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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

CHILE

Santiago, Chile

22 January to 2 February 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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Review Service

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
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Integrated Regulatory Review Service

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Mission dates:	*22 January to 2 February 2018*
Regulatory body visited:	*Comisión Chilena de Energía Nuclear (CCHEN)* *Ministerio de Salud (MINSAL)*
Location:	*Santiago, Chile*
Regulated facilities and activities in the mission scope:	*Radiation sources in industrial and medical facilities, research reactors, fuel cycle facilities, transport, emergency preparedness and response, medical exposure, occupational exposure, public and environmental monitoring.*
Organized by:	*International Atomic Energy Agency*

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

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EXECUTIVE SUMMARY

At the request of the Government of Chile, an international team of senior nuclear and radiation safety experts met with representatives of the Chilean Commission of Nuclear Energy (CCHEN) and of the Ministry of Health (MINSAL) from 22 January to 2 February 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the CCHEN Headquarters in Santiago. Meetings were organized with CCHEN and MINSAL. The purpose of the IRRS mission was to perform a peer review of Chile's national regulatory framework for nuclear and radiation safety.

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

The IRRS team consisted of 11 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the Government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; transport of radioactive material; emergency preparedness and response; occupational radiation protection; control of medical exposure; control of radioactive discharges and materials for clearance; environmental monitoring; control of public exposure; and control of existing exposure situations and remediation.

The IRRS mission included two policy issue discussions on independence of the regulatory body and education and training in nuclear and radiation safety.

The IRRS mission included observations of regulatory activities and interviews and discussions with staff of CCHEN and MINSAL. Activities included visits to: the nuclear research reactor RECH1, the nuclear fuel manufacturing facility, a radioactive waste management facility, an industrial radiography facility and a private medical facility.

The IRRS team observed regulated activities and performance of inspection activities, and held discussions with the authorized party personnel and management.

In preparation for the IRRS mission, Chile had conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. Throughout the mission, the IRRS team had full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The IRRS team observed that CCHEN and MINSAL counterparts were committed to provide the regulatory oversight of all nuclear and radiation facilities and activities. The invitation of the IRRS mission demonstrates Chile's commitment to improve the national legal and regulatory framework for safety.

The most significant challenges for the regulatory body are the lack of effective independence of CCHEN and MINSAL and the incompleteness of the regulatory framework for nuclear and radiation safety.

The IRRS team identified a good practice and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness

of regulatory functions in line with IAEA safety standards. The IRRS team recognized that the action plan prepared by CCHEN and MINSAL addresses a number of the IRRS findings.

Since CCHEN and MINSAL are also promoting nuclear and radiation applications and operating regulated facilities, and since the IRRS team conducts peer-review of the national regulatory authorities as well as the regulatory framework and infrastructure for safety, the report refers only to the divisions, sections and units of CCHEN and MINSAL that are responsible for regulatory functions regarding nuclear and radiation safety, as well as their respective upper management.

The good practice identified by the IRRS team is that Chile has developed technical capability to perform biological dosimetry in cases of overexposure.

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

- The Government should:
  - Review its legal and regulatory framework for nuclear, radiation, transport and waste safety to ensure full consistency with the latest IAEA safety standards;
  - Ensure that the Regulatory Body is effectively independent in its safety related decision making and that functional separation from entities having responsibilities or interests that could unduly influence its decision making;
  - Provide mechanisms that ensure it has the effective coordination of CCHEN and MINSAL to avoid any omission and undue duplication or conflicting requirements being placed on authorized parties.
- CCHEN and MINSAL should:
  - Allocate and manage their resources to allow them to discharge their responsibilities and perform their regulatory functions effectively;
  - Develop and update regulations and guides related to safety to be consistent with the latest IAEA safety standards within respective regulatory responsibilities.

All recommendations and suggestions are identified in the report and listed in Appendix V.

At the end of the IRRS mission, an IAEA press release was issued and a press conference was organized.

I. INTRODUCTION

At the request of the Government of Chile, an international team of senior safety experts met representatives of Comisión Chilena de Energía Nuclear (CCHEN) and the Ministerio de Salud (MINSAL) from 22 January to 2 February 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Chile's regulatory framework for nuclear and radiation safety. The IRRS mission was formally requested by the Government of Chile in June 2014. An IRRS preparatory meeting was conducted from 3 to 4 September 2014 at CCHEN Headquarters in Santiago to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Chile and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 11 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; transport of radioactive material; emergency preparedness and response; occupational radiation protection; control of medical exposure; control of radioactive discharges and materials for clearance; environmental monitoring; control of public exposure; control of existing exposure situations and remediation.

In addition, policy issues were discussed, including: effective independence of the regulatory body and education and training in nuclear and radiation safety.

CCHEN and MINSAL conducted their respective self-assessments in preparation for the mission and prepared their respective preliminary action plans. 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 Chile's advance reference material, conduct of interviews with management and staff from CCHEN and MINSAL and direct observation of the regulatory activities at regulated facilities. Meetings with the Minister of Energy, the Minister of Health and the Head, Direction of International and Human Safety of Ministry of Foreign Affaires were also organized.

The IRRS team also visited the Nuclear Fuel Fabrication Facility, the radioactive waste management facilities operated by SEGEDRA, the RECH1 Nuclear Research Reactor, the installation of PET-CT medical radio diagnostic in the German Clinic of Santiago, the industrial radiography facility/Technical Inspection Society (Inc.) to observe the performance of inspection activities and discuss the effectiveness of the inspections with the licensee personnel and the management.

CCHEN and MINSAL are identified as the national nuclear and radiation regulatory authorities in the legal and regulatory framework of Chile. However, CCHEN and MINSAL are also promoting nuclear and radiation applications and operating regulated facilities, such as research reactor, fuel cycle facility, industrial and medical radiation facilities as well as conducting several regulated activities. The activities of regulation, promotion and use are being carried out by different divisions, sections and units in their organizational infrastructure. The regulatory activities of CCHEN are being performed by the División Seguridad Nuclear y Radiológica (DISNR).

The regulatory activities of MINSAL are performed by: the Subsecretaria de Salud Pública, that is in charge of drafting regulations, norms and technical guidelines; the 15 Subsecretarias Regionales de Salud (SEREMI), that must ensure compliance with current regulations and perform audits; and the Instituto de Salud Pública de Chile (ISPCH), that exercises the functions of regulation in medical devices and radiology equipment.

Since the IRRS team conducts peer-review of the national regulatory authorities as well as the regulatory framework and infrastructure for safety, the report refers only to the divisions, sections and units of CCHEN and MINSAL that are responsible for regulatory functions regarding nuclear and radiation safety, as well as their respective upper management.

All through the mission the IRRS team received excellent support and cooperation from CCHEN and MINSAL.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of Chile's nuclear and radiation safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS scope included all facilities and activities currently regulated by CCHEN and MINSAL. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

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

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

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 Review 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 during 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; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Chile, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 3 to 4 September 2014. The preparatory meeting was carried out by the appointed Team Leader Mr Javier Zarzuela, Deputy Team Leader Mr Claudio Almeida and the IRRS IAEA Team representatives, Mr Ahmad Al Khatibeh, Ms Cristobal Amparo and Mr Ugur Bezdeguemeli.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of CCHEN represented by Executive Director Mr Jaime Salas, and the Ministry of Health represented by Mr Alfonso Espinoza, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Research Reactors;
- Nuclear Fuel Cycle Facilities;
- Waste facilities;
- Radiation source facilities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Control of radioactive discharges and materials for clearance; environmental monitoring for public radiation protection purposes; control of public exposure; control of existing exposure situations and remediation.

Mr Mauricio Lichtemberg, Head, Division of Nuclear and Radiological Safety CCHEN made presentations on the national context, the current status of CCHEN and the self-assessment results to date and Mr Alfonso Espinoza presented the regulatory funtions of the Ministry of Health.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in January 2018.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Chile Liaison Officer for the IRRS mission was confirmed as Mr Hugo Briso.

Chile provided IAEA with the ARM for the review in November 2017. In preparation for the mission, the IRRS team conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 21 January 2018, in Santiago, 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. 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 Liaison Officer was 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, 22 January 2018, with the participation of Mr Patricio Aguilera (CCHEN Executive Director), Mr Tito Pizarro, (Director of the Division of Healthy Public Policies and Promotion of MINSAL and Representative to the Directive Council of the CCHEN) and CCHEN and MINSAL senior management and staff. Opening remarks were made by Mr Patricio Aguilera and Mr Jarvier Zarzuela. Mauricio Lichtemberg (Head, Division of Nuclear and Radiological Safety, CCHEN) and Ms Norma Carreño Palacios (Representative of the Ministry of Health) gave an overview of the Chile context and CCHEN and MINSAL activities.

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

The IRRS team performed its review according to the mission programme given in Appendix III.

The IRRS team had a meeting with the Board of CCHEN to discuss two policy issues on the independence of the regulatory body and on education and training in nuclear and radiation safety.

The IRRS exit meeting was held on Friday, 2 February 2018. The opening remarks at the exit meeting was presented by the CCHEN Executive Director Mr Patricio Aguilera and was followed by the presentation of the results of the mission by the IRRS Team Leader Mr Javier Zarzuela. Closing remarks was made by Mr Peter Johnston, Director, IAEA, Division of Radiation, Transport and Waste Safety.

An IAEA press release was issued following the mission and a joint press conference organized by CCHEN and IAEA took place at the end of the mission.

Since the IRRS team conducts peer-review of the national regulatory authorities as well as the regulatory framework and infrastructure, the following text of the report only refers to the departments, sections and units that are responsible for regulatory activities in CCHEN and MINSAL as well as their respective upper management whenever it mentions about CCHEN and MINSAL.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Chile does not have a national policy and strategy for safety in the utilization of ionizing radiation for the protection of people and the environment against its harmful effects.

In 2016, the declaration of national politics of work safety and health was promulgated. Decree Nº 47/2016 issued by Ministry of Labour together with Ministry of Health and Ministry of Education, where it addresses occupational safety and health. The above-mentioned legislation provides for regulation of facilities and activities using ionizing radiation to protect the public and radiation workers. However, the laws and regulations do not establish the fundamental safety objective to meet the requirements of IAEA Fundamental Safety Principles, and a documented policy and strategy does not exist. Essential elements including long-term commitment to safety and promotion of leadership and management for safety, including safety culture, are not covered in the existing regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no specific national policy and strategy for safety that addresses the fundamental safety objective, fundamental safety principles and a long-term commitment for safety.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
(2)	**BASIS: GSR part 1 (Rev. 1) Requirement 1, para. 2.3 states that** *"The national policy and strategy for safety shall express a long-term commitment to safety. the national policy shall be promulgated as a statement of the government's intent. the strategy shall set out the mechanisms for implementing the national policy."*
R1	**Recommendation: The Government should establish a national policy and strategy for safety, whose implementation should follow a graded approach, to achieve the fundamental safety objective, to apply the fundamental safety principles and to express a long-term commitment to safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal bases for the national framework for safety are:

- Law 18,302 (1984) on Nuclear Safety, that assigns responsibilities among different authorities, mainly the CCHEN and Ministry of Health;

- Law 16,319 (1965) Creates the Chilean Nuclear Energy Commission, and assigns responsibilities for nuclear safety in fuel cycle and nuclear reactors;
- DFL 1/2005 organization of the MINSAL, issued by the MINSAL;
- DFL 725/1967 Sanitary Code, issued by the MINSAL. Article 86 and the Book X establishes procedures and sanctions enforcement rules;
- Circular B33 N° 37/2014, issued by the MINSAL, that gives instructions to applicate Supreme Decree Nº 133/1984 and Supreme Decree Nº 3/1985 MINSAL establishes competences of MINSAL and all the type of authorizations;
- Supreme Decree N° 133/1984 Regulations on authorizations, issued by the MINSAL. Establishes and classifies radioactive facilities in categories 1, 2 and 3, requirements for radioactive facilities and ionizing radiation generating equipment, personnel, import-export, distribution and sale, and disposal;
- Annex to the Supreme Decree 115/1975, issued by Ministry of Economy, promotion and reconstruction CCHEN and "Basic standard for radiation protection";
- Supreme Decree N° 3/1985, issued by the MINSAL. It approves regulation on radiation protection in radioactive facilities;
- Decree N° 47/2016, issued by the Ministry of Labour and Social Prevision. It establishes the Policy on Safety and Health Hygiene at the work place;
- Circular 1/2017, issued by CCHEN. Norm for special authorization to work in radioactive facilities (workers).

They basically establish the binding character of specific international legal instruments, the specification of the scope of the governmental, legal and regulatory framework for safety.

Laws 18,302 modified by law 19,825 and DFL Nº 725/1967 MINSAL establish a governmental, legal and regulatory framework for safety, as well as allocation of responsibilities. In this regulatory framework there are two main authorities:

- Chilean Nuclear Energy Commission (CCHEN), that has assigned the regulation of all nuclear facilities, reactors and fuel cycle, as well as radioactive facilities defined by Supreme Decree N° 133/1984 issued by MINSAL as category 1, and all the radioactive facilities located within a nuclear facility.
- Ministry of Health (MINSAL), that oversees regulation of radioactive facilities and other matters indicated in the regulation, defined by Supreme Decree N° 133/1984 MINSAL. This regulatory framework also specifies how human and financial resources are provided to CCHEN and MINSAL, and the framework for research and development.

The Nuclear Safety Law also assigns to the Ministry of Energy the competence for authorizing "nuclear power plants, enrichment plants, reprocessing plants and permanent storage repositories for long-lived hot waste".

The national framework addresses most of the items listed in GSR Part 1, Requirement 2; however, some are missing, such as: 2.5 (15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety, 2.5 (16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste, and for decommissioning of facilities and termination of activities, 2.5 (17) the Criteria for a release from regulatory control. Besides, the item 2.5 (7), the establishment of a regulatory body, as addressed in Requirements 3 and 4 is also missing, requirement 3 refers to the need of a regulatory body with

the competence and resources needed to fulfil its duties and requirement 4 refers to the independence of the regulatory body, neither of them being reflected in the legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal framework does not establish an effectively independent regulatory body; does not include safety provisions for acquiring and maintaining the necessary competence nationally for ensuring safety, and does not establish responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, for decommissioning of facilities and termination of activities, and the criteria for a release from regulatory control.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
(2)	**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*: (…) (*7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;* *(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;* *(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;* *(17) Criteria for a release from regulatory control."*
(3)	**BASIS: GSR Part 3 Requirement 2 para 2.13 states that** "*The government shall establish and maintain appropriate and effective legal and regulatory framework for protection and safety in all exposure situations. This framework shall encompass both the assignment and the discharge of governmental responsibilities, and the regulatory control of facilities and activities that give rise to radiation risks."*
R2	**Recommendation: The Government should review and revise the legal and regulatory framework to establish an effectively independent regulatory body, include safety provisions for acquiring and maintaining the necessary competence nationally for ensuring safety, establish responsibilities and obligations in respect of financial provision for the management of radioactive waste and spent fuel, for the decommissioning of facilities and termination of activities and criteria for release from regulatory control.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Law 16,319 (1965), that creates CCHEN, and Law 18,302 (1984), on Nuclear Safety, establishes CCHEN and MINSAL as the two regulatory authorities.

CCHEN and MINSAL are also promoting nuclear and radiation applications and operating regulated facilities, such as research reactor, fuel cycle facility, industrial and medical radiation facilities as well as conducting several regulated activities. All those regulatory, promotion and utilization activities are being conducted by different departments, divisions, sections and units in their organizational infrastructure.

The Nuclear Safety Law, stipulates that, to perform any activity related to the operation of nuclear facilities or Category 1 radioactive facilities, an authorization granted by the CCHEN is needed. Article N° 20 provides the CCHEN the faculty to perform regulatory inspections to verify compliance with safety requirements, and confers appropriate authority and enforcement power to CCHEN and even provides a comprehensive list of non-compliances subjected to enforcement action.

Similarly, DFL N°725/67 confers appropriate authority and enforcement power to MINSAL.

The regulations on authorization of radioactive facilities mentioned in section 1.2 above treat these requirements in further detail.

The regulatory framework currently in force provides the regulatory body with the authority to require licensees to comply with stipulated regulatory requirements, as well as to demonstrate such compliance, through the licencing process and the subsequent regulatory control.

The CCHEN is an autonomous institution inside the Government of Chile, directed and administered by a Board of Directors and an Executive Director.

The members of the Board of Directors and the Executive Director are chosen from among the persons who, because of their function, profession or office, have links with the purposes of the Commission.

The Board of Directors is constituted by:

- The President of the Commission, who will preside, appointed by the President of the Republic;
- A representative of the Minister of Energy, appointed by the President of the Republic, at the proposal of the former;
- A representative of the Minister of Health, appointed by the President of the Republic, at the proposal of the former;
- A representative of the Council of Rectors, appointed by the President of the Republic, at the proposal of the former;
- A representative of the Commander-in-Chief of the Army, appointed by the President of the Republic, at the proposal of the former;
- A representative of the Commander-in-Chief of the Navy, appointed by the President of the Republic, at the proposal of the former, and
- A representative of the Commander-in-Chief of the Air Force, appointed by the President of the Republic, at the proposal of the former.

CCHEN, according to its creation Law, has functions such as propose national plans to the Government for the research, utilization and control of nuclear energy and execute those plans.

In fact, CCHEN has built and is operating facilities such as a research reactor, a cyclotron, a nuclear fuel manufacturing facility and one interim storage facility for radioactive waste and used radioactive sources. CCHEN has also the function of promoting the civil use of nuclear energy and radioactive sources.

According to the Supreme Decree N° 133/1984, the MINSAL grants authorizations and performs inspections to facilities Category 2 and 3, including many that are owned and operated by MINSAL itself, such as laboratories of low radiotoxicity, X-rays for medical or dental diagnosis, radiotherapy and surface roentgen-therapy, radio-isotopic cardiac stimulators, markers or simulators for medical use.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN and MINSAL are promoting the use of radiation sources and are authorized parties. Besides, on the board of CCHEN, there are representatives of ministries that operate regulated facilities. Therefore, the effective independence in their regulatory decision making and effective conduct of their regulatory functions may be compromised.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 4** "*The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 4 para. 2.9** "*No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 4 para. 2.11** "*In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party."*
R3	**Recommendation: The Government should ensure that the national regulatory authorities are effectively independent in their safety related decision making and that they have functional separation from entities having responsibilities or interests that could unduly influence their decision making.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Nuclear Safety Law explicitly establishes that the licensee is responsible for the safety of the radioactive materials for which authorization has been granted.

Besides, legislation stipulates that compliance with regulations and requirements promulgated by the regulatory body does not relieve authorized parties of the prime responsibility for safety in whatever the status of the facility, as clearly specified in Art. 40 of the Nuclear Safety Law, and Art. 14 of the Supreme Decree N° 133/1984 issued by MINSAL.

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

The IRRS team was informed of the existence of a CCHEN and MINSAL Coordination Committee intended to deal with new or modified regulations and practical issues. However, the committee does have neither a Memorandum of Understanding nor any other written protocol that establishes its members, scope and way of documenting agreements made.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no formal mechanism for coordination between CCHEN and MINSAL on safety issues of common interest.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that** *"If responsibilities and functions do overlap, this could create conflict between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant."*
R4	**Recommendation: The Government should make provisions for the effective coordination of the regulatory functions of CCHEN and MINSAL to avoid any omission, or undue duplication and to avoid conflicting requirements being placed on authorized parties.**

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

An effective system for protective actions to reduce radiation risks associated with unregulated sources (of natural and artificial origin) and contamination from past activities or events has not been formally established.

The regulatory framework currently in force does not provide any disposition dealing with radiation risks arising from unregulated sources or from contaminations occurred in the past.

The current regulatory framework dates from the years 1984-1985. At that time the radiation risks from unregulated sources were outside the area of competence of the regulatory body and there were no past activities that had caused radioactive contamination.

The IRRS team was informed of a new draft law dealing with radiation risks from unregulated sources and from past activities that could have caused radioactive contamination.

The IRRS team was also informed of a project to modify Radiological Protection regulation, to regulate existing exposure situations due to radiation of natural origin; due to contaminated areas; and due to products potentially containing residual radionuclides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory framework currently in force does not establish any system to reduce undue radiation risks arising from unregulated sources or from contaminations that occurred in the past.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
R5	**Recommendation: The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.**

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

The regulatory framework currently in force does not explicitly establish governmental policies nor strategies about safety matters related to radioactive waste and spent fuel management including decommission of facilities. Nevertheless, the Nuclear Safety Law and the Supreme Decree N° 133/1984 issued by MINSAL, Regulations on Authorization of Radioactive Facilities, state that decommissioning and closure of nuclear and radioactive facilities category 1 and category 2 require a decommissioning authorization by the regulatory body.

The current regulatory framework does not provide financial guarantees for neither decommissioning nor the management of disused radioactive sources or radiation generators.

The IRRS team was informed of a draft new law proposed for dealing with these gaps of the regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no policy and strategy for radioactive waste management and spent fuel established, nor arrangements for the safe decommissioning of facilities and the safe disposal of radioactive waste.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 states that** "*The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 para. 2.33 states that** "Appropriate financial provision should be made for: a) Decommissioning of facilities b) Management of radioactive waste, including its storage and disposal c) Management of disused radioactive sources and radiation generators

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	d) Management of spent fuel.”
(3)	**BASIS: GSR Part 5 Requirement 2 states that** “*To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste*.”
(4)	**BASIS: SSR Part 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 shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need 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.”*
(5)	**BASIS: GSR Part 6 Requirement 4 states that** *“The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory.”*
R6	**Recommendation: The Government should establish a national policy and strategy for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel; and should make provisions, including the funding, for the safe decommissioning of facilities and the safe disposal of radioactive waste.**

1.8. COMPETENCE FOR SAFETY

There are regulations and national infrastructure to provide training on specific topics, such as qualifications to work under the risk of radioactive sources, and to operate and supervise radioactive facilities.

Some universities provide education and master degrees for medical physicist and other degrees.

The higher-level competences of parties involved and the technical personnel at the regulatory body are acquired by attending international training courses, often sponsored by the IAEA. The CCHEN has in place arrangements for sending people to these international education and training courses.

Policy issues on education and training in nuclear and radiation safety

The manpower development program for the whole nuclear sector of a country, both in the regulatory area and in the area of applications in industry and medicine, was discussed.

The insights of the Pronuclear Program created to support the transfer of technology agreement signed between Brazil and Germany in 1970's, which involved a detailed diagnostic of existing capabilities, a clear identification of the manpower needs, and a large training program in Brazil, with the support of Brazilian universities, and in Germany, with support of German industry and nuclear research institutes were presented.

The manpower need of Greece, a country with a small nuclear program similar to the one in Chile, was also introduced. The discussion touched upon the specific needs and the required national effort to provide the necessary amount of people with adequate qualification.

The Argentinian experience in relation to education and training in nuclear and radiation safety was also discussed. The process of educational development in correlation with the technological development (cause/consequence) was explained. Currently in Argentina there is a variety of courses and specializations, dictated by the National Atomic Energy Commission, by the Nuclear Regulatory Authority (in conjunction with universities and under the auspices of the IAEA), by Nucleoeléctrica Argentina, and other organizations in the area, several of which are annual and post degree. Emphasis was done in the experience of the Balseiro Institute, in which physics and nuclear engineering careers are taught, and a close relationship is maintained with the RA-6 nuclear reactor.

1.9. PROVISION OF TECHNICAL SERVICES

The Supreme Decree Nº 3/1985 issued by MINSAL provides the requirements for a dosimetry service to be approved (certified) by the MINSAL.

The Law No 16,319 establishes, among its functions, that CCHEN has the mission to perform environmental surveillance for its nuclear facilities.

The regulatory framework currently in force provides for technical services in dosimetry and environmental monitoring. The government has provided resources for a fully operational secondary standard dosimetry laboratory at CCHEN.

Dosimetry services can be provided by CCHEN or by private entities. In this case, MINSAL must authorize the services, upon receiving a positive assessment report from the Institute of Public Health.

In relation to the calibration services, they are provided nationwide by the Metrology Laboratory at CCHEN. The regulatory framework has not established the authorization of calibration services.

The IRRS team concluded that the elements explicitly mentioned in GSR Part 1 (Rev 1) para. 2.41 are in place.

1.10. SUMMARY

While Chile has not established a national policy and strategy for safety, a framework has been established through the set of laws and regulations that regulate the nuclear and radioactive material to protect the workers, the public and the environment from the risks of the harmful effects of radiation.

Chile has established CCHEN and MINSAL as regulatory authorities with clearly defined

powers and functions to carry out their regulatory functions.

However, there are several recommendations provided by the IRRS team to improve the regulatory framework and align it to the IAEA safety standards.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Government of Chile participates in all relevant international arrangements for the enhancement of global safety, it has subscribed the relevant international conventions, the Code of Conduct on safety and security of radioactive sources and the supplementary Guidance on import export of radioactive sources.

Chile acceded the following multilateral agreements of the global safety regime:

- Agreement on the Privileges and Immunities of the IAEA, Acceptance: 1987-12-08;
- Vienna Convention on Civil Liability for Nuclear Damage, Signature: 1988-08-18, Ratification: 1989-11-23;
- Convention on the Physical Protection of Nuclear Material, Accession: 1994-04-27;
- Amendment to the Convention on the Physical Protection of Nuclear Material, Acceptance: 2009-03-12;
- Convention on Early Notification of a Nuclear Accident, Signature: 1986-09-26, Ratification: 2005-11-15;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, Signature: 1986-09-26, Ratification: 2004-09-22;
- Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention, Signature: 1988-09-21, Ratification: 1989-11-29;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, Accession: 2011-09-26;
- Convention on Nuclear Safety, Signature: 1994-09-20, Ratification: 1996-12-20;
- Code of Conduct on the Safety and Security of Radioactive Sources, Support: 2004.

CCHEN has also signed the following bilateral agreements:

- Administrative Arrangement between the Canadian Nuclear Safety Commission and the Comisión Chilena de Energía Nuclear for Import and Export of Radioactive Sources, Agreement: December 2011;
- Statement of Intent between the United States Department of Energy and the Comisión Chilena de Energía Nuclear related to Nuclear and Radiation Emergency Management and Response Capacity, Agreement: September 2012.

The Government of Chile received a Radiation Safety and Security Infrastructure Appraisal (RaSSIA) in 2005; a second Occupational Radiation Protection Appraisal Service (ORPAS) in November 2017; and the IRRS in 2018.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

CCHEN identifies lessons to be learned from operating experience and regulatory experience, carries out analysis and disseminates the lessons learned for its own use and by authorized parties. When applicable, experience in other States are analysed as well, on a case by case basis.

Currently resources devoted to information acquisition and analysis are comprised in the management system on a reactive basis, i.e. when information is provided by international networks analysis is carried out.

Due to the limited availability of expert time, analysis of relevant events is prioritized.

MINSAL has not made arrangements for analysis to be carried out to identify lessons to be learnt from regulatory experience or operating experience.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no formal mechanisms to analyze operating experiences and distribute the lessons learnt. The scope of such analysis regarding international experiences, as well as regulatory experience is not clearly defined.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 15, para. 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to other lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience*."
S1	**Suggestion: CCHEN should consider establishing a documented process that provides for the analysis and dissemination of operational and regulatory experience, both national and international.**

2.3. SUMMARY

The Government of Chile participates in all relevant international arrangements for enhancement of global safety and it is party to the relevant international conventions.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The law No. 16,319, that creates CCHEN, grants it the power to organize itself according to the needs, to effectively perform its duties. The Law on Nuclear Safety and the Regulations on Authorizations establish an authorization system that commensurate with the risk associated with each facility type.

CCHEN, in its regulatory function carried out by DISNR, is organized to fulfil the tasks associated with regulation, authorization and regulatory control.

The annual budget of CCHEN is assigned, in the fourth quarter of each year, according to the needs expressed by the heads of organizational units, considering the projected expenditure for the following year. In preparing the budget for the next year, the head of the organizational unit responsible for the regulatory functions considers the projected needs in terms of authorizations and the number of inspections, for each type of installation.

CCHEN has a staff limited to 330 people but only 20 staff (17 of whom are technical) are assigned to regulatory functions. This fact results in a great workload for the staff dedicated to regulatory activities (DISNR), so that they are unable to discharge all their regulatory functions in matters such as the development of needed regulations, updating of existing ones (see Section 9) and lack of procedures and guidance for internal processes such as for authorization, review and assessment and inspections for specific types of facilities (see Sections 5,6 and 7).

MINSAL has 4 professionals working in relation to the development of norms and regulation, it also has 76 persons assigned to regulatory activities, distributed in 15 regional offices, from regional ministerial secretaries (SEREMI); however, these people are also responsible for other aspects of occupational health safety and public health associated to other risks agents (such us exposition to noise, solvents, silica, etc.).

The Public Health Institute has 8 professionals dedicated to radiological protection as the national and reference laboratory.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Divisions in charge of regulatory functions in CCHEN and MINSAL lack sufficient resources, particularly sufficient number of competent staff and funding, to perform all regulatory functions in an effective and timely manner.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities".* **BASIS: GSR Part 1 (Rev 1) Requirement 18 states that** *"The regulatory body shall employ enough 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"*
R7	**Recommendation: CCHEN and MINSAL should allocate and manage their**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	resources so as to allow them to discharge their responsibilities and perform their regulatory functions effectively.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Although the organizational unity of CCHEN that meets regulatory functions (DISNR) is independent of regulated facilities outside CCHEN, it has a direct dependence of the highest institutional authority, which is the operator of relevant nuclear and radioactive facilities.

MINSAL is subdivided in: Subsecretaria de Salud Publica (SSP) and Subsecretaria de Redes Asistenciales, with roles and functions defined in DFL Nº1/2005. The first one performs normative tasks among others, and the second one oversees welfare benefits and user and operator of radioactive facilities through health services, which have dependent and centralized administration (hospitals and clinics).

The IRRS team was informed that a law dealing with fundamental safety matters (policies and strategies) including the requirement for the government to create a new regulatory body, unique and independent from any other entity having interest in the uses of nuclear energy and on radiation sources has been drafted by CCHEN. The IRRS team was informed that MINSAL is not aware of mentioned law project.

Policy issue on independence of the regulatory body

The experience of Spain, France and Sweden on how an effectively independent regulatory body has been established and maintained was presented. The importance of the establishment of the regulatory body by law was highlighted, as well as the importance of having clear legal and regulatory requirements that enable the regulator to have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities, including the ability to charge and receive appropriate fees, are important aspects of effective independence.

It was also stressed that the higher level that the regulatory body reports to (e.g., legislative branch, parliament) the less likely that they are to receive undue influence during their decision-making and appeal processes.

It was discussed that in some of the countries, members of the Board are made full time members, instead of a group that convenes at certain time interval, to ensure that members are not affiliated to any organization avoiding any potential conflict in the decisions of the regulatory body. It was also mentioned that having a competent staff is an essential feature of an effectively independence of the regulatory body.

The experience of Spain was presented: the main regulatory functions are assigned to the Nuclear Safety Council (CSN), an institution created by law in 1980. CSN was detached from the Board of Nuclear Energy, that depends of the Ministry of Industry and oversaw promotion and regulation of nuclear energy and radiation facilities and activities, as well as regulating them. CSN is ruled by four commissioners and a chairman, proposed by the Ministry of Industry and confirmed by the pertinent commission of the parliament by three fifths of its members after passing a hearing. The five members are *The Council* and each of them has a fix mandate of six years. The Council is accountable to no Spanish governmental instance but the parliament to which they must submit an annual report and the CSN chairman must appear before the

parliament annually to account for the CSN activities. Besides, the CSN financial resources are based on taxes established by law to the regulated industry and recruits its technical staff according to public service procedures implemented by the CSN itself.

The experience of France was also introduced: The Nuclear Safety Authority (ASN) was created by law in 2006. It has the legal status of an independent administrative authority. It is composed of a Board of five commissioners, which are designated by the President of the Republic, the Parliament and the Senate, a Director General nominated by the ASN President, and by national and regional Services. The missions of ASN, based on four values which are independence, competence, rigor and transparency, are to regulate, control and inform all the publics in the matters of nuclear and radiation safety. The Board members are nominated for six years and are working at full time for ASN. The 400 staff members are affected either to departments at national level or to the 11 regional divisions. Funding is coming from the national budget voted annually by the Parliament. ASN President reports annually to a dedicated Commission of the Parliament. ASN is technically supported by the Institute of Radiation protection and Nuclear Safety (IRSN) and advised by permanent Advisory Committees.

The experience of Sweden was also discussed: The Swedish Radiation Safety Authority (SSM) is the regulatory body with mandates in the areas of nuclear safety and radiation protection. SSM's budget is received from the Government. The independence of SSM is codified in the fundamental law setting out the basic principles of Sweden's democracy. The Government has no power to intervene in the SSM's decisions. The Director General is appointed by the Government and reports to the Ministry of the Environment and Energy. SSM has an advisory council appointed by the Government, the council ensures public insight into SSM's operations. Each year, SSM undergoes an annual audit by the Swedish National Audit Office, an independent control body of the Parliament. The integrity of SSM has become increasingly important with the progression of the licensing review of the nuclear industry's application for a spent fuel repository. SSM has strict internal rules that apply to the Authority's independence in relation to the nuclear industry and to the interaction with an applicant.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Currently CCHEN does not have the required number of qualified personnel, with competencies in specialized disciplines necessary to effectively fulfill its regulatory functions regarding safety of nuclear and category 1 radioactive facilities.

CCHEN has a limit of 330 people, but the assignment to each division can be modified by the Director. The unity performing regulatory functions (DISNR) has currently 17 technical and 3 administrative people to authorize and control 173 institutions, 373 facilities and 1096 workers.

The competences available in the Division of Nuclear and Radiation Safety (DISNR) of CCHEN, to perform the regulatory activities related to the authorization processes, are not enough to comprehensively cover all technical areas, such as: neutronics, thermal hydraulics, instrumentation and control, materials and chemical.

MINSAL has 4 professionals working in relation to the development of norms and regulation, it also has 76 persons in charge of authorization and inspection, distributed in 15 regional offices, the Regional Sub secretaries of Health (SEREMI). However, these staff are also responsible for other aspects of occupational health safety and public health associated to other risks agents (such us exposition of noise, solvents, silica, etc.).

The Public Health Institute has 8 professionals dedicated to radiological protection as the national and reference laboratory.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

DISNR has some arrangements in place with other divisions of CCHEN to get technical advice.

In a few cases expert advice has been obtained out of CCHEN, such as assistance in seismic analysis from the university, legal advice was also contracted from an outside source in a specific case.

There are no special arrangements for ensuring the independency and objectivity of the advisors.

The information provided by the advisors to CCHEN is assessed by the staff of the DISNR. In any case CCHEN retains the ultimate responsibility for the safety decisions.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

CCHEN and MINSAL have established formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison. Mutual understanding among parties is a consequence of subjects involving both parties and normally, CCHEN sets up working groups to resolve or propose an action course. Consensus is achieved as part of the discussions in the working groups and the process concludes with a report that gives an account of the decision made.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Regulatory control is performed based on pre-established regulations, norms (legally binding standards) and procedures. CCHEN must propose laws and regulations to the Government for approval; however, CCHEN has the power to issue directly the legally binding safety standards.

CCHEN and MINSAL have established formal procedures for the implementation of their core processes to ensure that the implementation is homogeneous throughout the authorized parties. However, some specific procedures are not available and those are addressed in Module 5 to 9.

To prevent subjectivity in decision making by individual staff members of CCHEN, the processes comprising decisions include an independent technical review by a second individual, a legal assessment by the legal assessor and the approval by the head of the Nuclear and Radiological Safety Division.

3.7. SAFETY RELATED RECORDS

CCHEN and MINSAL have made provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.

All information related with the safety of facilities and activities is recorded in an Information System and in a documental management platform. Every installation, facility and activity has a folder that record any relevant information generated during the lifetime, from the construction phase to closure.

Regarding records of occupational doses, every worker must record his occupational doses by a service provided by specialized laboratories and registered in a national data base administered by the Public Health Institute.

CCHEN operates facilities that provide waste management services, and therefore maintains the corresponding records for the required time.

CCHEN and MINSAL clearly require that all applicants and authorized parties make adequate arrangements for recording all safety related information of their facilities and activities. During the inspections the different registers required by the regulator are verified.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

According to the Transparency Law, CCHEN and MINSAL should promote the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities and about the processes of the regulatory body.

The regulatory decisions pertinent to the safety of the installation are officially communicated by CCHEN.

CCHEN informs the community about changes, amendments or new regulatory proposals by publishing such event on the Official Gazette.

CCHEN follows the same process to report on its resolutions on violation of the laws and conditions under which the authorizations associated with the installation have been granted. This information is also available on the CCHEN internet site.

CCHEN and MINSAL internet sites also provide information to interested parties, the public and news media, the possible radiation risks associated with facilities and activities (including the protection of people and the environment) and the associated regulatory processes, but there is no formal procedure with the purpose to actively inform the public.

3.9. SUMMARY

CCHEN and MINSAL, form the Regulatory Body of Chile responsible for nuclear and radiation safety and cover the regulatory functions. Improvements should be made in some areas to achieve full compliance with the IAEA safety standards.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The self-assessment was prepared based on the IAEA Safety Standard GS-R-3; however, the review was performed according to the recently published IAEA Safety Standard GSR Part 2.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

Management commitment to the establishment, implementation, assessment, and continual improvement of the management system is expressed through the Quality Policy of CCHEN.

In MINSAL the Risk Management Policy of the Ministry of Health has been established. This policy is the framework from which the internal and external procedures of the organization emerge. The objectives of the policy are:

- to contribute to the fulfillment of the mission of both Undersecretaries, which is materialized through the objectives and strategic products that each one delivers;
- to establish responsibilities and authorities (roles) in risk management, ensuring individual competences in these matters;
- to establish a theoretical and methodological framework for Risk Management;
- to treat the risks identified as critical, and promote the continuous improvement of the identified processes, in each of the Undersecretaries, through the Risk Management methodology.

CCHEN and MINSAL have developed the quality policy in the management system. CCHEN supplemented its quality policy with the concept of environment and safety with regard to only occupational safety issues.

In the management system the behavioral expectation and fostering a strong safety culture has not been established.

Institutional values and expectations for safety are not defined in the management system, and there are no provisions to support safety conscious behavior, such as questioning and learning attitude.
This issue is addressed in recommendation R9 in Section 4.3.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT FOR SAFETY

CCHEN and MINSAL have established and are implementing a quality management system. However, it does not include all elements of a management system, and does not integrate safety, health, environmental, security, human and organizational factor, societal and economic elements.

In the Quality Manual of CCHEN quality policy is established, but safety policy is not defined.

Goals, strategies, plans and objectives for the organization are not established in such a manner that safety is not compromised by other priorities.

The consistency of the goals, plans and objectives with the organization’s safety policy cannot be assessed as the safety policy is not established. The IRRS team noted that strategies have not been established in the regulatory body.

The IRRS team noted that interested parties for CCHEN and MINSAL are not identified and an appropriate strategy of interaction with them is not defined in the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The organizational safety policies of CCHEN and MINSAL are not defined explicitly in their respectively management systems.	
(1)	**BASIS: GSR Part 2, Requirement 3, para. 4.2 states that** *"Senior management shall be responsible for establishing safety policy."*
R8	**Recommendation: CCHEN and MINSAL should define their safety policies in their management systems in line with GSR Part 2.**

4.3. THE MANAGEMENT SYSTEM

CCHEN and MINSAL have established and are implementing a quality management system based on ISO standard in the case of CCHEN 9001:2009 and in the case of MINSAL 9001:2015.

Alignment of the management system with the safety goals is not in place since that safety goals of the regulatory body are not defined. In CCHEN a project has been established with the support of the IAEA for fulfillment of the IAEA safety standards requirements. The IRRS team was informed that it is planned to be implemented in 2019.

Arrangements have not been established in the management system of CCHEN and MINSAL for an independent review to be made before decisions significant for safety are made.

The regulatory body's obligations are defined by law. The organizational structure of the regulatory body is specified in the management system. The regulatory body has institutional freedom to determine the structure for its internal organization and modify it as necessary.

There are no provision made in the management system to identify any changes, including organizational changes and the cumulative effects of minor changes, that could have significant implications for safety and to ensure that they are appropriately analyzed.

Application of the graded approach across the full spectrum of activities performed by the regulatory body is not documented in the management system, and criteria used to grade the development and application of Management System are not identified and documented.

Documentation of CCHEN management system is structured in four levels and consists of:

1st level: quality manual;

2nd level: procedures;

3rd level: instructions;

4th level: quality records.

In CCHEN the control of documents is carried out according to the procedure "Control of Documents" PRC-CNEC-001 based on the Decree 77, 2004 from Ministry of the Office of State.

Records of CCHEN are specified in the management system. The control of records is carried out according to the procedure "Record Control" PRC-CNEC-027, which guarantees that they remain legible, easily identifiable and recoverable. In this procedure it has been established:

- identification, readability, file, protection and recovery requirements;
- holding time;
- final disposition of the records.

The retention time of the regulatory documents is specified in the management system, that can be maximum 5 years and within this period the process owner defines the retention time of the document.

The management systems of CCHEN and MINSAL are not completely documented, since some processes and activities are not identified, inter alia description of interaction with external organizations and with interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing management systems of CCHEN and MINSAL do not include all elements of a management system, and do not integrate safety, health, environmental, human and organizational factor, societal and economic elements. The management systems have not been developed and applied using a graded approach.	
(1)	**BASIS: GSR Part 2 Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised."*
(2)	**BASIS: GSR Part 2 Requirement 7 states that** *"The management system shall be developed and applied using a graded approach."*
(3)	**BASIS: GSR Part 2 Requirement 10, para. 4.32 states that** *"Each process or activity that could have implications for safety shall be carried out under control conditions, by means of following readily understood, approved and current procedures, instructions and drawing."*
R9	**Recommendation: CCHEN and MINSAL should establish and implement an integrated management system in accordance with the IAEA safety standard GSR Part 2, including internal procedures for all regulatory functions and application of a graded approach.**

4.4. MANAGEMENT OF RESOURCES

The necessary resources in CCHEN are assigned annually by the Executive Director, through working meetings with the corresponding heads of divisions. The aspects related to budget management are carried out according to: PRC-CNEC-040 "Budgetary Management". In special cases these allocated resources can be managed through the procedures "Rendition Funds for Specific Expenses" PRC-CNEC-034, and "Global Funds" PRC-CNEC-035. When the development of a process requires an external service or support, it is contracted according to "Contracts and Agreements Procedure" PRC-CNEC-005.

CCHEN determines and maintains records of staff responsibilities, authorities and competencies (education, training, skills and experience) in the “Position Profiles”. The records of these profiles are the responsibility of the Personnel Division and are documented in this Division.

In MINSAL the Planning Division prepares a plan for all the needed resources and competences for the next year. This plan is authorized by the Minister of Health and sent to the Ministry of Treasury (Hacienda). After the negotiation by a committee, the funding is sent to MINSAL.

CCHEN and MINSAL have not determined in their management systems which competences and resources the organization must retain or has to develop internally, and which competences and resources may be obtained externally, for ensuring safety.

In CCHEN the personnel have access to the training to overcome the gaps of the required competences, through the "Training" procedure PRC-CNEC- 010. The effectiveness of the training is evaluated by meeting the specific objectives programmed annually.

In MINSAL there is a training division that conducts an on-line survey through the employees to gather information and identify training needs to prepare the training planning. A yearly training program is in place for all regional offices, but it is determined by the Department of Occupational Health and not by the senior management.

Knowledge management processes in CCHEN and MINSAL are not documented in their management systems.

This issue is addressed in recommendation R9 in Section 4.3.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

CCHEN has developed its processes in the management system necessary to achieve goals, and regulatory responsibilities. Some processes are not identified and documented in the management system, inter alia organizational changes and fostering and sustaining a strong safety culture.

In the management system of MINSAL two processes have been identified and documented; notification of radiological events and emergencies and authorization of operating facilities using X-ray generating devices.

In CCHEN the interaction between processes is specified in the process map. According to the Quality Manual each person in charge of any process must ensure the proper performance of the process, through the indicators and records identified in the process forms, determine corrective actions, improvements and training. They generate periodic reports with analysis of the generated data. During the yearly internal audits all processes are reviewed.

According to CCHEN Quality Manual the required products and services are acquired through the Procurement Section, according to procedures established by CCHEN "Acquisitions of Goods and Services in the country and abroad "PRC-CNEC-042 and the current regulations, Act Number19,886 "Law of Bases on Administrative Contracts of Supply and Provision of Services” and its regulation.

In MINSAL the procurement process, information relating to procurement, supplier selection and verification of purchased products are conducted by the Department of Occupational Health of the Public Policy Division.

The management systems of CCHEN and MINSAL do not include arrangements to retain responsibility for safety when contracting out any processes.

This issue is addressed in recommendation R9 in Section 4.3.

4.6. CULTURE FOR SAFETY

In 2006 at the request of the Executive Board, three IAEA experts conducted a training to a group for assessing the current level of safety culture in the organization of CCHEN, with the aim to fostering and sustaining a strong safety culture. For evaluation of safety culture in CCHEN three tools have been used, such as interviews, surveys and focus groups. The bases for preparation of surveys, interviews and focus groups was an Ibero American Forum of Radiological and Nuclear Regulatory Agencies' document. In 2007 CCHEN with the assistance of IAEA experts has implemented the IAEA tools to evaluate of the surveys and the results were sent to the IAEA in 2008.

The safety culture is not defined in CCHEN and MINSAL Quality Management Manuals.

CCHEN and MINSAL have no internal procedure for ensuring a common understanding of regulatory safety culture. This issue was also identified in the IRRS self-assessment action plan, by CCHEN, that has established a group for fostering and sustaining a strong safety culture and for the common interpretation of its major aspects.

This issue is addressed in recommendation R9 in Section 4.3.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

In CCHEN annual internal audits and management reviews are conducted for monitoring the effectiveness of the management system.

During the yearly management reviews, all established processes are regularly evaluated for their effectiveness and for ability to ensure safety.

Independent assessment and self-assessment of the management system are not conducted regularly to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any significant changes are not analyzed for their implication for safety.

Independent assessment of leadership for safety and of safety culture is not conducted for enhancement of the organizational culture for safety.

This issue is addressed in recommendation R9 in Section 4.3.

4.8. SUMMARY

CCHEN and MINSAL have established and are implementing their quality management systems. Many elements that should be part of the integrated management system of the regulatory body are already included in the management systems of CCHEN and MINSAL. However, there are no integrated management systems in place including all necessary elements such as safety, health, environmental, human and organizational factor, societal and economic elements as well.

Some processes have not been identified and documented yet. The management system has not been developed and applied using a graded approach,

5. AUTHORIZATION

5.1. GENERIC ISSUES

Chile has in force the law 18,302 Nuclear Safety and DFL Nº725/67 issued by MINSAL, which cover all the radiological and nuclear activities and installations.

The law states that the siting, construction, commissioning, operation, closure and dismantling, of the installations, plants, laboratories, nuclear equipment and entry or transit through the national territory of nuclear substances or radioactive material, requires a formal authorization issued by CCHEN.

According to DFL Nº725/67, the authorizations for operation of radioactive facilities are granted by the Health Services. Radioactive facilities are defined as those facilities in which radioactive materials or generating equipment of ionizing radiation are used, produced, manipulated or stored. Authorizations for production, manufacturing, acquisition, own, use, manipulation, storage, import, export, distribution, sell, transport, abandon or dispose of radioactive substances that are used in the facilities or in the generator equipment are also granted by the Heath Services.

The control of the radioactive facilities and the generator equipment, the prevention of risks for people and the environment arising from the use and application of radioactive substances and ionizing radiation correspond to the Heath Services.

The people who work in the radioactive facilities, use or manipulate the radioactive substances or operate equipment or devices that generate ionizing radiation, must have authorization of performance granted by the Health Services.

DFL 1/2005 separates this function from the Health Services and gives it to the Regional Sub secretaries of Health (SEREMI) within the territory of its jurisdiction.

Supreme Decree N° 133 (May 22nd, 1984) establishes the conditions and requirements that must be met by radioactive facilities, ionizing radiation generating equipment, the personnel who work in them or operate the equipment, the import, export, distribution and sale of radioactive substances and the abandonment or disposal of radioactive substances.

Supreme Decree N°133 divides radioactive facilities into three categories. It establishes that Category 1 facilities shall obtain authorization for construction, operation and temporal or definitive closure. Category 2 facilities shall obtain authorization for operation and temporal or definitive closure and for Category 3 only operation authorization is requested.

The procedure “Evaluation of Authorization Requests" PRT-DSNR-001 / v10 / 31OCT2017 describes how the Division of Nuclear and Radiation Safety (DISNR) of CCHEN will conduct the evaluation of applications for authorization to nuclear and category 1 radioactive facilities, key staff working at those facilities and radioactive materials and equipment generating nuclear substances and of ionizing radiation. The procedure applies to the following types of authorizations: siting of facilities and equipment, commissioning of facilities and equipment, dismantlement of facilities and equipment, construction of facilities or equipment, operation of facilities or equipment, closure (temporary or permanent) of plant or equipment, import of substances, materials or equipment, export of substances, materials or equipment, transport of substances and materials, transfer of substance, materials or equipment and special approval of persons in facilities or equipment.

CCHEN is responsible for the authorization of Category 1 facilities and MINSAL for the remaining Category 2 and 3, regardless of its application whether medical, industrial, or research.

CCHEN uses an application form “Authorization Request for first class radioactive facilities” where conditions and mandatory information to be submitted to the regulatory body is listed. Also, CCHEN issued a Regulatory guidance NS-GG-DL-11.0 “Contents of the radiation protection manual for1st Category facility” (which is one of the mandatory documents required for authorization) where the items that must be described in that manual are established and the format of it, is defined. Also, a Procedure for licensing nuclear or radioactive facilities from CCHEN (NCS-GG-02) from 1987 is in use.

Fuel cycle facilities in Chile are considered nuclear installations, considering the characteristics of the facility and the instruments laid out in Law 18,302. As such, they follow the regular authorization process for nuclear installations, as also established by such law.

For nuclear fuel facilities and for predisposal radioactive waste management facilities, CCHEN requires safety assessment for authorization, but not addressing all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions (see Section 5.3).

CCHEN has not established in its regulatory process the authorization of relevant modifications to the research reactors and new experiments.

For Category 3 facilities a closure authorization is not required.

The authorization for the closure of nuclear and radioactive facilities includes the requirement to present the decommissioning plan, which must be reviewed by the regulatory body despite not being requested in the regulations. If the plan is approved, the respective closure authorization is issued.

There are no legal or other formal mechanisms in place to ensure cooperation between CCHEN and MINSAL, related to authorization issues. Both CCHEN and MINSAL publish some specific requirements for applicants for the categories of radioactive facilities.

Carriers for transporting radioactive material have not been authorized in Chile. Transport authorizations are granted to consignors and consignees. Transport authorization application templates are available.

5.2. AUTHORIZATION OF RESEARCH REACTORS

The research reactor RECH-1 is owned and operated by CCHEN. It has an authorization for Operation, issued by CCHEN itself in December 2014, valid for 4 years.

The technical requirements for renewal of the Operation Authorization include a requirement to submit an updated version of the safety analysis report, operational limits and conditions, operation manual, radiation protection manual, manual for organization and procedures, maintenance manual, emergency plan and physical protection plan.

CCHEN grants authorizations for the key personnel of the research reactor, who are Operators, Supervisors, upon an application of the reactor manager, together with the required formal documentation. The reactor manager is one of the supervisors appointed by the Director of CCHEN.

There are no requirements for authorizations of modifications and new experiments for research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN has not established, in the existing authorization process, requirements for the authorization of modifications and new experiments.	
(1)	**BASIS: SSR-3 para. 3.4 Authorization Process, states that** "*The authorization process is ongoing, starting at the site evaluation stage and continuing up to and including the release of the facility from regulatory control. The authorization process may vary among States, but the major stages of the authorization process for nuclear research reactors shall include the following:*(a) *Site evaluation;*(b) *Design;*(c) *Construction;*(d) *Commissioning;* (e) *Operation, including utilization and modification* [9] *;*(f) *Decommissioning;*(g) *Release from regulatory control".* *(9) Although the utilization and modification of research reactors are activities that are normally included under operation, they may be considered separate stages in the authorization process, since their safety implications give rise to many review and assessment activities that are repeated many times over the lifetime of the reactor facility. (see paras 7.98–7.106)*
R10	**Recommendation: CCHEN should establish in its authorization process, requirements for the authorization of modifications and new experiments for research reactors.**

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

Chile has two fuel cycle facilities, which are defined as nuclear facilities: (i) a fuel assembly plant for manufacturing fuel elements for the research reactors (PEC); (ii) a conversion facility that processes UF_6 to metallic uranium or to other forms, and is also used for recovery of uranium originated from recovery of enriched uranium in U^{235} from fuel plates rejected during the fuel elements manufacturing processes. PEC was not operating during the IRRS mission. The IRRS team was informed of the plan to return to operations by March 2018, with the aim of producing nuclear fuel for CCHEN's research reactor until 2021. The conversion facility is not currently operating and has currently no plans to return to operation or to undergo decommissioning.

CCHEN operates the fuel cycle facilities in the country and DISNR (Nuclear and Radiological Safety Division) of CCHEN is responsible for the authorization process independently from the operators of the fuel cycle facility. However, although DISNR often performs independent assessments of the safety of the facility for the authorization process, some calculations may not undergo further verification by DISNR personnel, due to the lack of personnel assigned to the assessment of complex calculations such as those for criticality control, prevention of criticality accidents, occupational and environmental radiation protection.

Graded approach appears to be followed to an extent. The safety analysis is done considering the characteristics of the facility, so the licensing documentation is consistent (in size and content) with the processes, systems and components in the facility. However, there is no program for training staff of CCHEN in charge of safety review and assessment on several issues relevant to nuclear and radiation safety, general and specific to fuel cycle facilities, such as criticality control, prevention of criticality accidents, occupational and environmental radiation protection. Therefore, safety assessment of the facility for authorization purposes may be compromised.

The authorization of the fuel element manufacturing plant emphasizes the scope for the operation and the details and responsibilities associated with the operation of the plant, and indicates the conditions of the general and specific aspects of the operation, modifications and changes in the

facility, licensing documentation, communications, training, movement of material, and the retirement of service from the facility. However, the safety analysis report used as the basis for the initial operation authorization is more than 30 years old and has not been revised to fully reflect the current state of operation of the facility. The second and latest version of the safety report for the PEC is of 2016, but some safety analyses are still pending and so, not all radiation risks that could potentially arise from normal operation or from anticipated operational occurrences and accident conditions have been considered. This could potentially compromise safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN does not require that the safety assessments for authorization of fuel cycle facilities address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 24, para. 4.33 states that** "*Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* *(9) GSR Part 4*
(2)	**BASIS: GSR Part 4 Requirement 2, para. 4.5 states that** "*The safety assessment shall address all radiation risks that arise from normal operation (that is, when the facility is operating normally or the activity is being carried out normally) and from anticipated operational occurrences and accident conditions (in which failures or internal or external events have occurred that challenge the safety of the facility or activity). The safety assessment for anticipated operational occurrences and accident conditions shall also address failures that might occur and the consequences of any failures."*
R11	**Recommendation: CCHEN should require that the safety assessment for authorization of fuel cycle facilities addresses all radiation and nuclear risks that arise from normal operation and from anticipated operational occurrences and accident conditions.**

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The regulatory framework contains general provisions regarding the authorization process for radiological and nuclear facilities. No specific provisions for radioactive waste management facilities are included.

The operation of the facility for processing and storage of radioactive waste generated in Chile is carried out by the CCHEN through the radioactive waste management section, SEGEDRA, which is duly authorized by the regulatory authority in compliance with current regulations.

The SEGEDRA waste management facility consist in three units:

- Radioactive Waste Treatment Plant;

- Short and very short activity radioactive waste Storage Facility;
- Intermediate activity waste Storage Facility.

Chile does not have a final disposal facility.

For predisposal radioactive waste management facilities operated by SEGEDRA, CCHEN require safety assessment for authorization, but not addressing all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN does not require that the safety assessment for authorization of predisposal radioactive waste management facilities address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 24 para 4.33 states that** *Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* (9) GSR Part 4
(2)	**BASIS: GSR Part 4 Requirement 2 para. 4.5 states that** *"The safety assessment shall address all radiation risks that arise from normal operation (that is, when the facility is operating normally or the activity is being carried out normally) and from anticipated operational occurrences and accident conditions (in which failures or internal or external events have occurred that challenge the safety of the facility or activity). The safety assessment for anticipated operational occurrences and accident conditions shall also address failures that might occur and the consequences of any failures."*
R12	**Recommendation: CCHEN should require that the safety assessment for authorization of predisposal radioactive waste management facilities address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.**

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Chilean national radiation facility categorization according to Supreme Decree N° 133 (three categories including radioactive sources and radiation generators) corresponds to risk-based criteria involving source characterization, type of utilization, related processes and number of potentially exposed people.

As for radiation facilities, Supreme Decree N° 133 divides responsibilities for authorization between CCHEN and MINSAL according to radiation risk. This reflects a graded approach to a considerable degree.

There are facilities that are not clearly assigned to any category of radioactive facility, such as cyclotrons, nuclear medicine, cone beam dental computed tomography, geophysical neutron generator, borehole logging tools and blood irradiators.

The IRRS team was informed that CCHEN and MINSAL apply an agreed division within the nuclear medical sector using the high radiotoxicity laboratories/laboratories of low radiotoxicity delineation, (Category 1/Category 2). Iodione-131 therapy is a "high radiotoxicity practice" (not legally defined) regulated by CCHEN. Tc-99 is a "low radiotoxicity practice" (not legally defined) and is regulated by MINSAL. In this way, CCHEN issues authorizations for therapeutic nuclear medicine and MINSAL issue authorizations for diagnostic nuclear medicine. The demonstration of safety in complex medical radiation practices is therefore assessed in a complementary method by CCHEN and MINSAL. CCHEN has assumed the responsibility for regulatory control of cyclotrons and blood irradiators and MINSAL of cone beam dental computed tomography and, geophysical neutron generator and borehole logging tools.

There are no explicit legal or other formal mechanisms in place to ensure regulatory cooperation between CCHEN and MINSAL.

CCHEN issues a special certificate for operators and manipulators of Category 1 sources.

CCHEN and MINSAL have requirements as to the information for applicants to authorizations and application forms are available online.

The amount of information submitted with the application for Categories 1 to 3 is commensurate with the risk of the facilities. However, CCHEN and MINSAL do not have procedures to apply review and assessment in a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Decree N°133 establishes that for Category 3 radioactive facilities only operation authorization is required. The closure authorization is not required.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 6 states that** *"Compliance with regulations and responsibility for safety* *2.15. The prime responsibility for safety shall extend to all stages in the lifetime of facilities and the duration of activities, until their release from regulatory control, i.e. to site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure in the case of disposal facilities for radioactive waste) of facilities."*
(3)	**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)."*
R13	**Recommendation: MINSAL should request closure authorization for radioactive facilities Category 3 unless explicitly exempted.**

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The authorization for the closure of nuclear and radioactive facilities includes the requirement to present the decommissioning plan, which must be reviewed by the regulatory body. If the plan is approved, the respective closure authorization is issued.

In the operation authorization for predisposal radioactive waste management facility, CCHEN request that a decommissioning plan must be presented to the regulatory body 3 month in advance of requesting the closure authorization. For lower risk facilities the regulatory body must be notified two months in advance of permanent shutdown.

For the research reactors there is no requirement for a request for submitting decommissioning plan before applying for closure license.

In the operation license of nuclear fuel facility, CCHEN request that a decommissioning plan must be presented to the regulatory body 6 month in advance of requesting closure authorization.

5.7. AUTHORIZATION OF TRANSPORT

Supreme Decree12/1985 states that all transport of radioactive material will require authorization from CCHEN or another body expressly empowered to grant it. Moreover, it provides that CCHEN shall delegate to MINSAL the authority to authorize the transport of radioactive substances that are to be used for medical, research or industrial purposes. Transport authorization is also required by DFL725/1968 of MINSAL. Without explicitly stating transport, the Decree 133/1984 and the DFL1/1990 of the MINSAL provide respectively that health authorization and special sanitary authorization are required for the import, export, sale, distribution, storage and release of radioactive substances.

Till to date, carriers for transporting radioactive material have not been authorized in Chile. Transport authorizations are granted to consignors and consignees. The validity period of these authorizations (licenses) ranges from 30 days to 1 year.

Type A and Type B (U), Type B (M) packages, as well as industrial packages and excepted packages are mainly transported by land. Special form radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of uranium hexafluoride, Type B(U), Type B(M) packages or Type C packages are currently not designed or manufactured in Chile.

Validation of package design approval certificates issued by the Competent Authority of the country of origin of the package design are conducted by CCHEN and the relevant template is in place.

5.8. SUMMARY

For research reactors CCHEN has not established, in the existing authorization process, requirements for the authorization of modifications and new experiments.

CCHEN does not require that the safety assessment for authorization of predisposal radioactive waste management facility and fuel cycle facilities, address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.

For Category 3 facilities a closure authorization is not required and there are gaps in categorization of facilities.

To date, carriers for transporting radioactive material have not been authorized in Chile. Transport authorizations are granted to consignors and consignees.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

For issuing the construction license, the regulatory review and assessment is focused on design aspects of facilities and activities, such as safety systems and shielding calculations. In the case of operation license, regulatory review and assessment is focused on procedures, such as radiation protection, maintenance, and emergencies. In the case of decommissioning license, regulatory review and assessment is focused on facility radiological assessment and waste management.

Periodic Safety Review frequency is supposed to be carried out every three years, but there is no specific requirement for such and the IRRS team has identified that complete periodic safety reviews are not conducted in fuel cycle facilities.

CCHEN does not have regulatory guidance on the contents of safety case for authorizations of predisposal radioactive waste management facilities which are in line with the IAEA safety standards.

The application form for transport authorizations granted by the CCHEN was recently updated and the procedure for reviewing and assessing this application is in place. MINSAL, which grants authorizations for the transport of radioactive materials associated with facilities of Category 2 and 3, has included the application form and the approval template in the Circular B33N°37/2014 of Ministry of Health that provides instructions to the regional health authorities for the implementation of the regulations in Supreme Decree N° 3/85 and N° 133/84.

Transport of radioactive material is included in the Manual of Operation submitted by the applicant in terms of authorization as requested by CCHEN. The IRRS team reviewed a licensee file during the interviews and noted that the Manual of Operation is supported by documented procedures, also submitted to CCHEN, which specify the general wording of the relevant part in the afore-mentioned Manual, including, among others, the maintenance of transport packages whenever necessary, emergency response, quality management, resources, and training considerations.

The regulatory authorities review and access the facilities and activities commensurate with the radiation risk associated with them, in accordance with a graded approach.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

DISNR does not have access to technical competence for conducting review and assessment of some areas, such as complex specialized calculations on criticality, radiation protection or other safety issues.

Regarding the maintaining and improvement of competence for review and assessment, new staff at CCHEN is trained using IAEA TC opportunities. A one-year mentoring period is also implemented.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

In the requirements for applying for a license, CCHEN has established that any additional information required in the review and assessment process must be provided, otherwise the application will be rejected.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The review and assessment process is carried out in two steps. First, the comprehensiveness of the safety assessment is verified, against safety requirements. If necessary, an additional submission can be requested. After the first step, the quality of safety assessment is verified, against safety guidance, if it exists.

Inspections are focused on the verification of the fulfilment of procedures, limits and conditions established in the review and assessment process.

6.2. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

To renew the authorization, DISNR requests the operator to present an updated version of the safety report and the mandatory documents, 6 months in advance.

According to that requirement the operator (CCHEN) is asked to review the main safety aspects of the reactor, as well as the safety limits and operation conditions, and to improve the manuals.

The regulatory framework does not cover all the aspects related to radiological and nuclear safety for research reactors, and specifically requirements for periodic safety review and safety committees. This issue is addressed in the section Regulation and Guides (Section 9.2).

The control performed by DISNR during the operational stage of the research reactors, is mainly based on inspections, and does not include systematic review and assessment of relevant information related to radiological and nuclear safety, because they do not require the operating organization to submit periodically the above-mentioned information.

The staff that conducts review and assessment belong to DISNR. However, DISNR does not have access to technical competence for conducting review and assessment of some areas, such as neutronics and thermal hydraulics.

The IRRS team was informed that the existing competent staff are usually in difficulty to conduct an effective review and assessment on their competency areas due to the heavy work load from their other assignments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The operating organization is not required to submit periodically the information related to the safety of the research reactor.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 25 states that** *"The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	promulgated by the regulatory body or in the authorization.
R14	**Recommendation: CCHEN should require that the operating organization of research reactors submit safety related information in a periodic manner.**

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

DISNR does not have access to technical competence for conducting review and assessment of some areas, such as complex specialized calculations on criticality, radiation protection or other safety issues.

The IRRS team was informed that the existing competent staff are usually in difficulty to conduct an effective review and assessment on their competency areas due to the heavy work load from their other assignments. Furthermore, there is no guidance on the content of the safety assessment to be submitted by the applicant in support of an application for authorization in line with IAEA safety standards or procedures to review and assess the safety assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN does not provide guidance on the contents of safety assessment reports for authorization of fuel cycle facilities which are in line with the IAEA safety standards.	
(1)	**BASIS: GSR Part 1- Requirement 24 para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
(2)	**BASIS: GSR PART 1 Requirement 25 states that** "*The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."*
S2	**Suggestion: CCHEN should consider the development of guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization of fuel cycle facilities which are in line with IAEA safety standards, and the establishment of standard review procedures of such reports.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: DISNR does not have the sufficient and dedicated technical competence to fully review all technical areas, such as criticality or radiation protection of fuel cycle facilities.	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.43 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 25, para. 4.43 states that** *"The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable."*
R15	**Recommendation: CCHEN should strengthen its core competency that will allow it to make informed decisions on regulatory issues of fuel cycle facilities, especially on those decisions regarding complex calculations.**

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The authorization of radioactive waste management facilities in supported by the mandatory information requested by regulatory body in the authorization form and specifically radiological safety is stated in the Radiological Protection Manual and Shielding Calculation (see Section 5). The supporting documents must be sent to CCHEN three months in advance of submitting the application for operation authorization. That information is assessed by CCHEN following the Guidance GS-G-15 (see Section 5).

SEGEDRA facility has an operation authorization that has expired in December 2017. The authorization required that the information in support of the application of renewal be sent three months in advance of the expiration date and it was not sent in time. Moreover, finding from the last inspection have not been resolved and the current situation is that the facility has its operation authorization suspended.

CCHEN does not have regulatory guidance on the contents of safety case for authorizations of SEGEDRA facilities which are in line with the IAEA safety standards. There is no regulatory requirement for safety assessment to address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions. (See Section 5.4)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN does not provide guidance on the contents of safety case for authorizations of predisposal radioactive waste management facility which are in line with the IAEA safety standards.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 24 para. 4.34 states that** *"The*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."
(2)	**BASIS GSR PART 1 (Rev 1) Requirement 25 states that** "*The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."*
(3)	**BASIS: GSR Part 5 para. 5.2. states that** *"It is the responsibility of the regulatory body to derive and document in a clear and unambiguous manner the criteria on which the regulatory decision-making process is based. It is important that any additional guidance provided by the regulatory body takes account of the wide range of predisposal radioactive waste management facilities that may be developed and the wide range of activities that may be conducted at those facilities."*
S3	**Suggestion: CCHEN should consider the development of guidance on the format and content of safety case for the authorization of radioactive waste management facilities, which are in line with IAEA safety standards, as well as the establishment of standard review procedure of such report.**

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

CCHEN conducts review and assessment of Category 1 radioactive facilities. MINSAL conducts review and assessment of Category 2 and 3 radioactive facilities. Both conduct review and assessment of facilities and activities commensurate with the radiation risks, in accordance with a graded approach.

CCHEN and MINSAL review and assess relevant information submitted by the applicants to determine whether facilities and activities comply with regulatory requirements. These reviews are performed prior to authorization.

CCHEN captures the information required from the applicants for the review and assessment via relevant application forms published on their website.

MINSAL also captures the information required from the applicants for the review and assessment via relevant application forms made available to them.

CCHEN has internal procedures for evaluation of the safety-related information submitted by the applicant, which use documents such as NCRP Report No. 151 for the evaluation of accelerator structural shielding and IAEA Safety Report No. 47 for the evaluation of brachytherapy shielding.

CCHEN also has a documented process for review and assessment. CCHEN demonstrated to the IRRS team how this process works with their intranet website records.

As an example, to illustrate the authorizations provided by CCHEN and MINSAL, in a hospital with a linear accelerator and a CT and PET-CT:

- For the linear accelerator, CCHEN had granted the authorization for construction after they approved the design for the bunker for the specific linear accelerator, and later the authorization for operation to conduct the practice of radiation therapy with the equipment. CCHEN has responsibility for radiation protection in occupational exposure; however, MINSAL has the responsibility for radiation protection in medical exposure.
- For the CT and PET-CT, only the authorization for operation is required and is granted by MINSAL after the shielding designs has been reviewed and assessed by them. MINSAL has also the responsibility for radiation protection in occupational and medical exposure for this second-class facility.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

For radioactive facilities, CCHEN reviews and assesses the information sent by the operator in the following aspects: foreseen closure activities, waste management, cleaning or dismantling activities and removal of labels if applicable. There is no specific regulation nor guidance on review and assessment for decommissioning activities. This issue is addressed in Section 9.7.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The application form for transport authorizations granted by CCHEN was recently updated and the procedure for reviewing and assessing this application is in place. MINSAL grants authorizations for the transport of radioactive materials associated with facilities of Category 2 and 3. The application form and the approval template are included in the Circular B33N°37/2014 of MINSAL that provides instructions to the regional health authorities for the implementation of the regulations in Supreme Decree N°3/85 and N° 133/84-both of MINSAL.

Transport of radioactive material is included in the Manual of Operation submitted by the applicant in terms of authorization. The IRRS team reviewed an authorized party's file during the interviews and noted that the Manual of Operation is supported by documented procedures, also submitted to CCHEN, which specify the general wording of the relevant part in the afore mentioned Manual, including, among others, the maintenance of transport packages whenever necessary, emergency response, quality management, resources, and training considerations.

6.8. SUMMARY

CCHEN and MINSAL review and assess relevant information submitted by the applicants to determine whether facilities and activities comply with regulatory requirement. These reviews are performed prior to authorization.

DISNR does not have access to technical competence for conducting review and assessment of some areas.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

Regulatory inspections can be announced and unannounced, scheduled and unscheduled, and are performed to nuclear facilities and to radioactive facilities. The inspections of nuclear facilities are conducted at the research reactor and the fuel manufacturing facility, while the inspections of radioactive facilities are conducted at the facilities of the medical and industrial areas. These inspections are designed to cover all aspects related to radioactive sources, or can focus on specific issues, such as transport verification, operation, incidents, verification of records, and shielding, depending on the interest of the assessment.

The times of the inspections are variable and depend on the practice in the inspected facility. The frequency of the inspection is defined in the annual inspections plan, which defines the frequency based on the risks of each installation.

The inspection method consists in carrying out a passive evaluation (prior to inspection) of all background information related to the inspection being planned. During the inspection, the previous findings analysed are verified by means of a checklist, according to the inspected practice, verifying if the installation complies with the specific requirements of nuclear safety and radiation protection, as required by the regulations, the authorization conditions, the measures applied in case of noncompliance or by the authorized emergency plans.

The inspection plan is prepared based on a criteria report, developed by the authority, which defines the frequency, the period of the year, and which facilities will be included in the plan for the current year. These criteria are flexible to adapt to unforeseen circumstances. The contents of the plan include the installation to be visited, the location, the inspector in charge, the frequency, the area, number of equipment or material, month and number of days of the inspection and the justification for increasing or decreasing the frequency of inspections.

Other divisions of CCHEN provide technical support to DISNR, including participation in regulatory inspections when deemed necessary.

CCHEN and MINSAL do not carry out joint inspections to the same hospital. Each authority inspects the facilities assigned by law. If one of the regulatory authorities identifies any breach of regulatory control that is the responsibility of the other regulatory authority they transmit the relevant information to the other authority.

The authorization process includes inspections (if the inspector deems necessary) after analysing the documentation presented by the installation, to verify that the construction, operation or closure is carried out as authorized by the regulator or to verify if the installation complies the requirements to obtain an authorization.

CCHEN and MINSAL have inspection programmes with a frequency commensurate with the radiation risks associated with the facilities and activities in accordance with a graded approach. CCHEN undertakes additional inspections in response to abnormal events.

7.1.2. INSPECTION PROCESS AND PRACTICE

The CCHEN inspections are carried out in accordance to the procedure “Inspection of facilities" PRT-DSNR-002 / v10 / 31OCT2017”.

During the IRRS mission, many inspections were observed at facilities such as research reactors, fuel manufacturing facility, industrial radiography and radioactive waste management facility.

The overall process from preparation through communication, interaction with counterparts, discussion of findings, and record of results, was conducted according to the procedures.

The documents assisting the inspectors in their inspection include the inspection procedure, the inspection plan, the checklists classified by practice, the inspection minutes, the non-compliance registration procedure, and the inspection notification. It is also possible to indicate the use of regulations associated with the practice to plan the inspection.

The stages of the inspection are: preparation, execution and notification to the operator. For the preparation, the inspector defines a scope and, accordingly, reviews the conditions and requirements of the authorizations granted, the operation, maintenance and emergency procedures, the compliance with previous requirements, the reported incidents and the respective regulations.

When carrying out an inspection, the inspector verifies if the installation complies with what is indicated in the documentation analysed in the preparation stage.

The findings are recorded in the inspection minutes, which include the date of the inspection, the data of the installation and the people who conduct activities there, the proven facts (including noncompliance) and the measures adopted. By means of an official note, the minutes are sent to the operator, for notification.

The inspector is authorized by law to enter any facility that possesses radioactive material and request the information it deems important, in the interest of safety.

The results of the inspection are communicated to the operator at a meeting held after the inspection. In this meeting, the findings are discussed with the authorized party in such a way that both parties agree with what is described in the minutes. To ensure that the operator is notified (if a meeting after the inspection did not take place), an official letter is sent to the operator with the inspection report containing findings and conclusions attached. However, in most cases, inspection reports are not issued, as official minutes have legal provision for enforcement.

The corrective measures are verified at the next inspection or by the deadline indicated in the minutes. This verification can be through an inspection or via passive inspection (document verification).

There are criteria to develop the inspection plan which can be modified considering information collected from the inspections.

The IRRS team was informed that a project to redesign and improve the regulatory processes, including inspection process, is being developed, which includes the implementation of the lessons learned, improvement options and self-evaluations to carry out a continuous improvement of the process.

MINSAL inspectors use checklists while undertaking inspections of radiation facilities in accordance with a written inspection procedure. They also utilize previous inspection reports and company records as a basis for their inspections. MINSAL generates a radiological safety report and produces a record (legal document), that constitutes the inspection report.

7.1.3. INSPECTORS

DISNR has 12 formally designated inspectors, but 9 of them carry out inspections (usually), along with authorization and review and assessment functions. The IRRS team was informed that to discharge all the regulatory functions, it would be necessary to increase the number and qualification of personnel.

MINSAL has 76 inspectors, professionals that perform inspections to radioactive and non-radioactive facilities. They also inspect activities with dangerous substances that may pose a risk to health, such as management of flammable, narcotic or toxic substances.

The competences available in CCHEN, related to the inspection process, are: 2 Specialists in Risk Prevention, 1 environmental engineer, 1 civil engineer, 2 chemical engineers, 2 physicists and 1 mechanical engineer. These have a postgraduate degree in radiation protection and four of them have a master's degree. There is also one electronical engineer in training.

Through the official appointment (exempt resolution) signed by the Executive Director of CCHEN, the authorized inspectors are appointed. This appointment is based on the responsibilities and powers of an inspector indicated in the current legislation and considers the experience and training of the personnel to opt to be an inspector, in addition to their psychological and physical conditions.

7.2. INSPECTION OF RESEARCH REACTORS

During the IRRS mission, an inspection to the research reactor RECH-1 was observed. The inspection was prepared with the objective to verify the fulfilment of the procedures for irradiation of capsules and operation of the water treatment plant. On the other hand, the fulfilment of findings from past inspections was verified.

The inspectors conducted the overall process from preparation through communication, interaction with counterparts, discussion of findings, and record of results, appropriately.

Most of the human resources are dedicated to performing inspections to industrial and medical installations, and the inspections to the research reactor has the same frequency as these installations. So, the frequency of the inspections performed to the research reactors is not sufficient in accordance with the complexity of this type of installations.

The scope of the inspections to the research reactors does not cover safety aspects such as core management, irradiation and experiments management and abnormal events management, to confirm compliance with the relevant regulatory requirements and the conditions specified in the authorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The scope of the inspections to the research reactors does not cover all safety aspects to confirm compliance with the relevant regulatory requirements and the conditions specified in the authorization. Additionally, the frequency of the inspections performed to the research reactors is not sufficient in accordance with the complexity of this type of installations.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 29 para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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."
S4	**Suggestion: CCHEN should consider revising its regulatory inspection plan for research reactors to cover all aspects related to the safety and conduct the regulatory inspections in a frequency commensurate with the complexity of the facility and the associated safety related issues.**

7.3. INSPECTION OF FUEL CYCLE FACILITIES

Since the conversion facility is currently not operating and has no plans to return to operation, the only facility inspected is the nuclear fuel manufacturing plant (PEC). CCHEN has the legal provisions for conducting inspections, both announced and unannounced. Regular announced inspections are normally conducted once a year, according to the Inspections Plan, which is common to the other facilities under the competence of CCHEN. Special inspections are also conducted in case of events. The IRRS team observed a regular announced inspection to PEC, where many observations were made. There are 11 inspectors able to perform inspections at the PEC, including engineers, physicists and risk prevention professionals, and two of them conducted the inspection observed by the IRRS team.

The inspections of fuel cycle facilities have a specific or general scope which is defined by the inspector considering compliance with the inspection plan. It is worth noting that inspections of these facilities do not encompass protection of the public and the environment. DISNR does not conduct inspection or verify the effluent and environmental monitoring eventually performed by other divisions.

Despite having the provisions for conducting unannounced inspections in fuel cycle facilities, the IRRS team was informed that CCHEN currently does not do so, because it could place a burden on the reduced number of inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN currently does not carry out unannounced inspections in fuel cycle facilities, despite having the legal power for such.	
(1)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
S5	**Suggestion: CCHEN should consider to carry out unannounced inspections of fuel cycle facilities.**

Inspectors are required to take an external course in radiation protection, and commonly participate of the post-graduate courses on radiation protection in Argentina, Spain or similar courses in other countries. However, training and guidance of inspectors of fuel cycle facilities are not conducted on a systematic manner. The IRRS team was informed that this lack of training and guidance conducted in a systematic manner affects all areas of inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no systematic specific training for inspections of fuel cycle facilities .	
(1)	**BASIS: GSR Part 1 Requirement 18 para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.*
S6	**Suggestion: CCHEN should consider establishing a systematic specific training programme for inspections of fuel cycle facilities.**

7.4. INSPECTION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The IRRS team observed CCHEN inspectors during an inspection to radioactive waste management facilities operated by SEGEDRA in the Centre Lo Aguirre.

The inspection was well prepared and performed in line with CCHEN internal inspection procedure. The scope was clear.

The IRRS team had the opportunity to review the inspection procedure and noted and discussed with the counterpart that the checklist used in the inspection was a personal draft.

The IRRS team members conducted an interview with the facility management concerning authorization, inspections, how controls are implemented and the relationships with the inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN "Facilities Inspection" procedure is general. No specific check list for radioactive waste management facilities inspection is approved.	
(1)	**BASIS: GS-G-1.3 Para. 4.1 states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail."*
S7	**Suggestion: CCHEN should consider developing and approving check list for performing radioactive waste management facilities inspections complementary to the current "Facility Inspection" procedure.**

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

CCHEN has established inspection programmes. The frequency and extent of inspections depend on the potential magnitude and nature of the hazard as determined by the Decree 133/1984.

CCHEN undertakes additional inspections in response to abnormal events to verify the return to safe conditions. It is also required that the user carry out an investigation. Inspectors prepare and submit reports to users within two weeks and, where appropriate, follow up the implementation of ensuing corrective actions. During 2016, 263 inspections to radiation facilities were conducted, according to the annual inspection program.

The IRRS team was informed that each SEREMI's inspection obey to a regional annual program according to a risk approach. However, MINSAL does not have a comprehensive and coordinated inspection program that integrates the inspection needs for the 15 MINSAL regions incorporating a graded approach.

CCHEN and MINSAL verify effectiveness of the structural shielding of newly constructed radiation facilities through direct measurement prior to issuing an authorization.

Article 31 of the Nuclear Safety Law 18,302 states *"In the performance of its inspection functions, the Commission shall collaborate with other public entities, especially with those that perform functions in analogous aspects; and at the same time, request the collaboration of those entities in the exercise of their own faculties."* There appears to be no similar requirement for MINSAL in law and no explicit legal requirement for CCHEN and MINSAL to cooperate with respect to inspections. CCHEN and MINSAL do not conduct collaborative/ joint inspections for Category 1 medical radiation facilities.

The IRRS team observed inspections of Category 1 Industrial facility (radiography) and of Category 2 Medical facility (diagnostic radiology).

Overall, the IRRS team observed that CCHEN and MINSAL inspections were conducted according to their procedures, and that during inspections the communication with the authorized parties was frank, open and yet formal.

During both inspections, the IRRS team noted that the regulators had an open and yet formal relationship with the authorized parties, what contributed to the effectiveness of the inspections. Both practices were pleased to provide supporting evidence and respond accurately and factually to inspectors' questions promptly.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

The IRRS team was informed that after the regulatory body authorizes the closure of facilities. CCHEN performs an inspection for verifying that no contamination persists, that the activities approved by the closure authorization were performed and that no labels or signs indicating the presence of radioactive material remains. The IRRS team was informed that MINSAL performs an evaluation and inspection for the closure of diagnostic and investigation low toxicity nuclear medicine laboratories.

7.7. INSPECTION OF TRANSPORT

MINSAL performs general purpose inspections to facilities of Category 2 and 3; some of these facilities act as consignors or consignees besides their other activities. During the interviews, the IRRS team was told that transport activities are not specifically inspected.

CCHEN has performed transport inspections to the main radioisotope providers. Moreover, by adopting a graded approach, CCHEN inspected shipments of Type B (U) packages last year. The transport inspection checklists used are based on the currently existing regulatory requirements that are not in full compliance with the IAEA SSR-6 Regulation, as discussed in Section 9.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although CCHEN has recently started conducting transport specific inspections, transport activities are not systematically inspected.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 3 Requirement 3, para. 230 states that** *"The regulatory body shall establish a regulatory system for protection and safety that includes [8]: …(c) Inspection of facilities and activities."*
(3)	**BASIS: TS-G-1.5 para. 230 states that** *"To confirm compliance with the Transport Regulations in the case of the transport of radioactive material of foreign origin transiting its area of jurisdiction, the competent authority should inspect such packages or shipments. Cooperation with other competent authorities should also be considered."*
S8	**Suggestion: CCHEN should consider including transport specific inspections to its inspection programme.**
R16	**Recommendation: MINSAL should include transport specific inspections to its inspection programme.**

Package designs that do not require approval by the competent authority of the country of origin of the package design, namely Type A packages, industrial packages and excepted packages constitute most packages used in Chile. Neither MINSAL or CCHEN request the consignor to provide for inspection, documentary evidence of compliance of the package designs with the applicable requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: No documentary evidence of compliance of package designs that do not require approval by the competent authority, is requested by CCHEN and MINSAL.	
(1)	**BASIS: SSR-6, para. 801 states that** *"For package designs where it is not required that a competent authority issue a certificate of approval, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements."*
R17	**Recommendation: CCHEN and MINSAL should ensure that package designs which are not required to be approved by the competent authority, are in conformity with the regulatory requirements.**

7.8. SUMMARY

CCHEN regularly conducts regulatory inspections on nuclear facilities within its areas of competence. However, the frequency and scope of inspections are not commensurate to the complexity and risk of these facilities and unannounced inspections are not carried out. Announced inspections follow an annual plan, with a risk-based graded approach. CCHEN has a reduced number of inspectors and occasionally needs to rely on other divisions of the institution for technical support, which in practice hinder the ability of inspectors to conduct their activities in an independent manner. CCHEN should also standardize inspection procedures and checklists, and establish a systematic inspection training programme.

For radiation sources facilities and activities, the frequency and extent of inspections CCHEN conducts are based on a graded approach. MINSAL also conducts regulatory inspections on facilities within its areas of competence. Yet, MINSAL does not have a systematic integrated inspection programme for all the 15 regions. There is currently no requirement for either organisation to cooperate with each other regarding inspections and certain aspects of competences and responsibilities remain unclear. Yet, if either one of the authorities identifies any breach of radiological safety that is the responsibility of the other authority, it is obliged to inform the other one.

Regarding transport, CCHEN has started incorporating transport specific inspections to the annual inspection program. Nevertheless, transport activities are not systematically inspected.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Nuclear Safety Law has provisions for CCHEN to apply a structured enforcement policy. The Law describes:

a) Sanctions that CCHEN can impose (fines, depending on the seriousness of the infraction or non-compliance, suspension of authorization, for up to one year and final revocation of the authorization);

b) Procedures for making effective the sanctions and for the affected party to complain against the resolution imposing the sanction and resolution of claims;

c) Procedure for appealing the resolution of claims;

d) Role of the Santiago Court of Appeals.

CCHEN inspectors have powers to stop a facility or cease authorization, following an investigation that leads to sanctions. When the results of inspection (or another regulatory assessment), indicate that the protection of workers, the public and the environment might be inadequate, CCHEN inspectors can shut down the facility.

According to the Nuclear Safety Law, a summary judgment on radiological issues conducted by a lawyer with the support of technical experts and inspectors must be opened to determine responsibilities of abnormal events. If violations or offenses are demonstrated, a corresponding sanction should be imposed. Penalties are graded in fines, license suspension, or permanent revocation.

CCHEN has prepared an internal procedure "On the supervision process and the summary to first category facilities" This procedure, among other things, provides:

a) Guidance to elaborate written warnings to facilities when findings reveal that these involve risks, such as those indicated in the second paragraph of Article 24 of Law No. 18,302;

b) Norms to prepare the summary for first category facilities;

c) Notifications during the process of preparing and implementing the summary;

d) Periods;

e) Guidance for accountability during the process of implementing the summary;

f) Guidance on the classification of the infractions and offenses: very serious, serious, minor;

g) Guidance on the classification of the sanctions: maximum grade, medium grade and minimum grade;

h) Payment of fines;

i) Finalization of the summary.

However, CCHEN has no internal procedures for responding to non-compliances with regulatory requirements or with any conditions specified in the authorization for nuclear facilities.

MINSAL´s inspectors have the power to apply enforcement actions according to the provisions of The Book X on "Procedures and Penalties" of the Health Code. The Book X contains three titles: Title 1 on "Inspection and deficiencies", Title 2 on "Summary proceedings" and Title 3 on "Penalties and health precautionary measures".

But MINSAL has no written enforcement policies and procedures for facilities and activities in Category 2 and 3. MINSAL does not consider sanctions in its daily work. A hypothetical example was discussed with MINSAL, identifying an unauthorized Category 2 facility by inspectors in a remote area. MINSAL would allow the facility to apply for the authorization without stopping the service.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: CCHEN does not have defined enforcement policy and procedures for nuclear facilities.	
(1)	**BASIS: GSR Part 1 Requirement 30, states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
R18	**Recommendation: CCHEN should establish and implement an enforcement policy for nuclear facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no written enforcement policies for facilities and activities regulated by MINSAL.	
(1)	**BASIS: GSR Part 1 Requirement 30, states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
R19	**Recommendation: MINSAL should establish and implement an enforcement policy for facilities and activities in Category 2 and 3.**

8.2. ENFORCEMENT IMPLEMENTATIONS

CCHEN has implemented enforcement actions from written warnings to penalties, including the withdrawal and revocation of an authorization and prosecution for licensees in Category 1. These enforcement actions are published on CCHEN´s web site after removing names of natural and legal persons although this information is not updated. However, there are no records of implementing enforcement actions to nuclear facilities.

MINSAL has not implemented enforcement actions for facilities in Category 2 and 3.

8.3. SUMMARY

The legal framework provides a good basis for establishing and implementing an enforcement policy for facilities and activities. The Nuclear Safety Law allows CCHEN to apply an enforcement policy for nuclear facilities and facilities in Category 1. However, this has not been implemented for nuclear facilities.

The Health Code provides a good basis for establishing and implementing an enforcement policy for facilities and activities in Category 2 and 3. However, this has not been implemented.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

CCHEN is empowered by Law Nº 16,319 (1965) to issue regulations and rules for non-medical uses of ionizing radiation with the approval of the Supreme Government. About medical applications and labor hygiene, the regulations and rules are submitted to MINSAL. Law Nº 18,302 (1984) provides that the regulations on radiation protection and authorizations, in relation to radioactive facilities, will be signed jointly by the Ministers of Energy and Health.

Although a quite comprehensive set of regulations is available in Chile, specific elements related to requirements or conditions for disposal facilities, for safety case development and several safety significant issues specific to fuel cycle facilities are not contemplated. Moreover, some of the existing regulations, such as for the management of radioactive waste, the transport of radioactive material, are outdated, as no revision has been conducted following their initial promulgation.

Guides have been developed by both authorities, CCHEN and MINSAL, within their respective area of competence. Nevertheless, they do not cover the full range of facilities and activities in Chile.

9.2. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The regulatory framework does not cover all the aspects related to safety for research reactors, such as periodic safety review, safety requirements and authorization process for modifications and new experiments, decommissioning, extended shutdown, ageing and safety committees.

Many guides apply to design or commissioning of research reactors, but, as Chile has only the RECH-1 in operation and no new projects, it seems to be not necessary. On the other hand, where necessary, it does not include the following aspects:

- Concept of defense in depth;
- Design for decommissioning;
- Graded Approach;
- Interfaces of Safety and Security;
- Provisions to facilitate radioactive waste management;
- Design extension conditions;
- Design for emergencies;
- Design for ageing management;
- Deterministic criteria;
- Confinement.

The following generic CCHEN guides apply to nuclear facilities: Commissioning, Quality Assurance for commissioning and operation, Emergencies, and Inspections (partially cover Maintenance), Radiation Protection Manual. There is a specific guide for research reactors: Operation and safety analysis report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Currently there is no requirement for the systematic periodic safety review of the research reactor by the operating organization.	
(1)	**BASIS: SSR-3; para 4.25 states that** "*Systematic periodic safety reviews of the research reactor in accordance with the regulatory requirements shall be performed throughout its operating lifetime, with account taken of operating experience, the cumulative effects of ageing, applicable safety standards and safety information from all relevant sources."*
R20	**Recommendation: CCHEN should amend the regulations to require operating organization to conduct periodic safety review of its research reactor and submit a report to CCHEN.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing safety regulations do not cover all the aspects related to the safety of research reactors. Most of them are outdated and not fully in accordance with the latest IAEA safety standards.	
(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)	**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*."
R21	**Recommendation: CCHEN should review and update regulations and guides related to the safety of research reactors in line with the IAEA safety standards.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing CCHEN regulations do not include requirements for establishment of an independent safety committee to advise the operating organization on relevant aspects of the safety of the reactor and the safety of its utilization.	
(1)	**BASIS: SSR-3 Requirement 6 states that** "*A safety committee (or an advisory group) that is independent from the reactor manager shall be established to advise the operating organization on all the safety aspects of the research reactor."*
R22	**Recommendation: CCHEN should amend the regulations to require the**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	establishment of an independent Safety Committee for research reactors.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

CCHEN uses general principles originated from nuclear facility and research reactor regulations and guides in the authorization of fuel cycle facilities. However, there are several significant safety issues specific to fuel cycle facilities that are not contemplated by the regulations and guides currently available, such as criticality control, prevention of criticality accidents, and chemical, industrial and radiological hazards that might result in a nuclear or radiological accident. There are no specific provisions requiring the authorized party to put in place arrangements for the decommissioning of fuel cycle facilities (including funding arrangements). The IRRS team was informed of the intention to update the current set of regulations and guides, but fuel cycle facilities have not been contemplated so far.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no specific regulations and guides that cover the regulatory supervision of the entire life-cycle of fuel cycle facilities or that establish requirements and guidance for every safety issue specific for this type of installations, such as criticality control and prevention of criticality accidents in fuel cycle facilities.	
(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: NS-R-5 para. 6.43 states that** *"Criticality accidents can result in high radiation doses to nearby personnel and widespread contamination. As far as practicable, criticality hazards shall be controlled by means of design."*
(3)	**BASIS: SSR-4 Requirement 7 para. 6.4 states that** *"Subcriticality shall be ensured for all facilities handling fissile material."*
(4)	**BASIS: SSR-4 Requirement 38 states that** *"The design shall ensure an adequate margin of subcriticality, under operational states and conditions that are referred to as credible abnormal conditions, or conditions included in the design basis."*
R23	**Recommendation: CCHEN should develop regulations and guides that are specific for fuel cycle facilities.**

9.4. REGULATIONS AND GUIDES FOR RADIOACTIVE WASTE MANAGEMENT FACILITIES

Chile does not have the policy and strategy for Radioactive Waste Management and Spent fuel established nor arrangements for disposal and decommissioning. Due to this situation CCHEN has not established regulatory requirements nor conditions for development, operation and

closure of disposal facilities. No requirement for safety case development was included in the national regulations.

The current CCHEN regulation NCS-DR-01 Radioactive Waste Management is from 1987. It is not in compliance with the latest IAEA safety standards. The IRRS team has been informed that the values that appear in this regulation are not strictly used by the regulator in their control tasks, in some opportunities they use complementary discharge or clearance levels from latest IAEA safety standards. There is no spent fuel management regulation developed or approved.

A draft regulation on Spent Fuel and Radioactive Waste Management has been prepared by CCHEN and sent to both the Ministry of Energy and the Ministry of Health, for approval.

MINSAL has developed regulations on Waste Management from health care facilities (REAS). No Radioactive Waste Management guidance for other radiological facilities controlled by MINSAL was developed nor approved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulations for development, operation and closure of disposal facilities. No requirement for safety case development included in national regulation. No safety objective established.	
(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: 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 disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
R24	**Recommendation: CCHEN should establish regulations for development, operation and closure of disposal facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current CCHEN regulations NCS-DR-01 Radioactive Waste Management date from 1987, are not in line with the latest IAEA safety standards. The spent fuel management is not included in this regulation.	
(1)	**BASIS: GSR PART1 (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.*
R25	**Recommendation: CCHEN should review and update regulations and guides related to the safety of radioactive waste management and spent fuel**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	management in line with the IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: MINSAL developed regulations on Waste Management from health care facilities (REAS), however, no Radioactive Waste Management regulation is available for other radiological facilities controlled by MINSAL.	
(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 5 Requirement 3 states that** "*The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process."*
R26	**Recommendation: MINSAL should review and update regulations and guides related to the safety of radioactive waste management facilities in line with the IAEA safety standards.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The exemption limits in No.18,302 Nuclear Safety Law Article 3 number 4 are inconsistent with the requirements of GSR Part 3. The figure used is historical and excessively high and does not account for the variability of radiotoxicity that the GSR Part 3 exemption levels address.

The exemption of many radionuclides with high radiotoxicity at the current exemption value of 74 Bq/g from regulatory control can potentially create radiation exposure situations which would be considered unacceptable. Such risks can be avoided with the introduction of the GSR Part 3 exemption levels.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The exemption limits in N°18,302 Nuclear Safety Law Article 3 number 4 are inconsistent with the requirements of GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 8 states that** *"The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	within notified practices or authorized practices may be cleared from regulatory control."
R27	**Recommendation: CCHEN and MINSAL should review the regulations to state exemption level to be in line with GSR Part 3.**

Several non-nuclear circulars issued by CCHEN contain information describing various aspects of applicable regulations and guides such as Circular 4/2014 Standard on Industrial Radiography, which establishes the radiological safety requirements that must be met in the activities associated with non-destructive testing by industrial radiography facilities. It also explains what type of practice authorization will be required, the need for a radiation safety plan, requirement for worker authorization, occupational and public dose limits, requirement to comply with import-export controls, and failure to comply being subject to sanctions. It also includes requirements explaining the responsibility of the licensee, and what information needs to be submitted regarding the construction of facilities.

Supreme Decree N° 18/2015 of MINSAL, Article 5 provides a general list of items to be submitted as part of the application for authorization of a oncology radiotherapy facility. MINSAL also has issued Circular B33 Nº37/2014, which contains instructions and further detailed regulatory requirements for applications for radioactive facility.

Supreme Decree Nº 133/1984 of MINSAL establishes three categories for radioactive facilities in its Art. 7:

The first category includes particle accelerators, irradiation plants, high radiotoxicity laboratories, radiotherapy and deep roentgen therapy, gammagraphy and industrial radiography.

The laboratories of low radiotoxicity, X-rays for medical or dental diagnosis, radiotherapy and surface roentgen-therapy belong to the second category.

The third category includes sealed source equipment for industrial use, such as: pressure gauges, densitometers, flow and level meters, smoke detectors, thickness gauges, etc. Likewise, standard sources, radio-isotopic cardiac stimulators, markers or simulators for medical use, X-ray equipment for baggage control, correspondence, etc., industrial fluoroscopy and diffractometers are included in this category.

The team was informed that for the authorization of other radioactive facilities CCHEN and MINSAL have discussed and assigned a "de facto" category according to the risk and the corresponding regulatory authority has assumed the regulatory control. In some cases, documentation has been prepared, such as Circular N° 3/14 (September 26, 2014): Standard on cyclotrons for radiopharmaceutical production, that is part of the program of regulations prepared by the CCHEN to established requirements for these facilities. However, there are facilities and activities that are not covered by the regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There are some applications of radiation sources that are not included in the categories established in Supreme Decree N°133/1984 of MINSAL. Therefore, some of the facilities and activities are not covered by the regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 2 para. 2.13** *"The government shall establish and maintain an appropriate and effective legal and regulatory framework for protection and safety in all exposure situations…"*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(3)	**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."*
R28	**Recommendation: CCHEN and MINSAL should revise their regulations to ensure that all radiation facilities and activities are included.**

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Chile does not have Policy and Strategy for Radioactive Waste Management and Spent fuel established nor arrangements for disposal and decommissioning. Associated with this situation there are no regulations or guidance relating to decommissioning of nuclear and radioactive facilities, including the submission of Decommissioning Plan throughout the lifetime of a facility. See Section 1.7.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulations or guides covering all aspects of decommissioning throughout all stages of the facilities lifetime.	
(1)	**BASIS: SSR-4 Requirement 2, para. 4.2(e) states that** *"The operating organization shall allocate adequate financial resources to ensure safety, including provision for financial resources for decommissioning where these are not provided by the government."*
(2)	**BASIS: GSR PART6 Requirement 5 states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met.* *3.3. The responsibilities of the regulatory body shall include:* *(…)* *Establishing requirements for planning for decommissioning, including:* ● *Specification of the typical content of decommissioning plans and supporting documents for review or approval;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	● *Establishment of the review process for decommissioning plans and supporting documents (as prescribed in national regulations) and the timeframe for such reviews;* ● *Review of the initial decommissioning plan and updates, review and approval of the final decommissioning plan and supporting documents, and review and approval of updates after the final decommissioning plan has been approved."*
R29	**Recommendation: CCHEN and MINSAL should establish regulations and guides covering all aspects of decommissioning throughout all stages of the facilities lifetime.**

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The relevant government departments have initiated national legislation that give effect to the Modal Instrument about maritime and air transport (IMDG Code and ICAO TI). The requirements pertinent to the transport of radioactive material that are included in the modal instruments, come from the IAEA SSR-6 Regulation. Decree N° 298/1994 of the Ministry of Transport, regulates the road transport of dangerous goods and supplements without contradicting, the specific regulations for the transport of radioactive material issued by the Ministry of Energy that is the SD 12/1985.

Given that SD 12/1985 is based on an early version of the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6), several provisions of the current edition of the IAEA SSR-6 are missing. Moreover, there is not full consistency between the currently existing regulatory requirements for the transport of radioactive material in Chile, as activity concentration limits for exempt material and activity limits for exempt consignment are not present in the SD 12/1985. The IRRS team was informed that updated regulations for the transport of radioactive material drafted by CCHEN have been sent to the Ministry of Energy for approval.

Although templates for transport authorization and validation of package design approval certificates issued by the Competent Authority of the country of origin of the package design are available, lack of relevant guidance for the applicant, on the content and format of the supporting documentation has been identified. Moreover, there is no documented procedure for the afore-mentioned validations conducted by CCHEN.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Supreme Decree N° 12/1985 of MINSAL is based on an early version of the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6). Moreover, it is inconsistent with other current requirements for transport of radioactive material.	
(1)	**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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: SSR-6, para. 307 states that** *"The competent authority shall assure compliance with these Regulations."*
R30	**Recommendation: The Government should revise the current regulatory framework for the transport of radioactive materials to provide for an updated set of requirements which are fully consistent with the international regulatory framework.**

According to Supreme Decree N° 133/1984 of MINSAL, the interested party is requested to attend the radiological protection course provided by CCHEN, the Health Services, the Public Health Institute of Chile, or other bodies authorized by the MINSAL, in terms of obtaining the required authorization for working with radioactive substances. The IRRS team was informed that CEPRO course provides the basic knowledge for the transport of radioactive material in a 1-hour module. There are no regulatory requirements for training about the regulations for the transport of radioactive material in line with IAEA SSR-6.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no regulatory requirement for training or retraining people engaged in the transport of radioactive material.	
(1)	**BASIS: SSR-6, para. 312 states that** *"Persons engaged in the transport of radioactive material shall receive training in the contents of these Regulations, commensurate with their responsibilities."*
(2)	**BASIS: SSR-6, para. 315 states that** *"The training required in para. 313 shall be provided or verified upon employment in a position involving radioactive material transport and shall be periodically supplemented with retraining as deemed appropriate by the competent authority."*
R31	**Recommendation: CCHEN should provide requirements to ensure that persons engaged in the transport of radioactive material, receive training in the contents of the transport regulations and retraining is also conducted.**

9.8. SUMMARY

CCHEN and MINSAL are empowered to issue regulations and rules for the uses of ionizing radiation. Although a quite comprehensive set of regulations is available, some elements are either not contemplated or outdated. Guides have been developed by both authorities, CCHEN and MINSAL, within their respective area of competence. Nevertheless, they do not cover the full range of facilities and activities in Chile.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

The self-assessment was prepared based on the IAEA Safety Standard GS-R-2; however, the review was performed according to the recently published IAEA Safety Standard GSR Part 7.

In Chile, a sound emergency management system has been established which is coordinated by the National Office for Emergencies (ONEMI) and is commensurate, basically, with the natural hazards that the country is exposed (earthquakes, tsunamis, floods, landslides, etc.). There are two elements to be highlighted. There is National Plan for Emergency whose general objective is establishing response actions in different operational phases to face emergency situations caused by natural phenomena and man-induced events, with the goal of protecting people, property and the environment through the coordination of the National System for Civil Protection but response to nuclear and radiological emergencies are not integrated yet, to this national plan. Steps are being implemented toward this purpose. The second element is that the government has created National Commission for the Safety and Security in Radiological Emergencies (CONSER), by Decree Nº 647 of 2015, of the Ministry of the Interior and Public Security to advice the Presidency of the Republic. This commission is functional at the preparedness and response stages. It is important to point out that the CONSER is chaired by a representative of ONEMI and two representatives of CCHEN and MINSAL respectively oversee the Executive Secretariat of this Commission.

Although there is experience and expertise in the country to conduct hazard assessments for emergency planning purposes, the IRRS team was informed that a comprehensive hazard assessment for nuclear and radiological emergencies has not been carried out in the country.

It is important to stress that the hazard assessment provides a basis for applying a graded approach in all matters related to preparedness and response for a nuclear or radiological emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A comprehensive hazard assessment according to the requirements of the GSR Part 7 has not been carried out at the State level.	
(1)	**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.*"
R32	**Recommendation: The Government should ensure that a hazard assessment is performed with the technical support of CCHEN and MINSAL.**

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

Specific functions of CCHEN and MINSAL in relation to preparedness for and response to nuclear or radiological emergencies are not clearly established. There are general functions that have been assigned to CCHEN for regulating nuclear facilities and facilities and activities in Category 1. As a regulatory authority it is understood that CCHEN oversees regulating on-site emergency preparedness and response (EPR) arrangements of operating organizations for the aforementioned facilities and activities. Likewise, according to the legal and regulatory framework CCHEN is responsible for:

a) Receiving notifications of an accident or any other abnormality in the operation of nuclear facilities or equipment or in other activities related to the uses of nuclear energy and nuclear materials as well as the abandonment, loss, theft or robbery of nuclear substances. (Nuclear Safety Law);

b) Adopting all necessary measures, and requesting the cooperation and assistance of any other public or private authority or institution immediately after receiving a notification. (Nuclear Safety Law);

c) Participating in the accident investigation and assessment (GR-G-08);

d) Reviewing and approving licensee´s emergency plans (Nuclear Safety Law).

The legal framework assigns MINSAL responsibilities for regulating facilities and activities in Categories 2 and 3. For this reason, it is understood that MINSAL oversees regulating on-site emergency preparedness and response (EPR) arrangements of operating organizations for these facilities and activities and for response in a nuclear or radiological emergency.

CCHEN and MINSAL are functional and have resources to fulfil its responsibilities. CCHEN has the following sections and logistical support that can be available in case of a nuclear or radiological emergency:

a) Gamma spectrometry laboratories in both nuclear centers;

b) Laboratories for measuring radioactivity content in foodstuff;

c) An environmental monitoring network around the nuclear facilities plus 9 monitoring stations along the country;

d) One vehicle emergency for deployment of first line radiological assessor team;

e) Various portable detectors to measure radiation and contamination;

f) Portable detectors for identification of radionuclides;

g) Whole body counter facility;

h) Internal dosimetry laboratory;

i) External dosimetry laboratory;

j) Biological dosimetry laboratory;

k) Radioactive waste management facilities.

MINSAL is capable to provide specialized response teams for conducting radiological surveys and it is de facto responsible for managing the medical response in case of a nuclear or radiological emergency is its responsibility. The IRRS team was informed that the following resources are available:

a) Portable detectors distributed across the country (15 regions) to evaluate radiation levels;

b) External personal dosimetry laboratory;

c) Technical personnel with training in radiological protection, including doctor specialist in radio pathology and radioprotection;

d) Emergency health care centers;

e) Health care centers from law enforcement agencies of occupational diseases and accident.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Roles and responsibilities for preparedness and response for a nuclear or radiological emergency have not been allocated to CCHEN and MINSAL.	
(1)	**BASIS: GSR Part 7 para. 4.7 states that** *"The government shall ensure that all roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated in advance among operating organizations, the regulatory body and response organizations."*
R33	**Recommendation: The Government should allocate specific roles and responsibilities for preparedness and response to nuclear or radiological emergencies to CCHEN and MINSAL as regulatory authorities and response organizations.**

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

There are three specific regulations that requires licensees to incorporate the EPR into the management system of the facilities in Category 1. These are:

a) Nuclear safety law, articles 11 and 20;

b) Authorization Regulation, Supreme Decree Nº133/1984 of MINSAL, Title 3, Article 10, b);

c) Transport regulations, Decree N ° 12, title 1, article 1 and 2. It is necessary to point out that the Decree No 298 of Ministry Transport, for transport of dangerous cargo establishes complementary requirements on EPR.

In addition, for nuclear research facilities there is a CCHEN regulatory guide (GR-G-8), which establishes the requirement to perform an accident analysis for the facility, as a basis for the design of safety systems and as a basis for establishing the emergency response plan.

In the case of facilities in Category 1, there is no regulatory guidance document on how to develop a hazard assessment. There are no written guidance criteria to review and approve the operator´s emergency plan.

In the case of Category 2 and 3 facilities, Supreme Decree N° 133/1984. does not require applicants to submit emergency plans.

It is important to mention that Operational Intervention Levels for radionuclides in food have been established by MINSAL in Supreme Decree N° 977/1996, 1997, issued by MINSAL, article 166 and 167.

CCHEN has established regulatory requirements for the Emergency Planning Zones of the CCHEN´s nuclear facilities through the Metropolitan Regulatory Plan of Santiago de Chile.

It has been identified that some key international requirements for EPR of the GSR Part 7 are not appropriately addressed in the national regulations and guides such as:

a) Roles and responsibilities of all key response organizations;

b) Role of the regulator about the regulations on EPR;

c) Requirements to develop a hazard assessment as the basis of emergency plans; EPR categories are not applied;

d) Requirement to develop a protection strategy for an emergency;

e) The emergency classification system based on observables and emergency action levels (EAL). It is required only for nuclear research facilities;

f) Requirements for taking mitigatory actions, taking urgent protective actions and other response actions;

g) Provision of instructions, warnings and relevant information to the public for all facilities and activities. There are some for nuclear research facilities;

h) Detailed requirements for protecting emergency workers and helpers. There are some for radiation workers involved in response operations;

i) Taking early protective actions;

j) Managing the medical response;

k) Managing radioactive waste in an emergency;

l) Mitigating non-radiological consequences;

m) Terminating an emergency;

n) Guidance for preparing the emergency plans and procedures for all facilities and activities;

o) Detailed requirements on trainings, drill and exercises;

p) Requirement to implement a quality management system for EPR arrangements.

There is no mechanism in place to ensure that operating organizations review and, as appropriate, revise their emergency arrangements prior to any changes in the facility or activity that affect the existing hazard assessment and when new information becomes available that requires to confirm the adequacy of the existing arrangements.

There are some elements in the regulatory framework related to implement EPR arrangement for transport of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE	
Observation: CCHEN and MINSAL have not established or adopted regulations and guides that contain all the elements of GSR Part 7, for regulating on-site EPR of nuclear and radiation facilities and activities.	
(1)	**BASIS: GSR Part 7 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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE	
R34	**Recommendation: CCHEN and MINSAL should review the regulations and guides for emergency management in line with GSR Part 7.**

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

CCHEN and MINSAL do not verify effectively the compliance of the on-site emergency arrangements of facilities and activities before commencement of operation of the facility or before the conduct of the activity. For nuclear and Category 1 facilities, CCHEN approves the operator's emergency plan during the authorization process. For nuclear facilities and some facilities of Category 1 that will operate with high activity sources an inspection is conducted before commencement of operations and EPR arrangements are verified.

MINSAL´s inspectors do not verify the EPR arrangements on-site during inspections to Category 2 and 3 facilities and activities.

Inspection programs of both regulatory authorities do not cover the verification of EPR arrangements of operators systematically. CCHEN and MINSAL do not evaluate emergency exercises conducted by operators.

For transport of high activity sources EPR arrangements are reviewed and assessed and inspections are conducted. Coordination for ensuring integration of on-site emergency arrangements of operating organizations with those of relevant off-site response organizations is verified only in facilities of CCHEN.

CCHEN´s inspectors have checklists for inspections that contain elements such as the verification of the plan, personnel training and resources available for response to radiological emergencies.

Inspectors from CCHEN and MINSAL have general provisions in the legal framework for applying enforcement actions and follow up the corrective actions that can be applied during verification on-site of EPR arrangements.

CCHEN and MINSAL do not have procedures for verifying the integration of on-site emergency arrangements of operating organizations with those of relevant off-site response organizations and with other plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE	
Observation: CCHEN and MINSAL have not established internal processes, procedures and programmes to carry out the verification of EPR arrangements on-site for nuclear and radiation facilities and activities.	
(1)	**BASIS: GSR Part 7 para. 4.14 states that** *"Before commencement of operation of the facility or commencement of the activity, the regulatory body shall ensure, for all facilities and activities under regulatory control that could necessitate emergency response actions, that the on-site emergency arrangements:* *(a) Are integrated with those of other response organizations, as appropriate;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICE	
	(b) Are integrated with contingency plans in the context of Ref. [9] and with security plans in the context of the INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011); *(c) Provide, to the extent practicable, assurance of an effective response to a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 27 Inspection of facilities and activities states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
R35	**Recommendation: CCHEN and MINSAL should verify the adequacy of on-site EPR of operating organizations prior to commencement with operation and throughout the lifetime of the facility or activity in relation to:** • **Review and assessment of the documentation elaborating operator's emergency arrangements during the licensing process;** • **Inspections on EPR arrangements of operating organizations; and** • **Evaluating some of the exercises conducted by the operating organizations as applicable with a graded approach.**

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

CCHEN has in place the so called "Procedure of Attention to External Radiological Emergencies". This procedure describes the steps to be taken upon a notification that has been received of an accident or any other abnormality in the operation of nuclear facilities or equipment, or in other activities related to the uses of nuclear energy and nuclear materials as well as the abandonment, loss, theft or robbery of nuclear substances. This document cannot be considered an emergency plan. Some exercises have been conducted to train staff of CCHEN and test response plan of the nuclear facilities of CCHEN.

MINSAL, at SEREMIs level puts in place the "SEREMI Emergency and Disaster Plan" (SEDP) to establish, among other things, the roles and responsibilities of each SEREMI before, during and after an emergency or disaster. The role and responsibilities of SEREMIs in case of a radiological emergency are included in these plans. Besides MINSAL, at regional level, puts in place the "Regional Emergency and Disaster Plan for Medical Institutions" in which, among other things, the roles and responsibilities of each medical care institution of the region is established before, during and after an emergency or disaster. The role and responsibilities of the medical institutions that are involved in a radiological emergency for medical response are not included in these plans.

There are some other findings related to infrastructural requirements that are not appropriately met by CCHEN and MINSAL. They are as follow:

a) CCHEN has not implemented a clearly specified internal organizational relationship for response.

b) CCHEN and MINSAL have not prepared and implemented appropriate emergency plans and technical procedures for emergency response. MINSAL has not developed and implemented plans and technical procedures for managing the medical response to nuclear and radiological emergencies.

c) CCHEN and MINSAL have not prepared and implemented appropriate programs and procedures for the selection and training of personnel to fulfil their response functions.

d) CCHEN and MINSAL have not prepared and implemented appropriate programs of drills and exercise programs to ensure that they are able to perform their response functions effectively.

e) CCHEN and MINSAL have not implemented a quality management programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency.

RECOMMENDATION, SUGGESTION AND GOOD PRACTICE	
Observation: CCHEN as a response organization has not implemented: • A clearly specified organizational relationship for response. • Plans and technical procedures for emergency response. • Programs and procedures for the selection and training of personnel to fulfil their response functions and exercise programs to test plans. • A quality management programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency. MINSAL as a response organization has not implemented: • Plans and technical procedures for emergency response and for managing the medical response. • Programs and procedures for the selection and training of personnel to fulfil their response functions and exercise programs to test plans. • A quality management programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency.	
(1)	**BASIS: GSR Part 7 para. 6.7 states that** *"The organizational relationships for preparedness and response for a nuclear or radiological emergency and interfaces between all the response organizations shall be established."*
(2)	**BASIS: GSR Part 7 para. 6.17 states that** *"Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified* *in Section 5 and in accordance with the hazard assessment and the protection strategy."*

RECOMMENDATION, SUGGESTION AND GOOD PRACTICE	
(3)	**BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training."*
(4)	**BASIS: GSR Part 7 para. 6.34 states that** *"The operating organization, as part of its management system (see Ref. [14]), and response organizations, as part of their emergency management system, shall establish a programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency as specified in Section 5 (see para. 6.22). The programme shall include arrangements for inventories, resupply, tests and calibrations, to ensure that these are continuously available and are functional for use in a nuclear or radiological emergency."*
R36	**Recommendation: CCHEN and MINSAL should implement the appropriate infrastructural requirements of the GSR Part 7 for response organizations related to organization and staffing, plans and procedures, training, drills and exercises and a quality management programme for emergency preparedness and response.**

10.5. SUMMARY

A comprehensive hazard assessment to identify clearly the hazards associated with facilities, activities or sources within or beyond the borders of a State has not been conducted. This is the basis for applying a graded approach on EPR arrangements.

Authority and responsibilities of CCHEN and MINSAL for regulating on-site EPR of operating organizations and as response organizations are not clearly established.

The legal and regulatory framework for nuclear and radiation safety and other documents related to the national emergency management system do not address specifically EPR requirements for nuclear and radiological emergencies.

Effective mechanisms to verify the adequacy of on-site EPR of operating organizations prior to commencement with operation and throughout the lifetime of the facility or activity are not implemented.

CCHEN and MINSAL as response organizations have not implemented key infrastructural requirements according to the GSR Part 7.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The control of medical exposures is not covered in the current regulations.

CCHEN has responsibilities for the regulation of Category 1 medical radiation facilities. MINSAL has responsibilities for the regulation of Category 2 and 3. However, neither CCHEN nor MINSAL have responsibilities to control medical exposure.

Guidance regarding release of patients on exposure of volunteers participating in biomedical research and protection of carer and comforters was not available.

There are no clinical justification requirements, diagnostic reference levels or dose constraints.

The current regulations do not address requirements on protection and safety for medical exposure, except partially the Supreme Decree N°18/2015 of MINSAL approving the "Sanitary regulations for the installations of Radiotherapy and Oncology".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current regulations do not address requirements on protection and safety for medical exposure for patients, carers and comforters and volunteers, except what is partially addressed in the Supreme Decree N° 18/2015 of MINSAL approving the "Sanitary regulations for the installations of radiotherapy and Oncology".	
(1)	**BASIS: GSR Part 3 Requirement 3 para. 2.37 states that** *"The regulatory body, in consultation with the health authority, shall ensure that provisions are in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency."*
(2)	**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."*
(3)	**BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty."*
(4)	**BASIS: GSR Part 3 Requirement 36 states that** *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."*
(5)	**BASIS: GSR Part 3 Requirement 37 states that** "*Relevant parties shall ensure that medical exposures are justified."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(6)	**BASIS: GSR Part 3 Requirement 38 states that** "*Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure."*
(7)	**BASIS: GSR Part 3 Requirement 39 states that** *"There are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding."*
R37	**Recommendation: CCHEN and MINSAL should revise the regulations to give effect to the requirements on protection and safety for medical exposure for patients, carers and comforters and volunteers.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

Chile has established a legal and regulatory framework for radiation safety which includes provisions for protection against occupational exposure. Relevant requirements for the control of occupational exposures are established in the following documents:

- Law No.16,319/1965 of the Ministry of Mining;
- Law 18302 /1984 of the Ministry of Mining (Law of Nuclear safety), amended by Law 18,730 /1988 of the Ministry of Mining;
- Law 19.825/2002 of the Ministry of Mining;
- Law No.1968 /725 of the Ministry of Health;
- Law No. 16.744 /1968 the Ministry of Labour and Social Welfare;
- Law No. 19.937 / 2004 of the Ministry of Health;
- Supreme Decree N° 133/1984 of the Ministry of Health;
- Supreme Decree N° 3 of 1985 of the Ministry of Health;
- Decree Force Law N° 1 of 1989 of the Ministry of Health ;
- CCHEN Regulatory Guide GR-G-02 "Basic Criteria for Nuclear Safety and Radiation Protection";
- Circular B33 N° 37 /2014 of the Ministry of Health;
- CCHEN Circular 1/2017.

The Law 18,730 /1988 of the Ministry of Mining, Amendment to Law No. 18,302 / 84, establishes in its Article 67 that :

- CCHEN regulates nuclear installations, radioactive facilities that are inside a nuclear installation and category 1 radioactive facilities, including the control of occupational radiation protection in these facilities;

- MINSAL regulate category 2 and 3 radioactive facilities, in accordance with the provisions of the Health Code, including the control of occupational radiation protection in these facilities.

CCHEN and MINSAL enforce the requirements of the Supreme Decree No. 133/1984 and of the Supreme Decree N° 3/1985 for the radiation protection of the workers, whatever be the category of the installation/facility regulated.

Supreme Decree N° 133/1984 of MINSAL, require that any person who works in a radioactive facility or operates ionizing radiation generating equipment, and is exposed to said radiations, must have an authorization from the corresponding Health Service (today SEREMI). It also establishes the conditions for granting or renewing this authorization. MINSAL Circular B33N°37/2014 provides complementary information. This-authorization is valid for three years and allows the authorization holder to work in radioactive facility in any region of the country.

In addition, the Law No. 18,302 / 84 regulating nuclear installations, radioactive facilities that are inside a nuclear installation and Category 1 radioactive facilities requires that workers operating in such installation/facility have a special authorization issued by CCHEN. CCHEN Circular 1/2017 establishes the conditions to obtain this special authorization to work in first category radioactive facilities, without mentioning the nuclear installations. This authorization is valid for six years.

The Supreme Decree N° 3/1985 of MINSAL provides:

- Annual limits on doses to the whole body and to different organs, for workers of the age above 18 years, for women of procreating age and for pregnant women; workers under 18 cannot be exposed occupationally to ionizing radiation;
- For all workers exposed to internal contamination with any radionuclide, the provisions set forth in the regulations that the Ministry of Health provides for such purposes shall apply;
- For the case of radioactive iodine, the exposed workers will undergo a quarterly control of urine. The costs associated with such examinations will be borne by the employer.

These dose limits are not in compliance with GSR Part 3.

The Regulatory Guide “Basic Criteria for Nuclear Safety and Radiation Protection” published by CCHEN provides:

- The principles of limitation and optimization;
- Several types of dose limits (such as primary limits, secondary limits, derived limits, authorized limits and reference levels).

These dose limits are different from the ones provided by the Decree N°3/1985 and they are not in compliance with GSR Part 3.

There are no requirements in the regulations for the protection of workers against exposure of aircrew due to cosmic radiation and for the protection of emergency workers.

The existing regulations do not mention explicitly that the conditions of service of workers must be independent of whether they are or could be subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist.

General responsibilities of registrants, licensees and employers

The current legislation and regulations of the Ministry of Energy do not clearly define and assign the responsibilities for the protection of workers to the employers and the authorized parties.

The Law No. 18,302 / 84 requires, without assigning the responsibilities:

- Anyone who works to receive adequate training and to possess, when appropriate, university professional title, specialized studies or experience in matters of nuclear safety or nuclear radiation protection, as the case may be;

Persons who are or may be exposed to ionizing radiation during their work to be subject, before assuming their duties, to a medical examination, which will subsequently be periodic, as determined by the regulations and the specific conditions of the authorizations issued by CCHEN.

The Supreme Decree N° 133/1984 of MINSAL, establishes that the holder of an authorization for a radioactive installation will always be responsible of the personnel who work in this facility.

The Supreme Decree N° 3/1985 of MINSAL, requires that a personal dosimeter shall be provided by the employer whenever necessary. It will be the obligation of the employer to send, quarterly, to the Institute of Public Health the personal dosimeters of his exposed workers. The IRRS team has been informed that CCHEN provides its workers with monthly dosimeters. Likewise, the employers must grant all the elements of personal radiological protection necessary to reduce the risks of the exposed worker.

The current regulations on radiation protection of the Ministry of Health do not clearly require that:

- the radiation employer or authorized parties ensure that suitable and adequate facilities, personnel protective devices, monitoring equipment's and health surveillance are provided to exposed workers;
- every employer shall ensure that his workers are given appropriate training, information and instructions regarding the use of ionizing radiations;
- every employer shall provide calibrated equipment for workplace monitoring and ensure records of this monitoring are kept;
- employer shall ensure that arrangements are in place for the health surveillance of the exposed workers.

The current legislation and regulations do not include requirement on the responsibility for promoting safety culture, as well as on the cooperation between employers and authorized parties if they are different.

General Responsibilities of workers

The article 67 of the Law No. 16.744 (1968) of the Ministry of Labour and Social Welfare requires that the workers fulfil the obligations provided by the internal rules of the enterprises. There are no specific requirements related to protection and safety.

Requirements for radiation protection programmes

The Regulatory Guide "Basic Criteria for Nuclear Safety and Radiation Protection" published by CCHEN provides requirements on implementing relevant areas of workplaces as controlled or supervised areas.

There are no such requirements in the regulations of the Ministry of Health.

The current regulations do not require that the employer shall consult a radiation protection officer or qualified experts, as necessary, to check the compliance with the regulations. There are no criteria on a minimum qualification for appointing one radiation protection officer However, Circular 1/2017 establishes the physical, phycological and professional conditions required for a radiation protection officer to obtain a special authorization to work in Category 1 facilities.

Monitoring programmes and technical services

External dosimetry

The Supreme Decree N° 133/1984 of MINSAL requires that the personal dosimetry records of the worker are carried out by the Institute of Public Health, the personal dosimetry can be provided by another body authorized for such purposes by the Ministry of Health. The Institute of Public Health has the character of national laboratory and of reference in the matters to which this regulation refers. It also fixes the methods of analysis, sampling procedures and measurement techniques oriented to the exposed personnel.

The Supreme Decree N° 3/1985 of MINSAL, also establishes that the personal dosimetry of a person exposed to ionizing radiation in each period may be carried out by CCHEN or other bodies qualified by the Ministry of Health.

External dosimetry measurements are currently performed by the Institute of Public Health, CCHEN and 6 private companies. CCHEN and the private companies are authorized by MINSAL, with a technical report from the Institute of Public Health without limit of duration. The criteria for authorization are established in the Supreme Decree Nº 3/1985.The technical evaluation is carried out by a program of external evaluation based on technical and administrative requisites.

Currently, effective external doses and extremity doses can be assessed, but there is no technical provision in the country for assessing the dose at the lens of the eyes.

Internal dosimetry

The Supreme Decree N° 3/1985 establishes specific requirements on internal dosimetry for all the workers exposed to internal contamination, specifically radioactive iodine. CCHEN provides internal dose assessment by whole body counters, thyroid counters and urine bioassays for uranium. The results of the internal doses assessed by CCHEN are not loaded on the dosimetry platform of the Institute of Public Health.

Biological dosimetry

CCHEN has developed the technical capability to perform biological dosimetry in case of suspected overexposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Biological dosimetry is available in Chile.	
(1)	**BASIS: RS-G-1.1 para. 7.18 states that** *"Only at doses much higher than the dose limits (i.e. 0.2–0.5 Sv or higher) will special dose investigations involving biological dosimetry… be necessary."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 13 states that** *"The government shall make provisions, where necessary for technical services in relation to safety, such*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	as services for personal dosimetry, environmental monitoring and the calibration of equipment."
GP1	**Good Practice: Chile has developed the technical capability to perform biological dosimetry in case of overexposures.**

National dose register

The Supreme Decree N° 3/1985 del MINSAL establishes that the employer sends quarterly the doses received by the personnel during one period indicated, to the Institute of Public Health. The results of the individual dosimetry of the workers are sent by the dosimetry service providers to the employer of the workers and to the Institute of Public Health, currently through an internet platform developed by the Institute of Public Health. CCHEN also sends the dosimetry records to the Institute of Public Health through the internet platform.

The Institute of Public Health registers these doses in the exposure records of each worker and so maintains a national dose register, although there is no regulatory requirement for the long-term retention and maintenance of these records in a national data base.

The Institute of Public Health uses this register for issuing an individual certificate of exposure history which is required for a worker submitting for an individual or a special authorization.

Workplace monitoring services

There is no regulatory requirement for the workplace monitoring services.

Training of Workers and Training Services

There are requirements for training of exposed workers in the current regulations, but no requirement for maintaining records of the training provided to individual workers.

CCHEN, the Institute of Public Health and private organizations authorized by SEREMIs currently provide training courses to workers, especially for getting an authorization to work in Category 1, 2 and 3 facilities.

CCHEN, private organisations, approved by CCHEN currently provide training courses to workers, especially for getting a special authorization for operating in nuclear installations, radioactive facilities that are inside a nuclear installation and category 1 radioactive facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulations for occupational radiation protection, published in 1984 and 1985, are outdated and so do not fully comply with GSR Part 3.	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSR Part 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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 3 Requirement 19 states that** "*The government or the regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and the regulatory body shall enforce compliance with dose limits for occupational exposure. "Responsibilities of the regulatory body specific to occupational exposure."*
(4)	**BASIS: GSR Part 3 Requirement 20 states that** "*The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations."*
(5)	**BASIS: GSR Part 3 Requirement 21 states that** "*Employers, registrants and licensees shall be responsible for the protection of workers against occupational exposure. Employers, registrants and licensees shall ensure that protection and safety is optimized and that the dose limits for occupational exposure are not exceeded."*
(6)	**BASIS: GSR Part 3 Requirement 22 states that** "*Workers shall fulfil their obligations and carry out their duties for protection and safety."*
(7)	**BASIS: GSR Part 3 Requirement 23 states that** "*Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety."*
(8)	**BASIS: GSR Part 3 Requirement 24 states that** "*Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure."*
(9)	**BASIS: GSR Part 3 Requirement 25 states that** "*Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of occupational exposures and for workers' health surveillance."*
(10)	**BASIS: GSR Part 3 Requirement 26 states that** "*Employers, registrants and licensees shall provide workers with adequate information, instruction and training for protection and safety."*
(11)	**BASIS: GSR Part 3 Requirement 27 states that** "*Employers, registrants and licensees shall not offer benefits as substitutes for measures for protection and safety."*
(12)	**BASIS: GSR Part 3 Requirement 28 states that** "*Employers, registrants and licensees shall make special arrangements for female workers, as necessary, for protection of the embryo or fetus and breastfed infants. Employers, registrants and licensees shall make special arrangements for protection and safety for persons under 18 years of age who are undergoing training.*
R38	**Recommendation: CCHEN and MINSAL should review and update their**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	current regulations on occupational radiation protection in line with GSR Part 3, to enhance the protection of the workers.

11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

Control of discharges and materials for clearance

The Supreme Decree No 115/75 sets an annual dose limit for the protection of the public of 5 mSv, which is not in line with GSR Part 3. There are no requirements for the optimization of protection and safety of the public in the regulations. There are no established dose constraints to be used in the optimization of protection and safety of the public in planned exposure situations.

There are no regulatory requirements regarding discharge limits in line with GSR Part 3. Discharge limits for CCHEN nuclear and Category 1 facilities are established in the NORMA NCS-DR-01 which is from 1987 and not in compliance with GSR Part 3. The IAEA TECDOC 1000 is also used by CCHEN to establish authorized discharge limits. However, TECDOC 1000 is outdated and not in line with GSR Part 3.

MINSAL has not established discharge limits for Category 2 and 3 facilities. The low radiotoxicity nuclear medicine laboratories, where F-18 and Tc-99m are used, store contaminated liquids for decay on site for at least 10 half-lives, after which they are released into the environment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulations on public exposure are incomplete and do not fully address the requirements of GSR Part 3 regarding dose limits for public exposure, optimization of protection and safety of the public, dose constraints for public exposure in planned exposure situations, and discharge limits.	
(1)	**BASIS: GSR Part 3 Requirement 12 states that** *"The government or the regulatory body shall establish dose limits for occupational exposure and public exposure, and registrants and licensees shall apply these limits."*
(2)	**BASIS: GSR Part 3 Requirement 29 para. 3.121 states that** *"The government or the regulatory body shall establish, and the regulatory body shall enforce compliance with, the dose limits specified in Schedule III for public exposure."*
(3)	**BASIS: GSR Part 3 Requirement 11 states that** *"The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized."*
(4)	**BASIS: GSR Part 3 Requirement 29 para. 3.120 states that** *"The government or the regulatory body shall establish or approve constraints on dose and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	constraints on risk to be used in the optimization of protection and safety for members of the public."
(5)	**BASIS: GSR Part 3 Requirement 29 para. 3.123 states that** *"The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges."*
R39	**Recommendation: CCHEN and MINSAL should review and update regulations for public exposure to be in line with GSR Part 3.**

The concept of clearance is not included in the legal framework and clearance levels have not been established. In practice, MINSAL uses the exemption level 74 Bq/g as a general clearance level for solid waste from Category 2 and 3 facilities, which is inconsistent with the requirements of GSR Part 3. CCHEN has so far applied clearance levels according to GSR Part 3 in one case, regarding waste with uranium. During the IRRS team's site visit to the radioactive waste management facility, the operator expressed the view that the waste management suffers from the lack of established clearance levels, giving rise to the build-up of waste in storage, which causes problems in the long-term.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Clearance levels have not been established in the regulations.	
(1)	**BASIS: GSR Part 3 Requirement 8 para. 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies."*
R40	**Recommendation: CCHEN and MINSAL should establish clearance levels in the regulations in line with GSR Part 3.**

Environmental monitoring

The Law No.18.302 assigns CCHEN the responsibility to ensure that programmes for environmental monitoring are in place for nuclear and Category 1 facilities, when necessary. The Manual of Occupational Radiation Protection, which is part of the licence of each facility, includes conditions on environmental monitoring to verify compliance with the established discharge limits. The research reactor and the radioactive waste management facility plus four Category 1 facilities are required to have environmental monitoring programmes. MINSAL does not require environmental monitoring of the Category 2 facilities that produce F-18 and Tc-99m, because of the short half-lives and the decay storage.

Authorized parties of the nuclear and Category 1 facilities are required to verify compliance with the established discharge limits and keep periodic reports on environmental monitoring. The authorized parties are however not required to submit periodic reports on public exposure to CCHEN. Consequently, CCHEN is not able to perform assessments of the total public exposure related to discharges from the facilities. During inspections, CCHEN checks the records of environmental monitoring to verify compliance with the established discharge limits. Occasionally inspectors collect samples for independent monitoring. CCHEN has not established an independent monitoring programme to verify the quality of the results provided by the authorized parties and to confirm that the doses to members of the public are maintained below the dose constraints established in the Manual of authorization.

The fuel cycle facility has no requirements on environmental monitoring and the IRRS team noted during a site visit to the facility, that inspections of these facilities do not encompass protection of the public and the environment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no independent environmental monitoring programme for nuclear and relevant radioactive facilities. There is no assessment of the total public exposure related to the nuclear and radioactive facilities. CCHEN does not require environmental monitoring of the nuclear fuel cycle facility.	
(1)	**BASIS: GSR Part 3 Requirement 32 states that** *"The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available."*
(2)	**BASIS: GSR Part 3 Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:* *(c) Making provision for an independent monitoring programme.* *(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments."*
(3)	**BASIS: GSR Part 3 Requirement 32, para. 3.137 states that** *"Registrants and licensees shall, as appropriate:* *(a) Establish and implement monitoring programmes to ensure that public exposure due to sources under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization. These programmes shall include monitoring of the following, as appropriate:* *(i) External exposure due to such sources;* *(ii) Discharges;* *(iii) Radioactivity in the environment;* *(iv) Other parameters important for the assessment of public exposure."*
R41	**Recommendation: CCHEN should ensure that, for relevant facilities, monitoring programmes are established by the authorized parties. CCHEN should make provisions for an independent environmental monitoring**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	programme and assess the total public exposure related to these facilities.

Public exposure

An importer of consumer products must request for an authorization from MINSAL. A request for authorization must be followed by documentation on the consumer product, such as a description of the consumer product, its intended uses and benefits, the radionuclide incorporated and its chemical and physical forms and details of the configuration and design of the consumer product.

MINSAL does not require that the importer provides any information or instructions with each consumer product such as-content of radionuclides and activities-or its safe use,-how the product is installed and used, servicing and repair, dose rates or how the product should be disposed of.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulations requiring providers of consumer products to provide information with each product on contents of radionuclides and how to dispose of the product.	
(1)	**BASIS: GSR Part 3 Requirement 33 para. 3.143 states that** *"Providers of consumer products shall provide clear and appropriate information and instructions with each consumer product on:* *(a) Correct installation, use and maintenance of the consumer product;* *(b) Servicing and repair;* *(c) The radionuclides and their activities at a specified date;* *(d) Dose rates in normal operation and during servicing and repair;* *(e) Required or recommended options for recycling or disposal."*
R42	**Recommendation: MINSAL should establish regulations on consumer products in line with GSR Part 3.**

Existing exposure situations

There are no provisions on existing exposure situations in the legal framework. Chile has had extensive mining for years, and there is awareness in MINSAL and CCHEN that past activities might have resulted in contaminated areas, including waste, that need to be identified and evaluated. Also, MINSAL and CCHEN are aware that both public exposure due to radon indoors and exposure due to radon in workplaces need to be addressed.

Reference levels for radionuclides in milk and drinking water are established in Supreme Decree 115/1975. The Supreme Decree 977/1997 establishes derived intervention levels for radionuclides in food. The Decrees are outdated and not in line with either GSR Part 3.

Regulations on existing exposure situations are incomplete and do not fully address the requirements of GSR Part 3, such as identification and evaluation of existing exposure situations, identification of persons or organizations responsible for areas with residual radioactive material, radon indoors, remedial actions and protection of workers in existing exposure situations. Reference levels for drinking water, milk and food are not in line with GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulations on existing exposure situations are incomplete and do not fully address the requirements of GSR Part 3. Reference levels for drinking water, milk and food are not in line with GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."*
(2)	**BASIS: GSR Part 3 Requirement 49 states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management."*
(3)	**BASIS: GSR Part 3 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors."*
(4)	**BASIS: GSR Part 3 Requirement 48 states that** *"The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that protection and safety is optimized."*
(5)	**BASIS: GSR Part 3 Requirement 52 states that** *"The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations."*
(6)	**BASIS: GSR Part 3 Requirement 51 para. 5.22 states that** *"The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."*
(7)	**BASIS: GSR Part 3 Requirement 51 para. 5.23 states that** *"The regulatory body or other relevant authority shall consider the guideline levels for radionuclides in food traded internationally that could contain radioactive substances as a result of a nuclear or radiological emergency, which have been published by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Codex Alimentarius Commission. The regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in drinking water that have been published by the World Health Organization."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R43	**Recommendation: The Government should ensure that the regulatory body that is responsible for existing exposure situations provides regulations in line with GSR Part 3.**
R44	**Recommendation: MINSAL should update reference levels for drinking water, milk and food in accordance with GSR Part 3.**

11.4. SUMMARY

The current regulations do not address requirements on protection and safety for medical exposure for patients, comforters and volunteers.

The legislative and regulatory framework of Chile in the field of radiation safety for the workers is in place. However, the regulations enforced by CCHEN and MINSAL are outdated.

Regulations in the areas of control of radioactive discharges, materials for clearance, existing exposure situations and environmental monitoring are incomplete and not in line with the GSR Part 3.

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ADDITIONAL AREAS - Control of radioactive discharges and materials for clearance, Environmental monitoring associated with authorized practices for public radiation protection purposes Control of chronic exposures	
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APPENDIX III MISSION PROGRAMME

CHILE IRRS MISSION PROGRAMME 21st January – 2nd February 2018

IRRS MISSION PROGRAMME		
21 January Sunday		
IRRS Initial IRRS Review Team Meeting		
13:00 - 17:00	Opening remarks by the IRRS Team Leader (Mr Javier Zarzuela)	Venue: Park Plaza Hotel Pucara Meeting Room Participants: the IRRS Team + the LO
	Introduction of participants	Team Members
	Liaison Officer: Mission Logistics	Hugo Briso
	IAEA Coordinator: Presentation on the IRRS Process	Amparo Cristobal
	IRRS Team Members: Report on the Initial Review of the Advance Reference Material (ARM) - *Reviewers to briefly present (5-10 min max) their initial impressions of the advance reference material.* - *This is also an opportunity to raise any initial concerns or specific requests for clarification with the Liaison Officer.*	Team Members
	Review of Mission Schedule	Javier Zarzuela Amparo Cristobal
	Closing remarks/Questions	Javier Zarzuela Claudio Almeida Amparo Cristóbal Ugur Bezdeguemeli All
17:00 -18:00	Groups prepare for interviews; Module Leaders prepare slides for the TL presentation for the Entrance Meeting.	Participants: the IRRS Team

IRRS MISSION PROGRAMME		
22 January Monday		
IRRS Entrance Meeting		
09:00–09.05 09:05–09:20	Welcome address Opening remarks	Venue: La Reina Nuclear Centre – Cruz-Coke Meeting Room: Mauricio Lichtemberg - Head, Division of Nuclear and Radiological Safety, CCHEN Patricio Aguilera - Executive Director CCHEN Tito Pizarro Quevedo - Division of Public Policies of the Undersecretary of Public Health of the Ministry of Health, Representative to the Directive Council of CCHEN
09:20–09:40 09:40–09:50 09:50–10:30	Opening remarks and expectations Introduction of IRRS Team Regulatory Control of facilities and activities Responsibility CCHEN, self-assessment result	IRRS Team Leader IRRS Team Members CCHEN: Mauricio Lichtemberg
10:30–10:50	Tea/Coffee	
10:50–11:30	Regulatory control of facilities and activities responsibility MINSAL; self-assessment results	Norma Carreño Palacios - Department of Occupational Health of Division of Public Policies of the Undersecretary of Public Health of the Ministry of Health
11:30–11:40	Introduction of IRRS Module Counterparts	Module Counterparts
11:40–11:50	Working arrangements for the IRRS Mission	LO
11:50–12:00	Closing remarks	IRRS Team Leader
12:00–13:00	Lunch	
13:00–17:00	Interviews and Discussions with Counterparts (parallel discussions)	Counterparts/CCHEN offices

IRRS MISSION PROGRAMME		
17:00- 18:00	Daily IRRS Review Team meeting	Venue: Cruz-Coke Meeting Room Participants: the IRRS Team + the LO
23 January Tuesday,		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	Counterparts/CCHEN offices
09:00 -	Site visit Fuel making factory Waste treatment	
12:00 – 13:00	Lunch	
14:00 – 18:00	Visit Minister of Energy, Minister of Health and Representative Minister of External Affairs	TL, DTL, IAEA Coordinator, Patricio Aguilera, Mauricio Lichtemberg
17:00 – 18:00	Daily IRRS Review Team meeting	Venue: Cruz-Coke Meeting Room Participants: the IRRS Team + the LO
24 January Wednesday		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts for all modules	Counterparts/CCHEN offices: TBD
08:00 – 12:00	Site Visits: Research Reactor Category 1 Industrial	IRRS team
08:00 – 16:00	Site visits: Cat 1 Medical Private	IRRS team
12:00 – 13:00	Lunch	
13:00 – 17:00	Writing first draft of preliminary findings (recommendation, suggestions and good practices)	The IRRS Team
17:00 – 18:00	Daily IRRS Review Team meeting: discussion of findings (recommendation, suggestions and good practices)	Venue: Cruz-Coke Meeting room Participants: the IRRS Team + the LO
20:00 – 24:00	Discussions on Recommendations and Suggestions	Park Plaza Hotel Pucara Meeting Room Participants: the IRRS Team + the LO
25 January Thursday		
Daily Discussions / Interviews		
08:00 – 09:00	Briefing from the site visits	IRRS Team and LO.
09:00 – 17:00	Follow-up Interviews as needed	IRRS Team

IRRS MISSION PROGRAMME		
	Report preparation	
17:00 – 18:00	Daily IRRS Review Team Meeting: recommendation, suggestions and good practices	Venue TBD Participants: the IRRS Team + the LO
20:00 – 24:00	Discussions on Recommendations and Suggestions	Park Plaza Hotel Pucara Meeting Room Participants: the IRRS Team + the LO
26 January Friday		
Daily Discussions / Interviews		
09:00 – 14:00	Follow-up Interviews as needed Report preparation	Counterparts and Offices: TBD
09:00 – 12:00	Site Visits: Reactor Cat 3 Industrial (scrap treatment and melting	IRRS team
14:00 – 16:00	Policy issue discussion: parallel sessions if needed.	Reviewers and Counterparts and Offices: TBD
14:00 – 16:00	Site Visits: Category 1 Medical	IRRS team
16:00 – 18:00	Report preparation: finalize observations, basis, recommendations, suggestions and good practices	Venue TBD Participants: the IRRS Team + the LO
20:00 -	IRRS Team finalize Recommendations and Suggestions	Park Plaza Hotel Pucara Meeting Room Participants: the IRRS Team + the LO
27 January Saturday		
Daily Discussions/ Interviews (if needed)		
09:00 – 17:00	Team members write draft report. Finalize the Observations and Recommendations and Good Practices.	Reviewers and Module leaders Park Plaza Hotel Pucara Meeting Room
28 January Sunday		
Team rest day + cultural events		
29 January Monday		
Daily Discussions		
09:00 – 12:00	Individual discussions of the draft Report sections with the Counterparts Report writing	Reviewers + Counterparts
12:00 - 13:00	Lunch	

IRRS MISSION PROGRAMME		
13:00 – 18:00	Cross reading and draft Report editing	Reviewers + Module leaders, TL, DTL, TC and DTC
30 January Tuesday		
Daily Discussions		
09:00 – 12:00	Finalize report text and submit to the Host	Venue : TBD Participants : IRRS Team
18:00	Draft to be sent to CCHEN and Ministry of Health for review	
12:00 - 13:00	Lunch	
13:00 – 18:00	Exit presentations preparation	TL, DTL, TC and DTC
31 January Wednesday		
Daily Discussions		
09:00 – 15:00	CCHEN and Ministry of Health review the draft	CCHEN and Ministry of Health Staff and concerned organizations.
09:00 – 15:00	Executive summary and exit presentation finalization Press release draft preparation	TL, DTL, TC and DTC
15:00 –	IRRS Team to review Host comments	IRRS Team + LO
1 February Thursday		
09:00 – 11:00	IRRS Team continue to review host comments	IRRS Team + LO
11:00 - 17:00	Discussion with the counterparts on findings if required.	IRRS Team Module counterparts
12:00 - 13:00	Lunch	
17:00 -	Report finalization by the team and handover the report to CCHEN and Ministry of Health	Venue: TBD IRRS Team
17:00 – 18:00	Briefing of the IAEA Official and press release finalization	IAEA Official, TL, DTL, TC and DTC
2 February Friday		
09:00 – 11:00	Government official opening remarks	Venue TBD Participants: Government Officials, CCHEN and Ministry of Health Management and staff, the IRRS Team + the LO
	Main findings of the IRRS mission (Team Leader)	
	Remarks by CCHEN and Ministry of Health in response to the Mission findings.	
	IAEA Official (TBD): Closing remarks	

IRRS MISSION PROGRAMME		
	Move to press conference	Government official and Host Management, TL, DTL, IAEA Official

APPENDIX IV SITE VISITS

1. Fábrica de Elementos Combustibles / Nuclear Fuel Element Manufacturing Plant
2. Radioactive waste management facilities operated by SEGEDRA in the Centre Lo Aguirre
3. Reactor Nuclear de Investigación RECH1 / RECH1 Nuclear Research Reactor
4. Clinica Alemana de Santiago. German Clinic of Santiago
5. Sociedad Tecnica de Inspeccion S.A: Industrial gammagraphy and radiography facizzlity / Technical Inspection Society (Inc.)

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	R1	The Government should establish a national policy and strategy for safety, whose implementation should follow a graded approach, to achieve the fundamental safety objective, to apply the fundamental safety principles and to express a long-term commitment to safety.
		R2	The Government should review and revise the legal and regulatory framework to establish an effectively independent regulatory body, include safety provisions for acquiring and maintaining the necessary competence nationally for ensuring safety, establish responsibilities and obligations in respect of financial provision for the management of radioactive waste and spent fuel, for the decommissioning of facilities and termination of activities and criteria for release from regulatory control.
		R3	The Government should ensure that the national regulatory authorities are effectively independent in their safety related decision making and that they have functional separation from entities having responsibilities or interests that could unduly influence their decision making.
		R4	The Government should make provisions for the effective coordination of the regulatory functions of CCHEN and MINSAL to avoid any omission, or undue duplication and to avoid conflicting requirements being placed on authorized parties.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R5	The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.
		R6	The Government should establish a national policy and strategy for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel; and should make provisions, including the funding, for the safe decommissioning of facilities and the safe disposal of radioactive waste.
2.	**GLOBAL SAFETY REGIME**	S1	CCHEN should consider establishing a documented process that provides for the analysis and dissemination of operational and regulatory experience, both national and international.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R7	CCHEN and MINSAL should allocate and manage their resources so as to allow them to discharge their responsibilities and perform their regulatory functions effectively.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R8	CCHEN and MINSAL should define their safety policies in their management systems in line with GSR Part 2.
		R9	CCHEN and MINSAL should establish and implement an integrated management system in accordance with the IAEA safety standard GSR Part 2, including internal procedures for all regulatory functions and application of a graded approach.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5.	**AUTHORIZATION**	R10	CCHEN should establish in its authorization process, requirements for the authorization of modifications and new experiments for research reactors.
		R11	CCHEN should require that the safety assessment for authorization of fuel cycle facilities addresses all radiation and nuclear risks that arise from normal operation and from anticipated operational occurrences and accident conditions.
		R12	CCHEN should require that the safety assessment for authorization of predisposal radioactive waste management facilities address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions.
		R13	MINSAL should request closure authorization for radioactive facilities Category 3 unless explicitly exempted.
6.	**REVIEW AND ASSESSMENT**	R14	CCHEN should require that the operating organization of research reactors submit safety related information in a periodic manner.
		S2	CCHEN should consider the development of guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization of fuel cycle facilities which are in line with IAEA Safety Standards, and the establishment of standard review procedures of such reports.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R15	CCHEN should strengthen its core competency that will allow it to make informed decisions on regulatory issues of fuel cycle facilities, especially on those decisions regarding complex calculations.
		S3	CCHEN should consider the development of guidance on the format and content of safety case for the authorization of radioactive waste management facilities, which are in line with IAEA safety standards, as well as the establishment of standard review procedure of such report.
7.	**INSPECTION**	S4	CCHEN should consider revising its regulatory inspection plan for research reactors to cover all aspects related to the safety and conduct the regulatory inspections in a frequency commensurate with the complexity of the facility and the associated safety related issues.
		S5	CCHEN should consider carrying out unannounced inspections of fuel cycle facilities.
		S6	CCHEN should consider establishing a systematic specific training programme for inspections of fuel cycle facilities
		S7	CCHEN should consider developing and approving check list for performing radioactive waste management facilities inspections complementary to the current “Facility Inspection“procedure.
		S8	CCHEN should consider including transport specific inspections to its inspection programme.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R16	MINSAL should include transport specific inspections to its inspection programme.
		R17	CCHEN and MINSAL should ensure that package designs which are not required to be approved by the competent authority, are in conformity with the regulatory requirements.
8.	**ENFORCEMENT**	R18	CCHEN should establish and implement an enforcement policy for nuclear facilities.
		R19	MINSAL should establish and implement an enforcement policy for facilities and activities in Categories 2 and 3.
9.	**REGULATION AND GUIDES**	R20	CCHEN should amend the regulations to require operating organization to conduct periodic safety review of its research reactor and submit a report to CCHEN.
		R21	CCHEN should review and update regulations and guides related to the safety of research reactors in line with the IAEA safety standards.
		R22	CCHEN should amend the regulations to require the establishment of an independent Safety Committee for research reactors.
		R23	CCHEN should develop regulations and guides that are specific for fuel cycle facilities.
		R24	CCHEN should establish regulations for development, operation and closure of disposal facilities.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R25	CCHEN should review and update regulations and guides related to the safety of radioactive waste management and spent fuel management in line with the IAEA safety standards.
		R26	MINSAL should review and update regulations and guides related to the safety of radioactive waste management facilities in line with the IAEA safety standards.
		R27	CCHEN and MINSAL should review the regulations to state exemption level to be in line with GSR Part 3.
		R28	CCHEN and MINSAL should revise their regulations to ensure that all radiation facilities and activities are included.
		R29	CCHEN and MINSAL should establish regulations and guides covering all aspects of decommissioning throughout all stages of the facilities lifetime.
		R30	The Government should revise the current regulatory framework for the transport of radioactive materials to provide for an updated set of requirements which are fully consistent with the international regulatory framework.
		R31	CCHEN should provide requirements to ensure that persons engaged in the transport of radioactive material, receive training in the contents of the transport regulations and retraining is also conducted.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R32	The Government should ensure that a hazard assessment is performed with the technical support of CCHEN and MINSAL.
		R33	The Government should allocate specific roles and responsibilities for preparedness and response to nuclear or radiological emergencies to CCHEN and MINSAL as regulatory authorities and response organizations.
		R34	CCHEN and MINSAL should review the regulations and guides for emergency management in line with GSR Part 7.
		R35	CCHEN and MINSAL should verify the adequacy of on-site EPR of operating organizations prior to commencement with operation and throughout the lifetime of the facility or activity in relation to: • Review and assessment of the documentation elaborating operator's emergency arrangements during the licensing process; • Inspections on EPR arrangements of operating organizations; and • Evaluating some of the exercises conducted by the operating organizations as applicable with a graded approach.
		R36	CCHEN and MINSAL should implement the appropriate infrastructural requirements of the GSR Part 7 for response organizations related to organization and staffing, plans and

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			procedures, training, drills and exercises and a quality management programme for emergency preparedness and response.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R37	CCHEN and MINSAL should revise the regulations to give effect to the requirements on protection and safety for medical exposure for patients, carers and comforters and volunteers.
11.2	**OCCUPATIONAL RADIATION PROTECTION**	GP1	Chile has developed the technical capability to perform biological dosimetry in case of overexposures.
		R38	CCHEN and MINSAL should review and update their current regulations on occupational radiation protection in line with GSR Part 3, to enhance the protection of the workers.
11.3	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES CONTROL OF CHRONIC EXPOSURES**	R39	CCHEN and MINSAL should review and update regulations for public exposure to be in line with GSR Part 3.
		R40	CCHEN and MINSAL should establish clearance levels in the regulations in line with GSR Part 3.
		R41	CCHEN should ensure that, for relevant facilities, monitoring programmes are established by the authorized parties. CCHEN should make provisions for an independent environmental monitoring programme and assess the total public exposure related to these facilities.
		R42	MINSAL should establish regulations on consumer products in line with GSR Part 3.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R43	The Government should ensure that the regulatory body that is responsible for existing exposure situations provides regulations in line with GSR Part 3.
		R44	MINSAL should update reference levels for drinking water, milk and food in accordance with GSR Part 3.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

List of ARMS provided by CHCHEN and MINSAL

1.	ARMS Report V2
2.	Basic Standards for Radiation Protection (1975 Ed).docx
3.	Circular 1_2013 Provisions Regarding the Import, Operation and Final Closure of Industrial Gammagraphy Equipment.doc
4.	Circular 1_2017 Norm for Special Authorization to Work in Radioactive Facilities.docx
5.	Circular 2_2012 Instructions Regarding Mobile Equipment Emitters or Generators of Ionizing Radiations.doc
6.	Circular 3_2014 Standard on Cyclotrons for Radiopharmaceutical Production.docx
7.	Circular 4_2014 Standard on Industrial Radiography.doc
8.	Circular 5_2014 Standard for Deferred Manual Loading Brachytherapy.docx
9.	CNEC Quality Management System.doc
10.	Decree 12_1985 Regulations for the Safe Transport of Radioactive Materials.doc
11.	Supreme Decree N° 133_1984 of MINSAL. Regulations on Authorizations.doc
12.	Supreme Decree N° 3_1985 of MINSAL. Regulations on Radiation Protection.doc
13.	Supreme Decree N° 18_ 2015 of MINSAL Sanitary Regulation on Oncological Radiotherapy Establishments
14.	Decree 87_1984 Regulation on Physical Protection of Facilities and Nuclear Materials.doc
15.	FOT-DSNR-018 Authorization Request for First Class Radioactive Facilities.docx
16.	GR-C-01 CRITERIOS GENERALES DE DISEÑO DE ESTRUCTURAS CLASES A, B, y C PARA INSTALACIONES NUCLEARES DE INVESTIGACION.docx
17.	GR-E-01 CRITERIOS GENERALES DE DISEÑO DE SISTEMAS CLASE E PARA INSTALACIONES NUCLEARES DE INVESTIGACION.docx
18.	GR-G-02 Basic Criteria for Nuclear Safety and Radiation Protection.doc
19.	GR-G-03 Contents of the Safety Reports for Research Nuclear Reactors.doc
20.	GR-G-08 Contents of the Emergency Plan for Research Nuclear Facilities.doc
21.	GR-G-09 Contents of the Pre-Operational Test Plan for Research Nuclear Facilities.doc
22.	GR-G-10 Contents of the Quality Guarantee Manual for the Commissioning and Exploitation of Nuclear Research Facilities.doc
23.	GR-G-11 Contents of the Operating Manual of Research Nuclear Reactors.doc
24.	GR-G-13 Contents of the Periodic Inspection Plan for Nuclear Research Facilities.doc

25.	GR-G-14 Contents of the Organization and Procedures Manual for Nuclear Research Reactors.doc
26.	GR-G-NN Contents of the Security Report of First Category Radioactive Facilities DRAFT.doc
27.	GR-M-01 CRITERIOS GENERALES DE DISEÑO DE SISTEMAS HIDRAULICOS CLASES A, B y C PARA INSTALACIONES NUCLEARES DE INVESTIGACION.docx
28.	GR-N-01 General Criteria of Core Design for Pool Type Research Reactors.doc
29.	Law 16,319 Creates the Chilean Nuclear Energy Commission.doc
30.	Law 18,302 Nuclear Safety Law.doc
31.	National Policies for the Protection of the Public DRAFT.doc
32.	NCS-DR-01 Radioactive Waste Management.doc
33.	NCS-GG-03 FORMATO DE DOCUMENTOS DE SEGURIDAD PARA EL LICENCIAMIENTO DE INSTALACIONES NUCLEARES E INSTALACIONES RADIACTIVAS.docx
34.	NCS-SV-01 Accountability and Control System for Nuclear Materials.doc
35.	Normas Básicas de Protección Radiológica Dto. 115_1976.es.en.docx
36.	NRN-G-01 Contents of the Operational Manual for First Category Radioactive Facilities.doc
37.	NS-EVCR-01.0 Radiation Protection Basic Criteria DRAFT.docx
38.	NS-GD-01 Radioactive Waste Management DRAFT.doc
39.	NS-GG-02 Procesos de Licenciamiento - Proyecto.doc
40.	NS-GGDL-11.0 Contents of the Radiation Protection Manual for First Category Radioactive Facilities DRAFT.doc
41.	NS-GGDM-01.1 Dosimetric Control Requirements for Operating Personnel of Nuclear or Radioactive Facilities DRAFT.docx
42.	Physical Protection Guide in the Transport of Radioactive Materials DRAFT.docx
43.	Project Agreement-Redesign and Improvement of DISNR Processes.docx
44.	PRT-DSNR-001 Authorization Applications Evaluation.docx
45.	PRT-DSNR-002 Facilities Inspection.docx
46.	Redesign and Improvement of NRSD Processes.docx
47.	Regarding the Supervising Process and the Summary Judgment to First Category Radioactive Facilities.docx
48.	Regulations for the Management of Spent Nuclear Fuels and Radioactive Waste DRAFT.doc
49.	Regulations for the physical protection of radioactive material used in first category radioactive facilities DRAFT.docx

50.	RSA DECRETO_977_96_recorte.es.en.docx
51.	Sanctions Regulations to Infringements to Nuclear or Radiological Legal and Regulatory Framework DRAFT.doc
52.	DTO-647_02-DIC-2015 (1).pdf
53.	LEY-1552_30-AGO-1902.pdf
54.	LEY-16744_01-FEB-1968 (1).pdf
55.	LEY-18164_17-SEP-1982.pdf
56.	LEY-19880_29-MAY-2003.pdf
57.	LEY-19937_24-FEB-2004.pdf
58.	LEY-20120_22-SEP-2006.pdf
59.	LEY-20123_16-OCT-2006 (1).pdf
60.	Norma General Técnica N.º 51 2011 (1).pdf
61.	DFL-1_16-ENE-2003.pdf
62.	DFL-1_21-FEB-1990.pdf
63.	DFL-1_24-ABR-2006.pdf
64.	DFL-725; DTO-725_31-ENE-1968 (1).pdf
65.	DTO-3_25-JUN-2011 (1).pdf
66.	DTO-40_07-MAR-1969.pdf
67.	DTO-47_16-SEP-2016.pdf
68.	DTO-100_22-SEP-2005.pdf
69.	DTO-156_13-JUN-2002.pdf
70.	DTO-298_11-FEB-1995.pdf
71.	DTO-329; DFL-329_20-JUN-1979.pdf
72.	Informe MINSAL SARIS 2017 traducida al inglés.pdf

73.	Informe MINSAL SARIS 2017 (Spanish).pdf
74.	ORD 4474_ NOV 22_INFORME SARIS_SSP.pdf
75.	RESOLUCION EXENTA 1242_OCTUBRE 13_2017_SSP.pdf
76.	ORD 4448_ NOV 17_INFORME SARIS_SSP.pdf
77.	CHILE_IRRS ARM Report V2.pdf

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, Safety Fundamentals No. SF-1, IAEA, Vienna (2006)
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1(Rev 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety, General Safety Requirements 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, Vienna, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for Facilities and Activities, General Safety Requirements Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirements Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirements Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements No. SSR-3, IAEA, Vienna (2017)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements No. SSR-4, IAEA, Vienna (2017)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
15. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
16. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)

17. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)

18. 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)

19. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)

20. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

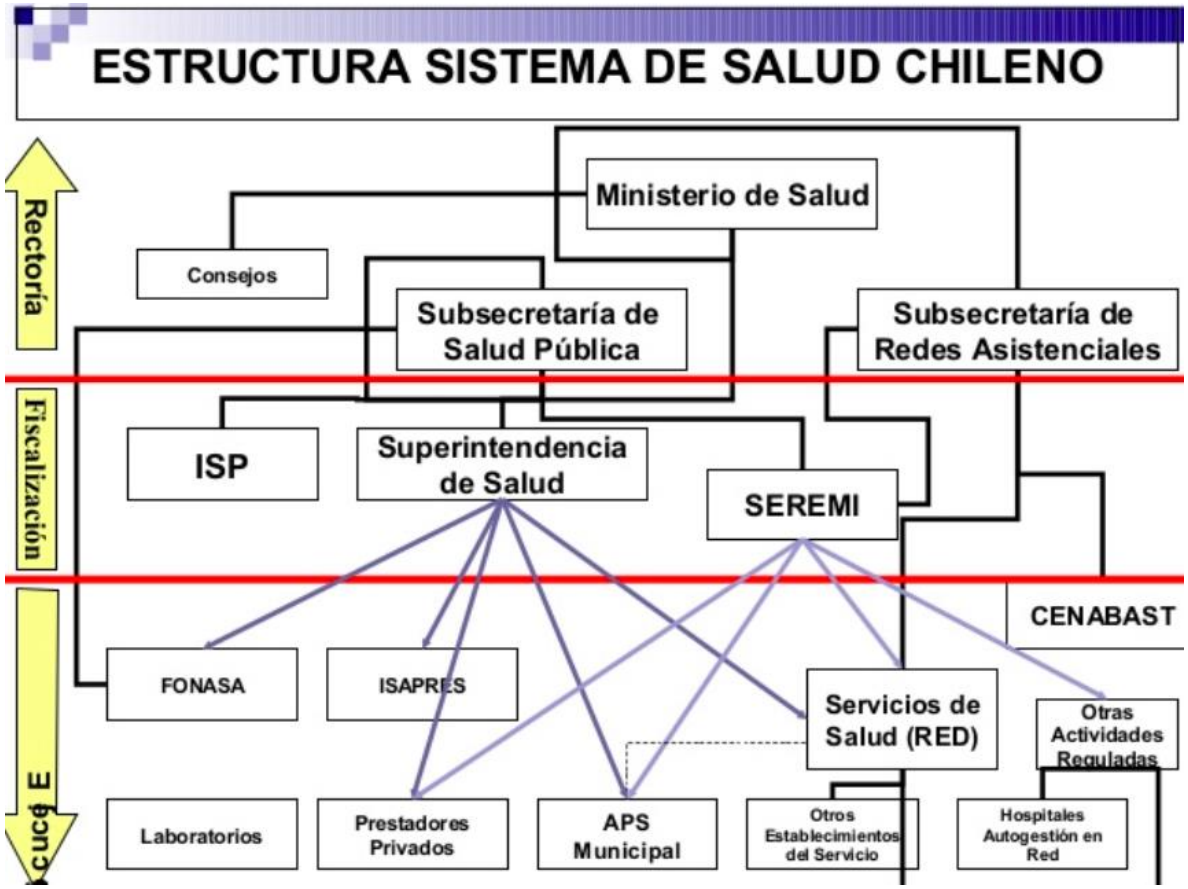
21. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

22. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

23. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

24. 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)

APPENDIX VIII ORGANIZATION CHART




Ministerio de Salud
Gobierno de Chile
ORGANIGRAMA SUBSECRETARÍA DE SALUD PÚBLICA
SUBSECRETARIO SALUD PÚBLICA
Jefe de Gabinete
Departamento de Bioética, Investigación y Regulación
Departamento de Gestión y Coordinación de Calidad
Comisión Médica de Reclamos
Oficina de Coordinación Ley Ricarte Soto
SEREMIS DE SALUD
Secretarías Regionales Ministeriales de Salud
DIPRECE
División de Prevención y Control de Enfermedades
Coord. Administrativa
Depto. Enf. Transmisibles
Depto. Enf. No Transmisibles
Depto. Ciclo Vital
Depto. Discapacidad y Rehabilitación
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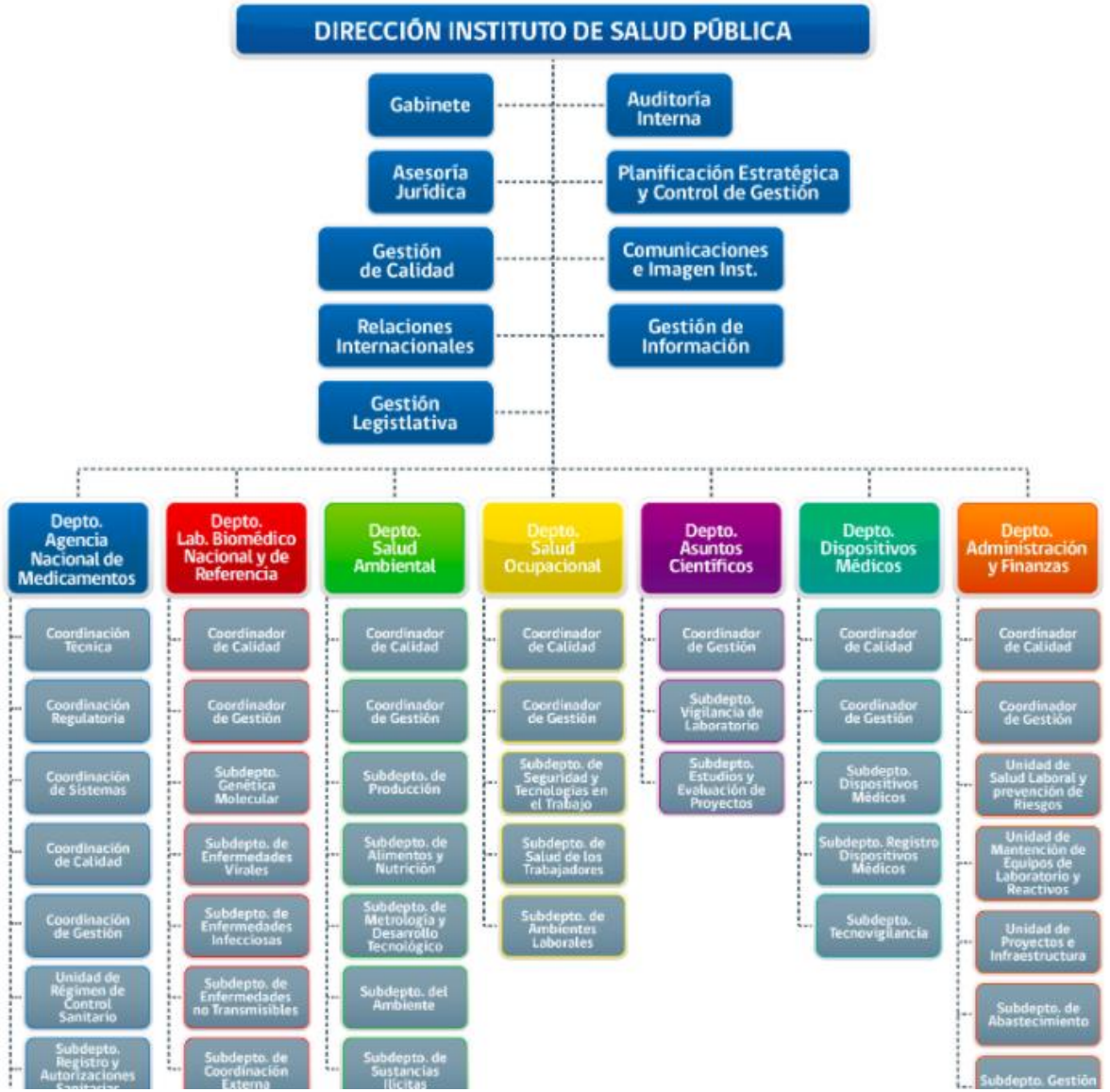
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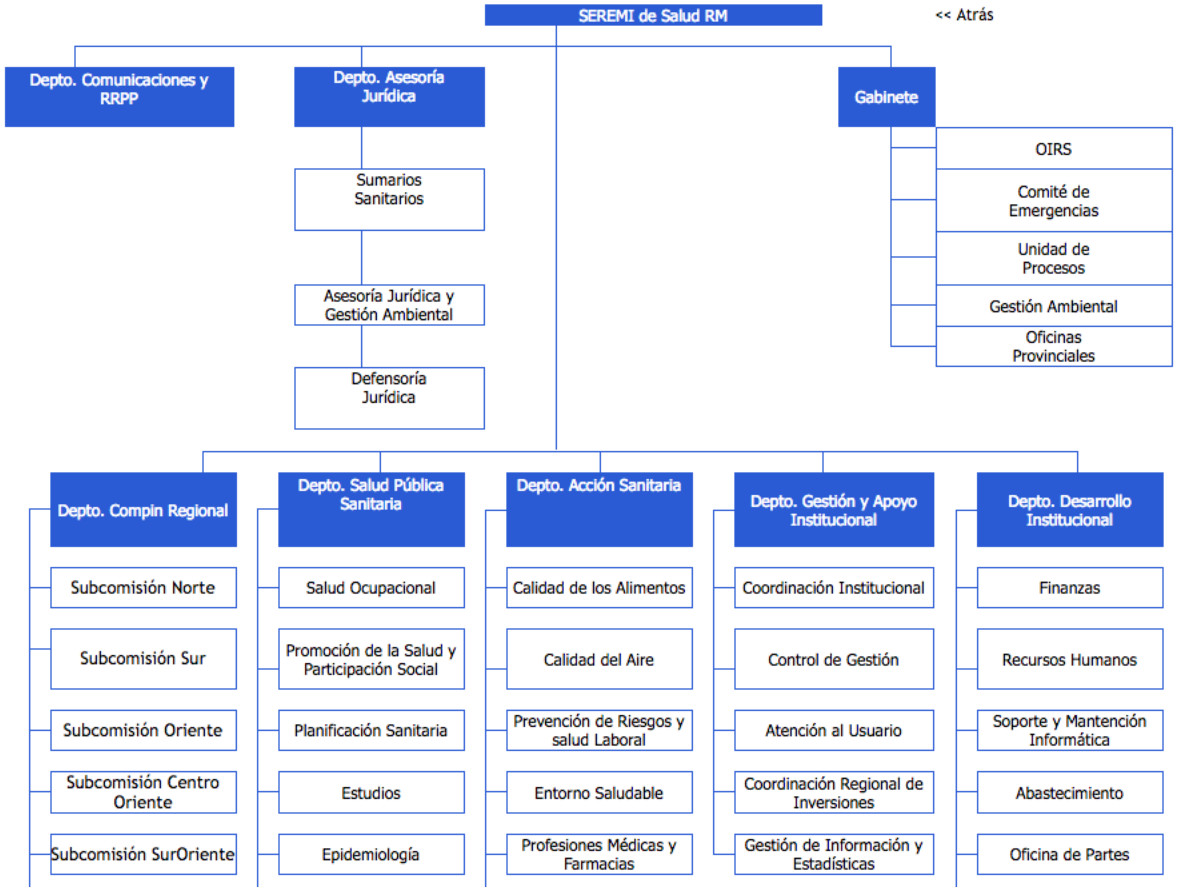
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