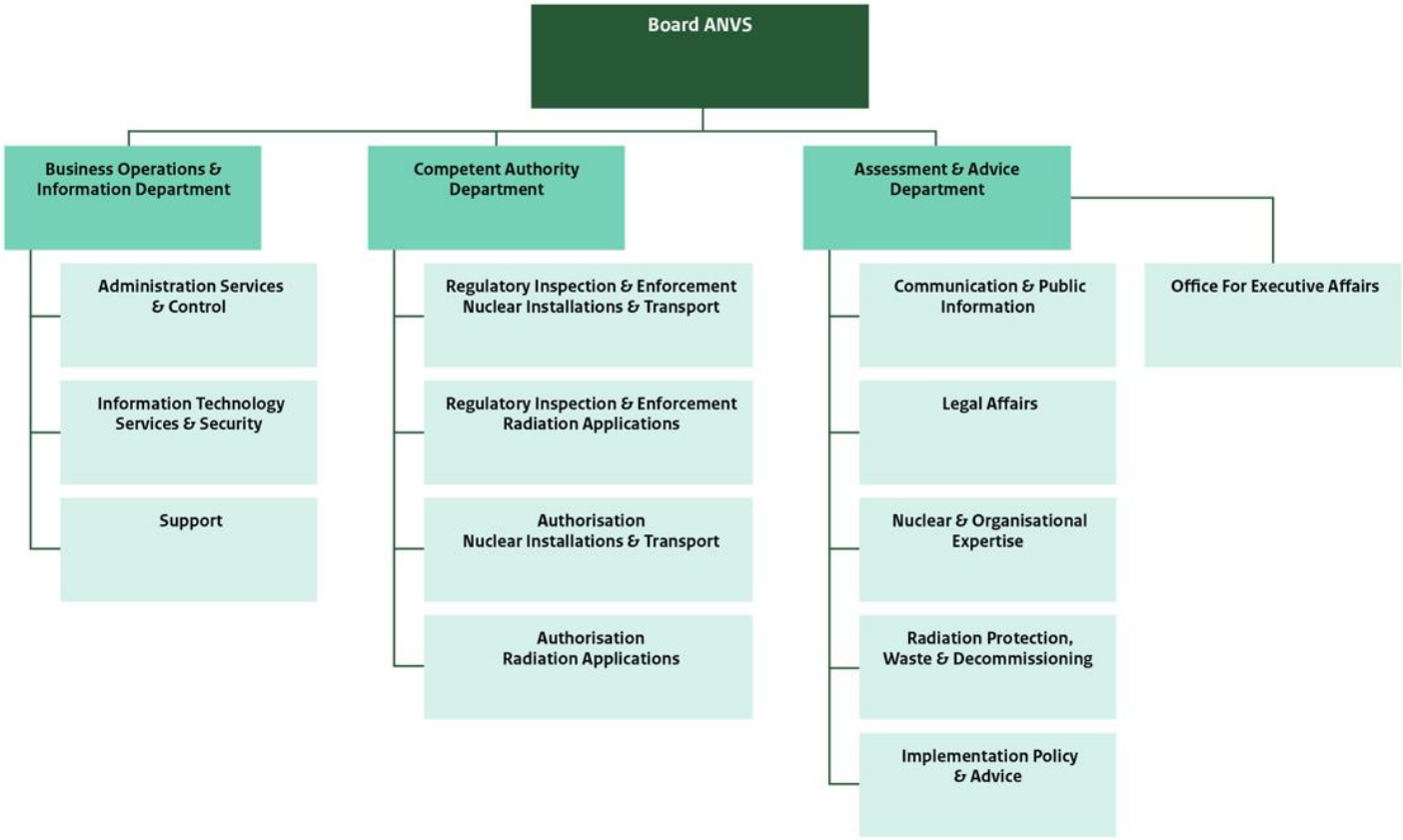
1.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	**INTERNATIONAL 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 Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series 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 Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series 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, Safety Guide Series No GSG-2, IAEA, Vienna (2012)
18.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
19.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. GSG-7, IAEA, Vienna (2018)
20.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)
21.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
22.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).

23.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
24.	**INTERNATIONAL ATOMIC ENERGY AGENCY** Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide Series No GSG-16, IAEA, Vienna (2022)
25.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
26.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Operating Experience Feedback for Nuclear Installations, Safety Guide Series No. SSG-50, IAEA, Vienna (2018)
27.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Modifications to Nuclear Power Plants, Safety Guide Series No SSG-71, IAEA, Vienna (2022)
28.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
29.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
30.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
31.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
32.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
33.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
34.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
35.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)
37.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
42.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition), Specific Safety Guide No SSG-26 (Rev.1), IAEA, Vienna (2022)
43.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
44.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
45.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)

46.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
47.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide Series No SSG-46, IAEA, Vienna (2018)
48.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
49.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
50.	**INTERNATIONAL ATOMIC ENERGY AGENCY** –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
51.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
52.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
53.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material, Safety Guide No SSG-65, IAEA, Vienna (2022)
54.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna (2007)
55.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna (2008)
56.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna (2009)
57.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2018Edition), Specific Safety Guide No SSG-33 (Rev.1) IAEA, Vienna (2021)
58.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
59.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
60.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – THE ANVS AND THE MINISTRY OF I&W ORGANIZATIONAL CHARTS

ANVS ORGANIZATIONAL CHART



MINISTRY OF I&W ORGANIZATIONAL CHART