

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

Vietnam

Hanoi, Vietnam

28 September to 9 October 2009

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The Integrated Regulatory Review Service (IRRS) is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other non-binding legal instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than eighty Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as feedback for the improvement of existing safety standards and guidance and for the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work

towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) REPORT TO

THE GOVERNMENT OF VIETNAM

Hanoi, Vietnam

28 September to 9 October 2009



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Hanoi, Vietnam

Mission date: 28 September to 9 October 2009

Regulatory Body: Vietnam Agency for Radiation and Nuclear Safety (VARANS)

Location: Hanoi

Organized by: International Atomic Energy Agency (IAEA), Department of

Nuclear Safety and Security

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The number of recommendations, suggestions and good practices is not a measure of the status of the regulatory body. 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 Vietnam Agency for Radiation and Nuclear Safety (VARANS), an IAEA convened team of international experts performed a peer review of Vietnam's national regulatory infrastructure for radiation and nuclear safety, in accordance with the Guidelines of the IAEA Integrated Regulatory Review Service (IRRS).

The IRRS mission took place from 28 September to 9 October 2009.

Through an evaluation of the effectiveness of VARANS' regulatory activities and organizational structure, this IRRS mission identified regulatory improvements in safety and provided the opportunity to share experience and knowledge among the staff of VARANS and the international reviewers. Noting that bodies other than VARANS are involved in the regulatory process for radiation and nuclear activities, the IRRS team also considered the relative interdependencies, functions and responsibilities of those other bodies.

The IRRS Review Team consisted of senior experts from Member States supported by IAEA staff (Appendix I). The mission programme is given in Appendix II.

The IRRS Team reviewed the following areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; and the management system of the regulatory body. In addition, at the request of the regulatory body, the mission scope included a review of regulatory oversight of the following thematic areas: Code of Conduct on the Safety and Security of Radioactive Sources; emergency preparedness and response; control of medical exposures; education and training. A review was also made of the existing safety infrastructure for a national nuclear power programme, in accordance with DS-424, the draft safety standard for establishing a safety infrastructure for a national nuclear power programme.

The mission included a series of interviews and discussions with key personnel at VARANS and other organizations, together with observation of inspections of several facilities (Appendix III). VARANS supplied the documentation and a comprehensive self-assessment in advance of the mission. The review team based its findings on the results of the VARANS self-assessment using IAEA Safety Standards and Codes of Conduct as reference material. Additionally, the team and regulatory body staff discussed a number of regulatory policy issues of particular interest to Vietnam. The results of the mission will serve as a useful basis for the evolution of future IRRS missions to other Member States and will assist with continuous improvement in the regulation of nuclear and radiation safety globally.

The IRRS Review Team noted the transparent and learning attitude of VARANS staff in performing a very thorough self-assessment prior to the mission and their openness throughout this mission. It was evident that significant effort had been put into the preparation for the mission; in particular the self-assessment using the IAEA methodology and tools. The team members also appreciated the openness and co-operation they received from staff of the other organizations met during the mission, including the Ministry of Science and Technology (MOST), Vietnam Atomic Energy Institute (VAEI), Ministry of Health (MOH), Department of Science and Technology (DOST) of Hanoi, Ministry of Industry and Trade (MOIT), the Nuclear Power and Renewable Energy Project Pre-investment Board (EVN), Ministry of Natural Resources and Environment (MONRE), Friendship Hospital in Hanoi, Institute of Science and Technology, Hanoi University of Technology, and Vinagamma Irradiation Centre (HCM City).

The IRRS Review Team appreciated and acknowledged VARANS' participation in international cooperation activities and encouraged it to continue its active role in the exchange of experience and expertise among regulators.

Particular strengths of the Vietnamese regulatory system and VARANS include:

- Strong leadership of VARANS that has improved the recognition of VARANS' authority to implement its regulatory programme, hence strengthening regulatory oversight of radiation and nuclear safety in the country;
- Questioning attitude and a willingness to learn by staff of VARANS;
- VARANS' efforts to continually review and assess its practices against internationally recognised standards and good practices;
- Dedication of VARANS' staff to improving legislation and regulation in the field of nuclear and radiation safety;
- Good co-operation between VARANS and the DOSTs in relation to coordinating inspection programmes; and,
- Comprehensive provisions to take comments from all interested parties into consideration during the processes to issue legal documents.

The IRRS Review Team believes that consideration of the following items should be given high priority either because they were identified in several review areas or because the review team considers that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

Independence

There is a potential for conflict of interest because MOST, MOIT and MONRE all contain bodies that are involved in regulating, promoting and operating radiation and nuclear activities. In order that the regulatory system of Vietnam meets the IAEA safety standards requirements for effective independence:

- The Government should ensure that the regulatory bodies in Vietnam are effectively independent from:
 - o organizations or bodies charged with the promotion of nuclear technologies; and,
 - o those bodies responsible for the operation of radiation and nuclear facilities and activities.
- The Government should, in particular, ensure that the licensing for nuclear power plants (NPPs) is effectively independent from operation and promotion.

Resources

• A human resources national strategy is needed, both for the current situation, as well as in anticipation of the proposed introduction of nuclear power. This strategy should, in particular, ensure:

- o that the Government provides timely and additional resources for the development of appropriate regulatory expertise, taking into consideration the fact that regulatory oversight is needed from an early stage in the planning process for nuclear power; and
- o that MOST strengthens, without delay, VARANS' human and financial resources, and its technical capability to meet immediate needs for regulating existing activities and, in particular, for the introduction of nuclear power; and,
- o that other (non-regulatory) bodies tasked with development of the nuclear power programme have access to sufficient, competent resources.

Technical capability

MOST should ensure that VARANS is provided adequate technical expertise to conduct independent review and assessment, both now and in the future. This should be achieved through strengthening VARANS' capability, or by providing other technical expertise that is free from conflict of interest with promotion or operation of radiation and nuclear activities. Accomplishing this objective should not jeopardize the ability of VARANS to regulate existing radiation and nuclear activities.

Other activities

- The development of a road map for strengthening the regulatory body would help to ensure the safety and success of the nuclear power programme;
- Control of medical exposure, and in particular the protection of patients, should be given high priority;
- VARANS should establish a documented management system, including establishing a safety culture. In the future, the concept of management system should be extended to all organizations involved in radiation and nuclear safety;
- Vietnam may wish to consider the benefits that would be obtained by becoming a party to the various international instruments that are relevant to radiation and nuclear safety, such as the Convention on Nuclear Safety or the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Similar instruments in the field of nuclear security, safeguards and liability could be considered;
- Vietnam should take further actions to fully implement its political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources;
- VARANS and other relevant authorities should develop regulations and guides, in a timely manner, based on a comprehensive strategic plan covering all fields of radiation and nuclear safety;
- A national strategic plan for the sustainable safe management of radioactive waste should be developed by the Government. This strategy should include consideration of the current situation plus waste arising from the introduction and operation of nuclear power plants; and,

• MOST should ensure that a national radiological emergency response plan is developed, issued and implemented without undue delay.

The IRRS team considers that implementation of the Action Plan developed by VARANS as part of their self assessment would address many of the recommendations and suggestions in this report.

The IRRS Review Team findings are given throughout the report and are summarised in Appendix IV.

I. INTRODUCTION

At the request of the Vietnam Agency for Radiation and Nuclear Safety (VARANS), an IAEA convened team of international experts performed a peer review of Vietnam's national infrastructure for radiation and nuclear safety, in accordance with the Guidelines of the IAEA Integrated Regulatory Review Service (IRRS).

A preparatory meeting to Hanoi was conducted in April 2008 by the two IAEA co-ordinators to discuss the purpose, objectives, scope and schedule for the review, followed by a self-assessment workshop in Hanoi in December 2008, with a second preparatory mission involving the team leader and IAEA lead co-ordinator visiting VARANS HQ in July 2009 to finalize the mission scope and logistics.

The IRRS main mission took place from 28 September to 9 October 2009.

The purpose of this IRRS mission was to conduct a peer review of the following areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; and the management system of the regulatory body. In addition, at the request of the regulatory body, the mission scope included a review of regulatory oversight of the following thematic areas: Code of Conduct on the Safety and Security of Radioactive Sources; emergency preparedness; medical exposures; education and training; safety of the research reactor. A review was also made of the existing safety infrastructure for a national nuclear power programme, in accordance with DS-424, the draft safety standard for establishing a safety infrastructure for a national nuclear power programme. Additional policy-level discussions were held with VARANS senior management on new build; communication and public information; establishment of a management system for the regulatory body; and development of inspection and enforcement programme for nuclear facilities. The outcomes of those discussions are integrated within the relevant parts of this report.

Before and during the mission, VARANS made available numerous reference materials in English to the review team. This material consisted of legal, regulatory and internal documents, including the report of the self-assessment made using the IAEA methodology and tools. During the mission the team performed a systematic review of all topics using the self-assessment report, the advance reference material (ARM) and related presentations, interviews with VARANS staff, together with direct observation of working practices during inspections. In addition, there were discussions with the Vice-Minister of Science and Technology and representatives from the Vietnam Atomic Energy Institute (VAEI), Ministry of Health (MOH), Ministry of Natural Resources and Environment (MONRE), Department of Science and Technology (DoST), Ministry of Industry and Technology (MoIT) and the proposed operator of the NPP facility (EVN).

IRRS activities took place mainly in Hanoi with visits to the Dalat (research reactor and isotope production facilities) and to Ho Chi Minh City (industrial and research facilities) as noted in Appendices II and III.

II. OBJECTIVE AND SCOPE

The objective of the mission was to review the legal and governmental infrastructure for nuclear and radiation safety in Vietnam, the effectiveness of the regulatory body and to exchange information and experience among Vietnamese counterparts and the IRRS team, with a view to contributing to the harmonization of regulatory approaches and creating mutual learning opportunities among senior regulators.

The key objectives of this mission were to facilitate the enhancement of safety by:

- providing Vietnam (regulatory body and governmental authorities) with a review of radiation and nuclear safety regulatory technical and policy issues;
- providing Vietnam with an objective evaluation of its regulatory practices with respect to IAEA safety standards;
- contributing to the harmonization of regulatory approaches among Member States;
- promoting sharing of experience and exchange of lessons learned;
- providing key staff in Vietnam with an opportunity to discuss and compare their practices with peer reviewers from other countries;
- providing Vietnam with recommendations and suggestions for improvement;
- in due course, providing other States with information regarding good practices identified during the review;
- providing the reviewers from Member States and IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- providing Vietnam with an opportunity for self-assessment of its activities against IAEA safety standards using IAEA self-assessment methodology and tools.

The scope for this IRRS mission, as agreed with VARANS, included:

- legislative and governmental responsibilities;
- responsibilities and functions of the regulatory body;
- organization of the regulatory body;
- the authorization process;
- review and assessment:
- inspection and enforcement;
- development of regulations and guides;
- management system of the regulatory body.

In addition, at the request of the regulatory body, the mission scope included a review of regulatory oversight of the following thematic areas:

- Code of Conduct on the Safety and Security of Radioactive Sources;
- emergency preparedness;
- medical exposures;
- education and training;
- safety of the research reactor;
- safety infrastructure for embarking on nuclear power.

III. BASIS FOR THE REVIEW

PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was conducted by the IRRS Team Coordinator John Wheatley of IAEA's Division of Radiation, Transport and Waste Safety, and by the IRRS Deputy Team Coordinator, Lingquan Guo of IAEA's Division of Nuclear Installation Safety.

The review team was led by John Kinneman (USA) and included Shahid Mallick (Pakistan deputy team leader) and the following expert reviewers Igor Grlicarev (Slovenia); Peter Fundarek (Canada); Hassan Kharita (Syria); Laurent Kueny (France); and Ana Larcher (Argentina). The peer reviewers were supported by two IAEA review area facilitators: Trevor Boal and David Graves; and IAEA administrative support was provided by Irene Bollozos (prior to the mission) and Jacky Neufing (prior to and during the mission).

During the preparatory period, advance reference material (ARM) was provided by VARANS to the IAEA and then distributed to the reviewers (the list of the reference material is included in Appendix V). The VARANS counterpart was Ms Nguyen Hong Loan, and a significant amount of VARANS support was also provided by Ms Dang Anh Thu.

Prior to the mission, a significant amount of work was carried out by the review team and IAEA staff in order to prepare the initial impressions about the ARM, to review the VARANS self-assessment report, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary for the conduct of the mission.

A review team briefing was conducted on Sunday 27 September 2009 in Hanoi, during which the specifics of the mission were discussed, together with the basis for the review, background, context and objectives of the IRRS. The VARANS Liaison Officer attended the briefing. Based on the ARM, the reviewers reported their first impressions of the current status of all topic areas within the scope of the mission during this briefing.

REFERENCES FOR THE REVIEW

The main reference documents provided by VARANS for the review mission are indicated in Appendix V. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VI.

CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted of all review areas with the objective of providing the regulatory body with recommendations and suggestions and identifying good practices.

The review was conducted through meetings, interviews and discussions with regulatory body personnel; visits to relevant organizations; assessment of the ARM and direct observations regarding national practices and activities particularly in the context of inspections.

The team performed its activities based on the Mission Programme given in Appendix II. The entrance meeting was held on Monday 28 September 2009 with the participation of Professor Tran Quoc Thang, Standing Vice Minister of the Ministry of Science and Technology, Dr. Ngo Dang Nhan, VARANS Director General and his staff. Mr John Kinneman, the team leader, gave opening remarks on behalf of the peer review team, and Mr Wheatley from

IAEA's Division of Radiation, Transport and Waste Safety gave opening remarks on behalf of the IAEA.

The exit meeting, held on Friday 9 October 2009, was attended by Dr. Ngo Dang Nhan VARANS Director General and his staff, IRRS peer review experts and IAEA staff and Mr Philippe Jamet, Director of IAEA's Division of Nuclear Installations Safety.

A preliminary draft of the IRRS mission report was provided to the Regulatory Body at the conclusion of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1 INTRODUCTION

There is a wide range of radiation facilities and activities in Vietnam that need to be regulated, as described below and detailed in Appendix VII.

There is a TRIGA MkII research reactor at the Nuclear Research Institute (NRI) Dalat. The reactor was commissioned in 1963 at 250 kW and used highly enriched uranium fuel. It was shutdown in the mid 1970's and the fuel removed, then it was later re-commissioned to operate at 500 kW, and is in the process of being converted to run on low enriched uranium since 2007. The reactor is used to produce radioisotopes and radiopharmaceuticals (mainly I-131, P-32 and Tc-99m) for domestic use. The reactor is also used for research on neutron physics, physics and dynamics of nuclear reactor, nuclear data, neutron activation analysis; neutron radiography, as well as training and education.

Medical uses include Cobalt-60 teletherapy units, multi beam teletherapy 'Gamma Knife' units, brachytherapy sources, linear accelerators, Cyclotron and PET CT facilities, and diagnostic radiology facilities.

Industrial and research uses include large industrial irradiators, neutron generator, NDT facilities, gauges, and research and training facilities. There are a number of disused sources and a waste storage facility. There is a monazite processing pilot plant with a capacity of 60 tons per year.

Facilities and sources licensed by VARANS:

Fig. 1. Facilities (number as of July 2009: 360)

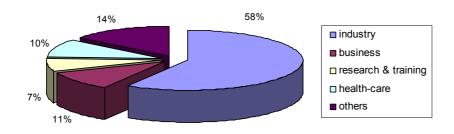
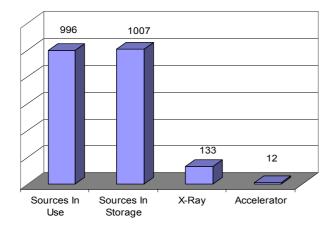


Fig. 2. Radiation sources (number as of July 2009: 2,148)



Facilities and sources licensed by Department of Science and Technology

X-ray diagnosis facilities (as of September 2009): 2,200 X-ray diagnosis equipment (as of September 2009): 2,900

With regard to plans for introducing nuclear power to Vietnam, a pre-feasibility study concluded that the first NPP of 2×1000 MW should be in operation by 2020 and NPPs with total power of 4,000-10,000 MW should be constructed in period of 2021-2030. The priorities for the first NPP locations are Phuoc Dinh and Vinh Hai, in the Ninh Thuan province.

1.2 LEGISLATIVE SYSTEM OF CONTROL

1.2.1 General Requirements

Background

The principle law is the Law on Atomic Energy (Law no. 18/2008/QH12) that came into effect on 1 January 2009. The scope of the law covers activities in the field of atomic energy and the assurance of safety and security for those activities. The law includes the following Chapters: I General provisions; II Measures to promote atomic energy development and applications; III Radiation safety, nuclear safety and security of radioactive sources and nuclear material; IV Radiation facilities; V Nuclear facilities; VI Exploring, mining, milling radioactive ores; VII Transportation and export, import of radioactive materials and nuclear equipment; VIII Supporting services in atomic energy; IX Notification and license issuance; X Emergency preparedness, compensation for radiation and nuclear damage; XI Implementation. Beneath the Law of Atomic Energy is implemented through a matrix of Decrees, Joint Circulars, Circulars, Decisions, Directives, Documents and technical standards. A general explanation of the hierarchy of those various types of instruments is given in Appendix V.

Article 7 of the Law on Atomic Energy assigns responsibilities for the State management of activities^{1,2} in the field of atomic energy to the Ministry of Science and Technology (MOST), with specific responsibilities assigned to the Vietnam Agency for Radiation and Nuclear Safety (VARANS). Other bodies are also required to perform State management activities in the regulation of atomic energy in accordance with their responsibilities designated by the Government. These other bodies include:

- Departments of Science and Technology (General radiation and nuclear safety in the provinces, including licensing and inspection of diagnostic X ray equipment)
- Ministry of Health and Departments of Health (protection of patients, health checks on workers, and irradiated or radioactive consumer products, emergency planning)

¹ Activities in the field of atomic energy includes activities involving scientific research and technological development in the field of atomic energy; construction, operation, maintenance, exploitation, management and decommissioning of nuclear facilities and radiation facilities; exploration, exploitation, processing and utilization of radioactive ores; production, storage, use, transportation, transfer, exportation and importation of radioactive sources, radiation devices, nuclear fuels, source materials, nuclear materials and nuclear devices; treatment and storage of radioactive wastes; and supporting services for the application of atomic energy.

² The definition of 'activities in the field of atomic energy' includes promotional activities as well as regulation of safety; this report considers only those aspects related to regulatory safety issues.

- Ministry of Natural Resources and Environment (exploring, mining, milling, processing radioactive ores, environmental impact assessment for NPP & waste facilities, environmental monitoring)
- Ministry of Construction (planning sites for future radwaste disposal and storage)
- Ministry of Industry and Trade (licensing of the future NPP)

Responsibilities for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides are described in the Law on Atomic Energy, Articles 8, 33 & 77. Additionally, inspection is covered by Law on Inspection No. 22/2004/QH11 and Decree No. 87/2006/ND on the organization and operation of the Science and Technology Inspectorate. Sanctions against administrative violations in the field of radiation safety and control are given in Decree No. 51/2006/ND-CP which is now under revision.

The functions, tasks, authorities and organization of the Ministry of Science and Technology are given in Decree No. 28/2008/ND-CP; and the functions, responsibilities and authority of Divisions under the Vietnam Agency for Radiation and Nuclear Safety (VARANS) are specified in Ministerial Decision No: 136/QĐ-ATBXHN. Human resources are described in Article 16 of the Law on Atomic Energy, and the financing of VARANS is mentioned in DECISION No. 2248/QĐ-BKHCN on Promulgating the Charter of Organization and Operation of the Vietnam Agency for Radiation and Nuclear Safety. In addition to VARANS, the Vietnam Atomic Energy Institute (VAEI) is part of MOST and, among other responsibilities, has a role in the operation of nuclear facilities and promotion of atomic energy in Vietnam.

The organization and mandate of the VARANS's Inspectorate is given in Decision No. 483/QD-BKHCN by the Minister of Science and Technology dated on April 2nd 2007, and this is modified in Decision No. 1112/QD-BKHCN by the Minister of Science and Technology dated on June 20th 2007. Additional information concerning the authorities, operation and duties of VARANS are contained in Decision No. 2248/QD-BKHCN by the Minister of Science and Technology dated on October 10th 2008.

Additional information on staffing and resources are further discussed in Chapter 3, Organization of the Regulatory Body.

VARANS is charged only with ensuring safety, as described in Article 8 of the Law on Atomic Energy. However, the Ministry of Science and Technology, Ministry of Industry and Trade and Ministry of Natural Resources and Environment have both promotional and regulatory roles described in Article 14 of the Law on Atomic Energy.

Radiation facilities are required to submit a safety analysis report when applying for a license and a safety analysis report must include the tentative plan for operation termination, dismantlement and decontamination (Articles 35 and 39 of the Law on Atomic Energy). Dismantlement and decontamination of radiation facilities are covered by Article 36, and nuclear facilities are covered by Article 40 of the Law.

The safe transport of radioactive material is covered by the Law on Atomic Energy Chapter VII Part I, and Circular No. 14/2003/TT-BKHCN which is now under revision.

Requirements for emergency preparedness and response are specified in the Law on Atomic Energy Chapter X, Part 1 – in which Article 83, Paragraph 4, specifies plans for radiation and nuclear incidents response at national level.

Security is covered by several articles of the Law on Atomic Energy, plus there is Directive No. 13/2006/CT-BKHCN on Strengthening the State management on Radiation Safety and Radioactive Source Security; and Decision No. 115/2007/QD-TTg on issuing Regulations on Ensuring the Security of Radioactive Sources.

The manager of the licensed organization and licensees conducting radiation practices are responsible for safety and security, and for compliance with provisions of the Law on Atomic Energy, Article 26.

Comments

Regulatory independence

The main responsibility for regulating radiation and nuclear safety has been assigned to MOST and VARANS (which is within MOST). However, one of the biggest licensees, the Vietnam Atomic Energy Institute (VAEI) is also within MOST. Moreover, MOST is involved in both operational and promotional activities. VAEI operates the research reactor (including radioisotope production), a waste storage facility at Dalat, and many other licensed facilities where radiation sources are used. In addition, VAEI provides technical support for the development programme for nuclear power. This situation, where the operator of a research reactor (that produces isotopes for health care and many other facilities requiring a license or authorization) reports to the same Minister as the regulatory body, may raise questions about the independence of regulatory decisions.

Furthermore, VARANS is a relatively new organization compared to VAEI, and, therefore, does not have so many staff that are as experienced as staff at VAEI. Because of its technical expertise, VAEI is often called upon to provide advice to a variety of portions of the Government, including VARANS, and at the Ministerial level, which, because of its promotional responsibilities, could also lead to other possible conflicts of interest.

The issue of independence between the regulator and promotional uses of radiation can also be seen in the Ministry of Natural Resources and Environment, where that ministry issues licences to bodies for ore mining and processing that are located within the same ministry.

Looking to the future introduction of nuclear power, a possible conflict of interest may occur if MOIT issue licences for reactors to EVN which is within the same ministry. This is further complicated by the fact that VAEI (which is in MOST) will likely provide technical services to EVN, but at the same time regulatory functions (including when the license should be issued, inspection and enforcement during both construction and operation of the facility) will be carried out by VARANS who are also in MOST.

Staffing and financing

While legislative mechanisms are in place to provide staffing and financing for VARANS, there is nothing explicit in the legal system to ensure that such resources are adequate. See also Chapter 3 and Appendix VIII.

Emergency preparedness and response

While the legislative basis for emergency response has been established, it has not yet been implemented, as discussed in Chapter 6.

1.2.2 Legislative Requirements

Background

The objectives for protecting individuals, society and the environment from radiation hazards are established by the Law on Atomic Energy, and the facilities and activities included in the scope of the Law are described in the relevant Articles.

The Ministry of Science and Technology is required to provide detailed regulations and guidelines on exemption levels for notification and licensing, clearance level, procedures for verification, appraisal, approval and measures for clearance of radioactive sources, radioactively contaminated objects (Article 33 (k)).

Notification and issuing of licenses (authorization) is covered by Chapter IX of the Law on Atomic Energy.

Removal from regulatory control for both radiation and nuclear facilities is covered by Articles 36 and, 40 of the Law on Atomic Energy, and these articles specify the requirements for licensees to follow. These Articles also require that MOST specify procedures, formalities for verification and approval of plans for dismantlement, decontamination and handling of radioactive sources, nuclear fuel, nuclear equipment and radioactive waste.

Provisions for the review of, and appeal against, regulatory decisions are covered by Decree No. 51/2006/ND-CP (on sanctioning administrative violations in the field of radiation safety and control).

Continuity of responsibility when activities are carried out by several successive operators and for the recording of the transfers of responsibility are covered by the Law on Atomic Energy in Articles 29, 72, and 73.

The creation of independent advisory bodies to provide expert opinion to the Government and Regulatory Body are covered by the Law on Atomic Energy in Articles 9 and 68.

The State policy on atomic energy (Article 5 of the Law on Atomic Energy) mentions a commitment to 'invest' in many areas, inter alia, nuclear power development, infrastructure, technology and human resource so as to ensure safety and security; but research and development in safety is not explicit.

The arrangements for provision of financial security in respect of liabilities are covered by the Law on Atomic Energy Chapter X, Part 2, 'Compensation for Damage.'

Responsibilities and obligations in respect to financial provisions for radioactive waste management and decommissioning are placed on the radiation facility (Law on Atomic Energy, Article 36) and on nuclear facilities (Law on Atomic Energy, Article 40).

A description of offences and the corresponding penalties is in Decree No. 51/2006/ND-CP 'Sanctioning administrative violation in radiation safety and control'.

The application of other laws and international treaties is specified in Article 4(3) of the Law on Atomic Energy, which states that in case of conflict between the provisions of this law (Law on Atomic Energy) and those of the international treaties of which Vietnam is a party, the provisions of those treaties shall apply.

The public and other bodies are required to be involved in the regulatory process (Articles 7, 46, and 47 paragraph 2 (k) of the Law on Atomic Energy). Because of its long history of technical competence, the Vietnam Atomic Energy Institute (VAEI) has a specific role in providing technical support and advice in the drafting and review of regulatory instruments.

In relation to the GS-R-1 requirement (2.4(17)) for legislation to apply to both new and existing facilities and activities, the Law on Atomic Energy came into effect on 1 January 2009 and nullified the previous legal instrument, the 'Ordinance on Radiation Safety and Control.' The Ordinance required that an organization or individual that possessed a radiation establishment, a radiation source, a place for storing radioactive waste, or conducted radiation work before the date when the Ordinance took effect must make a declaration and apply for registration papers and permits.

In relation to legislation ensuring that the safety requirements of the Regulatory Body remain in force where other authorities fail to meet the requirement of independence, the principles for the assurance of safety and security are stated in the Law on Atomic Energy (Article 6(2)). In Article 77(c) and (d), the Law requires that other specified Ministries should base their licensing decisions on recommendations from MOST. Inspection Law No. 22/2004/QHI I, and Decree No. 87/2006/ND-CP dated August 28th 2006 on the Organization and Operation of the Science and Technology Inspectorate require that inspections be based on facts and the law (in general, not just the Law on Atomic Energy).

The regulatory bodies are granted authority to develop safety principles and criteria; and to establish regulations and issue guidance in Articles 8 and 33 of the Law on Atomic Energy.

The regulatory body has the authority:

- to require any radiation or nuclear facility to conduct a safety assessment. This authority is specifically set forth in Articles 19, 35, 39 of the Law on Atomic Energy. Articles 8 and 20 provide additional support for this authority;
- to require that any operator provide it with all necessary information, as set forth in Articles 29(2), Article 26(6), and Article 84 (1)(d) of the Law on Atomic Energy, specified information must be submitted when requested. In addition, Articles 75 and 76 prescribe the documents required for the application process;
- to issue, amend, suspend or revoke licenses and to set conditions, as set forth in Articles 77, 78, and 79;
- to require an operator to perform a systematic safety reassessment or a periodic safety review, as set forth in Articles 19 and 20 of the Law on Atomic Energy, which require that those conducting radiation practices must submit a report annually or whenever requested by VARANS. In addition, Articles 35, and 39 require assessments at the time of application or request for modification of an authorization;
- to conduct a variety of inspection types, including "unscheduled" inspections as set forth in Inspection Law No. 22/2004/QHI I, and Decree No. 87/2006/ND-CP dated 28 August 2006;
- to enforce regulatory requirements. Article 8(4) of the Law on Atomic Energy empowers VARANS to conduct enforcement actions. In addition, the Decree No. 28/2008/ND-CP, Defining the Functions, Tasks, Powers and Organizational Structure of the Ministry of Science and Technology directs MOST to inspect and handle violations in atomic energy development and use as well as to assure radiation and nuclear safety. Circular No. 10/2006/TT, Guides on Inspection Specializing in

- Radiation Safety and Control, in Section A.II recognizes the authority of the Departments of Science and Technology to conduct inspections and enforcement;
- Since VARANS is within MOST, it can communicate directly with the Minister of MOST. Furthermore, MOST has regulatory responsibilities, and the Minister can communicate with governmental authorities at higher levels.
- to obtain documents and opinions from private or public organizations or persons as may be deemed necessary and appropriate. There are requirements in the Law on Atomic Energy in specific areas such as developing legal documents, inspection and penalizing violations. In addition, the Law on Promulgation of Legal Documents, No. 17/2008/QH12, requires that agencies/organizations must collect comments on legal documents and issues from those affected and others. In addition, that law assigns specific responsibility for review and comment on particular issues to various Ministries;
- to communicate independently its regulatory requirements, decisions and opinions and their basis to the public. In accordance with a law in press, the Regulatory Body has the right and duty to provide the mass media correct information in a timely manner and is legally responsible for the information provided. In addition, Article 85 of the Law on Atomic Energy requires that prompt and accurate information be provided to the local population regarding incidents, but it is not specific about making other documents public. In addition, the Law on the Press, dated 28 December 1989, in Article 4, provides a general authorization for citizens to provide information to the press. As explained by VARANS leadership, this provides authorization for VARANS to provide appropriate information to the press and public;
- to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information. Article 84(4) of the Law on Atomic Energy authorizes the provision of information by MOST to the media and other countries and organizations. Article 85 requires that prompt and accurate information be provided to the local population regarding incidents;
- In accordance with the Law on Atomic Energy, to co-ordinate among the governmental bodies in areas of radiation and nuclear safety, and radioactive source security. Article 57 of the Law on Atomic Energy requires the co-ordination of a number of Ministries in the provision of public information concerning nuclear power plant operation. Article 81 requires the collaboration of the MOST and the Ministry of Industry and Trade in the process for constructing and licensing nuclear power plants. Article 83 of the Law requires the collaboration of various Ministries in the development of national response plans;
- to "carry out international cooperation activities" as set forth in Article 8(9) of the Law on Atomic Energy.

Comments

Objectives of protection

The Law on Atomic Energy sets out the objectives for protecting individuals, society and the environment, but it does not explicitly mention considerations for the future. The IRRS team was however informed that in the Vietnamese language, these issues are covered implicitly in the Law.

Graded approach to notification and authorization

All practices and activities that are above exemption levels require notification and licensing (Chapter IX of the Law on Atomic Energy). The Ministry of Science and Technology is responsible for developing regulations and guides relating to exemption, notification and licensing (Article 33 item 1 clause 1 and Article 81). A technical regulation on exemption levels for notification, licensing and learance level is now under development. Moreover, the graded approach was also considered in the Circular no. 10/2006/TT-BKHCN Guiding on Inspection specializing in Radiation Safety and Control dated 17 May 2006.

Exemption and clearance

At present, the TCVN 6870:2001 referred to in Circular 05 has provisions on exemption from notification, registration and licensing. It is currently under revision and amendment in order to comply with the Law on Atomic Energy, and clearance levels will be included.

Removal from regulatory control

MOST has not yet specified the procedures and formalities specified in Articles 36(5) and 40(5) of the Law on Atomic. VARANS is drafting a proposed circular (legal instrument) to be issued by MOST.

Research and development for safety

In the Master Plan for implementation of the Strategy for peaceful uses of atomic energy up to 2020, there is Project 17 on developing scientific research and technological development programme for applications of radiation energy and ensuring radiation and nuclear safety.

Liabilities in the event of nuclear damage

It is understood that a legal instrument is being prepared that will require insurance and the establishment of a support fund for damage compensation.

Contact and co-ordination at the staff level

Efficiency and effectiveness of the Regulatory Body would be enhanced if the Ministries involved in the Regulatory Body developed and implemented an agreed protocol or Memorandum of Understanding, to facilitate co-ordination at all levels.

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:**

GS-R-1, para 2.2 (2) states that "A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgments can be made, and enforcement actions taken, without pressure from interests that may conflict with safety."

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R1 **Recommendation:**

The Government should make legal provisions to clarify and strengthen regulatory independence within and across MOST, MOIT, and MONRE, to ensure there is clear separation between the functions of regulation and promotion or operation of radiation and nuclear activities.

(1) **BASIS:**

GS-R-1, para 2.2. (4) states that "The regulatory body shall be provided with...adequate staffing and financial resources to discharge its assigned responsibilities."

R2 Recommendation:

The Government should ensure that VARANS has adequate staffing and financial resources to discharge their assigned responsibilities, both now and in the future.

(1) **BASIS:**

GS-R-1, 2.4(2) states that "Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation:... (2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation"

R3 Recommendation:

The Ministry of Science and Technology should provide detailed regulations and guidelines on exemption levels for notification and licensing, clearance level, procedures for verification, appraisal, approval and measures for clearance of radioactive sources, radioactively contaminated objects, as required by Article 33 (k) of the Law on Atomic Energy.

(1) **BASIS:**

GS-R-1, 2.4(3) states that "Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation:... (3) shall establish authorization and other processes (such as notification and exemption), with account taken of the potential magnitude and nature of the hazard associated with the

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

facility or activity, and shall specify the steps of the processes."

R4 Recommendation:

A graded approach to authorization, inspection and enforcement should be incorporated into the legal structure.

(1) **BASIS:**

GS-R-1 Para 2.4(6) states that "The legislation...shall specify the process for removal of a facility or activity from regulatory control."

R5 **Recommendation**

MOST should issue the Circular proposed by VARANS which specifies the procedures and formalities described in Articles 36(5) and 40(5)).

(1)**<u>BASIS:</u>**

GS-R-1 para 2.4 (10) states that "The legislation... shall set up a means whereby research and development work is undertaken in important areas of safety."

S1 Suggestion:

VARANS should be involved in the development of the national strategy for research and development to improve safety and such research and development should be further expanded.

(1) **BASIS:**

GS-R-1, 2.4 (11) states that "The Legislation...shall define liabilities in respect of nuclear damage."

S2 **Suggestion:**

Even though the legal basis for liabilities is in place, the proposed draft legal instrument to implement the requirements of the Law on Atomic Energy by Articles (90(2) & 91(3)) should be issued.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

2.1 FULFILLING STATUTORY OBLIGATIONS

2.1.1 Definition of safety principles and associated criteria

Background

Article 5 and Article 6 of the Law on Atomic Energy define policy and safety principles. Article 5 defines priority for investment in developing peaceful use of nuclear energy and safety and security infrastructure. Article 6 states that "State Management on safety and security shall be independent and scientific based".

Other principles are given by several articles in the Law, such as prohibitions (art. 12) and defence in depth (art. 23).

Article 26 of the Law on Atomic Energy clarifies the "Responsibilities of the manager of the licensed organization and licensees conducting radiation practices". Among other responsibilities, the licensee is "responsible for safety and security, and for compliance with provisions of this Law in conducting radiation practices".

The Law on Atomic Energy does not include a provision about the promotion of safety culture.

Comment

The "prime responsibility of the operator" safety principle is defined by IAEA safety Fundamental n°1:

- "the prime responsibility for safety must rest with the person or organization responsible for facilities that give to radiation risks" (principle 1);
- "The person or organization responsible for any facility or activity that gives rise to radiation risks or for carrying out a programme of actions to reduce radiation exposure has the prime responsibility for safety." (§3.3);
- "The licensee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated" (§3.5).)

In addition to the article 6 of the Law on Atomic Energy, the decrees and regulations under the Law could develop and explain more in details this safety principle, as well as they could promote safety culture.

When developing the regulation, more development on the promotion of safety culture could be included. The action 5.2 of the action plan has to be extended to all activities regulated by VARANS.

2.1.2 Discharge of regulatory body's responsibilities and functions

Background

As described in Chapter 1, responsibilities and functions of the regulatory body, MOST and VARANS (which is inside MOST), are assigned by the Law on Atomic Energy and its related decrees, and by the law on inspection.

MOST and VARANS, on behalf of the Minister, are empowered to issue regulations and guides on radiation safety, nuclear safety, security of radioactive sources, nuclear material and nuclear facilities through (see Chapter 4.4 on the development of regulation and guides):

- Legally binding Circulars;
- Legally binding National Technical regulations;
- Technical Standards;
- Minister decisions.

Article 19, 41 and 47 of the Law on Atomic Energy provide clear provisions for the submissions of safety assessment reports by the operator when applying for an authorization. The requirement for an annual report on safety is one condition specified in the authorizations granted by the regulatory body.

MOST and VARANS issue, amend, suspend or revoke authorizations, and moreover review and assess submissions on safety from the operators prior to authorization in the fields for radiation activities (see Chapter 4.1 on authorization and 4.2 on review and assessment).

Application dossiers prepared by operators are required to include emergency response plans which provide for reporting to the Regulatory Body in cases of incidents or abnormal events. Plus the operators are required, through a licence condition, to submit an annual report on safety, which has to include reports on incidents. However, there are no provisions for the prompt reporting of incidents that are not considered to be emergencies.

The discharge of responsibilities of VARANS in the area of inspection and enforcement are addressed in Chapter 4.3 and in the area of authorization in chapter 4.1.

Chapter X of the Law on Atomic Energy assign responsibilities in the field of emergency preparedness, including the role devoted to MOST in such cases (see Chapter 6).

VARANS reports on an annual basis to MOST on its own activities (such as the number of inspections and licensees issued). However, the annual report does not include a description of the status of radiation and nuclear safety in Vietnam and no report is submitted to the government or to the public. Since the research reactor at Dalat produces a significant quantity of radionuclides for domestic medical use, the Ministry of Health may consider taking a more active interest in the safety of the reactor. Indeed, the domestic production of some radioisotopes in Vietnam relies only on DALAT research reactor (I131, Tc99m). This reactor was commissioned in 1963 and now faces ageing management difficulties, so that the renewal of the licence was limited to 5 years in 2009, and under the conditions of reviewing ageing management of the operator on an annual basis.

If unsafe or potentially unsafe conditions are detected and corrective actions are taken by the operator, the regulatory body does not assess the impact of corrective actions using root cause analysis or operating experience feedback (domestic or international).

The competence of personnel responsible for the safe operation of facilities or operation is provided through the certification of radiation workers (art. 28 of Law on Atomic Energy).

Comment

IAEA Safety Fundamental 1 states in chapter 3.17 that "Despite all measures taken, accidents may occur. The precursors to accidents have to be identified and analysed, and measures have to be taken to prevent the recurrence of accidents. The feedback of operating experience from facilities and activities — and, where relevant, from elsewhere — is a key means of enhancing safety."

The report of abnormal events or incidents is very important for a regulatory body in order to discharge its responsibilities to apply this principle and regarding assessing the safety of licensees. Moreover, if no provisions are made, a licensee could underestimate the effect of an incident or even an accident and might not inform the regulatory body at an early stage. National feedback of experience can also in some cases be necessary after occurrence of an incident. Incidents can indeed occur, for instance in radiotherapy, and it is a priority for the regulatory body to analyze such incidents. The early information on abnormal events, incident or accident is also needed to make it possible for the regulatory body to decide whether to make a reactive inspection (as defined in GS-G-1.3). In order to put such process of notification in place, the criteria for evaluating the severity of an incident or abnormal event are needed. For each criterion, a time limit for notification is needed, as well as provision for public information. VARANS can easily have access to criteria used in foreign countries to help issuing a regulation in this field.

The IAEA Safety Fundamentals states in chapter 3.10 states that "The regulatory body shall (...) set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes". The annual report of VARANS does not include general information on the status of radiation and nuclear safety in Vietnam. Publication of this information, for instance on internet, could help to keep the public and other governmental bodies informed about the control of radiation and nuclear safety in Vietnam.

In particular, specific information could be provided to other governmental bodies on the safety situation of the Dalat research reactor. In case of occurrence of a long shut-down of the Dalat reactor, for safety reasons, the Government could face a risk of shortage of some radioisotopes whose supply is needed for domestic nuclear medicine diagnosis or treatment. This situation is particularly topical in the context of a potential world shortage of such radioisotopes. In such a case, the Government could have to make a difficult cost-benefit decision: either restarting the reactor with increased safety risks, or to give priority to safety and face a radioisotope shortage. As the government is in charge of unifying the overall State Management, VARANS and MOST could usefully inform the government of the situation of the Dalat research reactor on a regular basis, in order to make its State Management easier if a long shut-down of the reactor would be necessary for safety reasons.

2.2 REGULATORY BODY – COOPERATION WITH OTHER RELEVANT AUTHORITIES

2.2.1 Environmental protection, public and occupational health, water use and consumption of food, emergency planning and preparedness, land use and planning

Background

Article 32 of the Law on Atomic Energy assigns a common responsibility to the Ministry of Natural Resources and Environment and to VARANS to "identify locations having natural exposure level that would possibly pose harmful impacts on people and require the intervention of the competent body; organize investigation and assessment of hazardous potentials; inform the Provincial's People's Committees for cooperation in making plan and implementing necessary measures to minimise the harmful impacts". VARANS has moreover under article 33 the responsibility to provide detailed regulations and guidelines on "identifications of locations where natural exposure would possibly pose harmful impacts on people and would require intervention from the competent body".

In 2009, a university expert published a report about a high background level of radioactivity in a region of Lai Chau province. The various relevant bodies then had to cooperate without a clear assignment of responsibilities apart from article 32 of the Law on Atomic Energy. MOST has collaborated with DOST and local authorities, with VARANS assessing the situation from a technical point of view.

The responsibilities are also not clarified in the area of control of the radiological quality of water. MOST and VARANS have never been contacted by other ministries to regulate this area or to make any measurements.

Article 33 and Article 66 define responsibilities for the Ministry of Health in the field of periodic health check for radiation workers, and control of medical exposure, import of irradiated or radioactive consumer products.

The safety assessment report of Dalat research reactor is based on an exclusion area within a 300 meter radius circle centred on the stack of the facility. However, a city street, Nguyen-Tu-Luc, transverses the exclusion area 100 meter distant from the reactor. Beyond the 300 meter radius there are a few residential houses but three institutions are in the area of a 1,5km radius of the reactor, so that the population in this circle exceeds 10000 people every day.

Comment

A regulation or an administrative instruction needs to be developed to prescribe more clearly the collaboration needed in all areas for which VARANS has to cooperate with other authorities (MOH, MONRE, etc). Cooperation between relevant bodies of the government in these areas needs to be proceduralized to be more effective. Actions listed in chapter 1.2 of the action plan, which lead to several joint circulars and regulations, the actions 2.1 and 2.2 will help to address this issue but have to be reviewed and completed.

In particular, the land use and planning around the Dalat research reactor needs to be reviewed to ensure optimization of doses in normal operation and in case of any accidents.

2.2.2 Radioactive waste management

Background

According to article 14 of the Law on Atomic Energy, the Ministry of Construction is responsible for the long-term planning for radioactive waste disposal sites. According to article 33 of the Law on Atomic Energy, the Minister of Science and Technology shall provide detailed regulations and guidelines on handling and storage of radioactive waste, disused radioactive sources and spent nuclear fuel, requirements for the national radioactive waste storage and disposal sites of radioactive waste.

Comment

Currently, there is no national policy for radioactive waste management, and the responsibilities to issue such a policy are not clearly mentioned in the legislation. IAEA Safety fundamentals states in its chapter 3.29 that "Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management. The generation of radioactive waste must be kept to the minimum practicable level by means of appropriate design measures and procedures, such as the recycling and reuse of material."

A national policy and strategic plan for a sustainable management of radioactive wastes are needed to appraise the existing management modes of radioactive wastes, to identify the foreseeable needs for storage or disposal installations, to state the necessary capacities for these installations and the storage timeframes and, for radioactive wastes which are not yet the subject of a definitive management mode. This would also provide for the implementation of research and studies on the management of radioactive materials and wastes by setting dates for the implementation of new management modes and the creation of installations or the modification of existing ones so as to meet the needs and aims defined in the strategic plan. Roles and responsibilities between the various State bodies and Ministries regarding the regulation of management of waste have to be more clearly defined in the regulations.

2.3 REGULATORY BODY – ADDITIONAL FUNCTIONS

Background

The technical support centre for VARANS provides radiation safety services to licensees, such as quality control measurements for X ray diagnostics, environmental monitoring or calculation of shielding.

Comments

There is the potential for conflict of interest because the technical support centre, which is part of VARANS, provides advice to both VARANS and to licensees.

RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

GS-R-1 §3.1 states that "the regulatory body shall define policies, safety principles and associated criteria."

(2)**BASIS:**

GS-R-1 §2.3 states that "the prime responsibility for safety shall be assigned to the operator. (...) Compliance with the requirements imposed by the regulatory body shall not relieve the operator of its prime responsibility for safety."

S3 <u>Suggestion:</u>

The "prime responsibility for safety of the operator" principle, addressed in article 6 of the Law on Atomic Energy, should be more developed and explained in further regulation.

(1)**BASIS:**

GS-R-1 §3.3 states that "The regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public."

(2)**BASIS:**

GS-R-1 §3.4 states that "the regulatory body shall co-operate with other relevant authorities, advise them and provide with information on safety matters in the following areas, as necessary: environmental protection, public and occupational health, emergency planning and preparedness, radioactive waste, public liability, physical protection and safeguards, water use and consumption of food, land use and planning."

S4 Suggestion:

VARANS should expand its communication and information policies and report to other governmental bodies and to the public on the safety aspects (including health and environmental aspects) of facilities and activities and on its regulatory processes.

S5 Suggestion:

MOST should keep the Government informed about the safety aspects of the Dalat research reactor, due to the role played by the reactor in the supply of radioisotopes for Vietnam.

Recommendation:

VARANS should identify all areas where it has to cooperate with other relevant authorities.

RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S6 Suggestion:

The Government should develop a regulation or an administrative instruction for these areas to clarify the roles and responsibilities, and facilitate more direct communication.

(1)**BASIS:**

GS-R-1 §3.2 states that "(...) authorizations, (...) shall specify (vii) the requirements for incident reporting".

BASIS:

GS-R-1 §3.3 states that the regulatory body "shall ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated."

(3)**<u>BASIS</u>**:

GS-G-1.4 §4.14 states that "The operator should notify the regulatory body of any event considered significant to safety. The time limit for and type of notification should be established in regulations (...)."

BASIS:

GS-G-1.4 §4.15 states that "(...) a report [shall be] prepared and submitted to the regulatory body within a specified period of time (...".

S7 <u>Suggestion</u>:

A regulation should be issued to:

- put a process in place for notification of abnormal events, incidents or accidents according to criteria defining the severity of the event;
- establish a time limit for notification considering these criteria;
- establish a requirement for the operator to report on the events occurring, to the regulatory body within a specified period of time, depending on their severity;
- facilitate dissemination.

(1) BASIS:

GS-R-1 §3.4 states that "The regulatory body shall co-operate with other relevant authorities, advise them and provide with information on safety matters in the [area] of radioactive waste (including determination of national policy".

(2)**<u>BASIS</u>**:

GS-G-2.7 § **3.1 states that** "The management of all radioactive waste is required to take place within an appropriate national legal infrastructure

RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

that provides a clear allocation of responsibilities".

(3)**BASIS**:

GS-G-2.7 § **3.2 states that** "A national strategy for the Management of radioactive waste should be developed in accordance with the safety objectives and principles"

R7 Recommendation:

VARANS and MOST should cooperate with other relevant governmental bodies to issue a national strategy plan for a sustainable management of radioactive wastes, which defines aims and needs. This plan should appraise the existing management modes of radioactive wastes, identify the foreseeable needs for storage or disposal installations, provide for the implementation of research and studies on the management of radioactive wastes and define roles and responsibilities between State Agencies and Ministries.

(1)**<u>BASIS</u>**:

GS-R-1 §3.5 states that "when [additional functions] are undertaken care shall be taken by the regulatory body to ensure that any conflict with its regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished".

R8 Recommendation:

VARANS should takes steps to satisfy themselves that the work of their Technical Support Centre does not lead to conficts of interest, especially when advice is provided to licenees.

R9 Recommendation:

The Government should conduct a review to determine other places in the regulatory body where there may be conflicts of interest as a result of technical support services, and take action to avoid the conflict.

3. ORGANIZATION OF THE REGULATORY BODY

3.1 GENERAL ORGANIZATION

Background

The "Regulatory Body" in Vietnam consists of more than one organization (authority) and the regulatory responsibilities of each authority as they are outlined in the legislation are described below. If not stated otherwise the Law means the Law on Atomic Energy No. 18/2008-QH12.

The Agency for Radiation and Nuclear Safety (VARANS) is the institution which covers the majority of the functions of the regulatory body. Its organizational structure is defined in the Decision No. 2248/QD-BKHCN on Promulgating the Charter of Organization and Operation of the VARANS of 10 October 2008 and issued by the Minister of Science and Technology. VARANS was established in 2003 and it grew from 8 people in 2005 to 61 at present. VARANS is within the Ministry of Science and Technology (MOST) whose functions, tasks, powers and organizational structure is defined in the Governmental Decree no. 28/2008/ND-CP of 14 March 2008. MOST has many entities, one of them being the Vietnam Atomic Energy Institute, which does research in the area of nuclear energy and safety as well as in the application of nuclear and radiation techniques. The Director General of VARANS is responsible for the day-to-day management of the VARANS and he reports to the Minister of Science and Technology.

VARANS is divided into seven divisions for organizational and administrative matters, and a technical support unit and compliance between the functions and structure are described below. (See Appendix IX for the VARANS organizational chart).

Table 1: Matching of VARANS functions and responsibilities with its organizational structure (both taken from the Decision No. 2248/QD-BKHCN)

| VARANS responsibility | Responsible VARANS unit |
|---|----------------------------|
| Development of drafts of regulations, standards, technical regulations, guidelines on radiation safety, nuclear safety and security | All Divisions |
| Development for submission to the Ministry of Science and Technology the development orientation, 5 year- and yearly plans on the duties of ensuring safety, security and nuclear control/safeguards; | Management + All Divisions |
| Directing, instructing, executing and verifying the implementation of the approved programmes and plans | Management |
| Declaration of radioactive materials, radiation devices, nuclear material, nuclear equipment and the issuance, extension, amendment or revocation* of licenses for conducting radiation practices and safety certificates for | Licensing Division |

| radiation workers | |
|---|--|
| Safety verification of radiation practices; security verification of radioactive sources, nuclear material and nuclear facilities | Licensing Division Nuclear Safety Division |
| Checking, inspecting, and enforcing the law | VARANS Inspectorate |
| The implementation of nuclear control/safeguards activities | Nuclear Control Division |
| Carrying out the state management on radioactive waste, to monitor the radioactivity of the environment, to control occupational exposure, public exposure and medical exposure | Technical Support Centre for radiation safety and emergency response |
| Providing guidance on the development of and check the implementation of emergency preparedness for nuclear incidents; to participate in emergency response | Technical Support Centre for radiation safety and emergency response The Agency's Inspectorate |
| Developing and updating the information system on safety, security; to develop and manage the system of nuclear accounting and control | Nuclear Control Division Legislation and Information Division |
| Organizing and cooperating in the organization of basic training, supplementary training, occupational training on safety, security and nuclear control | Administration and Personnel Division |
| Providing technical support to the state management on safety, security; to conduct researches on the application of scientific and technological advances; and to carry out safety and security services | Technical Support Center |
| Organizing international cooperation activities in nuclear safety, security and control | International Cooperation Division |

^{*} VARANS inspectors can revoke and suspend licenses only by the decision issued by the MOST Chief Inspector.

The other institutions which may assume the role of regulatory body are stipulated in Art.7 of the Law: (a) MOST has the authority to issue all licenses for conducting radiation activities except for those listed in (b), (c) and (d); (b) Provincial Committees issue licenses for X-ray equipment in medical diagnostics; (c) MONRE issues licenses for exploring, mining, milling, processing radioactive ores based on safety assessment report provided by VARANS; (d) MOIT will issue licenses for operating nuclear power plants after obtaining consensus from MOST and the National Nuclear Safety Committee. Therefore MOST, MONRE and MOIT are the authorities which issue licenses.

The Prime Minister has also the following roles:

- in case of NPP he/she receives a set of documents (dossier), which consists of: application for permit of construction investment; detailed design of the nuclear power plant; report on assessment of environmental impacts; results from verification of the report on assessment of environmental impacts; safety analysis report; quality assurance programme for the construction; (Art. 48)
- in case of shipment of radioactive materials through the territory of Vietnam (transit) he/she issues a license; (Art. 64).

The Law in Art. 48 does not state who should review and implement the documents which come to the Prime Minister. According to counterparts these activities should be done by the National Council for Nuclear Safety which is defined in Art. 9. The Council consists of permanent members and assisting sub-committees. The assisting sub-committees can be assembled and its structure adapted to the actual needs.

The Ministry of Health also has a regulatory role, because it is responsible for:

- providing detailed regulations and guidance on periodic health check for radiation workers and for guidance levels and control of medical exposure (Art. 33),
- specifying the list of irradiated or radioactive consumer products that are permitted to be imported (Art. 66).

The Decree on the organization and operation of the Science and Technology Inspectorate No.87/2006/ND-CP authorizes the MOST Inspectorate to penalize administrative violation as regulated by the laws on penalizing administrative violations (Art.6 (4) of the Decree).

The status of VARANS inspectors is as follows:

- it was recognized that radiation and nuclear safety is a specific area, which needs special qualifications, thus with the Decision of the Minister of Science and Technology (Ministerial Decree) an inspection unit was established within VARANS;
- VARANS Inspectorate was established in April 2007. VARANS inspectors thus have not yet been granted with inspector badges in accordance with the Law on Inspection;
- VARANS inspectors are not authorized to perform enforcement against violations in the field of atomic energy. For issues relating to enforcement, VARANS inspectors have to go through MOST's or DOST's Inspectorate.
- MOST inspectors are entitled to enforce the law, while the VARANS inspectors do not have this power;
- in most cases, the inspections consist of VARANS and MOST inspectors. VARANS inspectors perform joint inspections also with DOST inspectors. Sometimes all three institutions cooperate in carrying out inspections.

The VARANS Director General issues written inspection orders for each inspection to VARANS inspectors, which enable them to carry out the inspection.

There is a mechanism for appeal, and as a last resort, the licensee can take the case to the court.

Provincial Departments of Science and Technology (DOSTs) are assigned to grant authorizations for X-ray machines in diagnostic medicine and to carry out radiation safety inspections in line with the provisions of Article 8(13). In the DOST, there is a division charged with authorization and the Department Inspectorate inspects individuals and

organizations using radiation sources in the provinces. Within DOST, the division responsible for authorization and inspection also carry out other tasks at the same time.

Technical Service Organizations (TSOs) and consultants have not been widely used. Most consultancies were provided cost-free to VARANS (i.e. some consultant support was also provided from the VAEI in case of licensing of research reactor, independent peer reviews of licence applications have also been undertaken through the IAEA). Procedures and criteria how to select (authorize) consultants do not exist. There are, however, no formal arrangements (requirements) in place to ensure that the consultants are independent from the operator.

The various regulatory authorities are not entirely self-sufficient in all technical and functional areas therefore they need to occasionally utilize the services of consultants. Procedures and criteria how to select (authorize) consultants do not exist.

Comments

While VARANS is not responsible for the promotion of nuclear energy or radiation practices, VARANS is part of MOST and VARANS supports the work of other ministries, who issue licenses and who are also responsible for promotion. This situation in the absence of clear arrangements between various authorities with regulatory responsibilities can compromise independence as well as efficiency and effectiveness of the regulatory body.

The Law does not provide for clear separation between promotional and regulatory roles of different organizations involved in licensing of radiation practices, sources and nuclear installations. Both MOST and MOIT are explicitly accountable for the promotion of atomic energy (Art. 7(2)). For instance, VARANS and VAEI belong to MOST and are under direction of the same Vice Minister, while EVN belongs to MOIT. Another example how promotion and independence can come very close is Art. 2 (11) of the Governmental Decree no. 28/2008/ND-CP which contains in the same paragraph the tasks and powers regarding atomic energy and radiation and nuclear safety.

There is a lack of detailed regulations for information exchange and feedback among regulatory authorities, since the regulatory body consists of many authorities.

A decision-maker is also the Prime Minister, who has promotion and safety aspects separated in the two advisory bodies advising him/her (i.e. National Council for Nuclear Safety and State Assessment Council), but in practice and by the Law both aspects combined at the Prime Minister level.

The coordination among the various regulatory authorities addressed in the Law on Atomic Energy does not appear to be guided by procedure. One example is the various authorities involved in site assessment in Article 47 of the Law. Since the Law was effective only in this year, decrees have not been issued to describe the levels and processes to be used for coordinating the necessary feedback and exchange of information.

DOST is the licensing authority for X ray machines in the provinces. However, DOST has other functions apart from those related to radiation safety. On the other hand, DOST is a unit under the People's Committee, not the specialized agency for radiation and nuclear safety. Therefore, in the future, VARANS may consider establishing branches in other parts of the country (e.g. the Middle and the South of Vietnam) to provide more direct support to the regulatory activities in provinces/cities.

The Technical Support Center is a unit within VARANS which offers services to other institutions, especially in the area of checking of medical equipment (X ray machines, fluoroscopy, computed tomography). The Ministerial Decision also assigns some responsibilities for "carrying out the state management on radioactive waste" to the Center. Such activities of Technical Support Center might compromise the independence of VARANS.

VARANS inspectors cannot be considered as fully fledged inspectors as the name suggests, because they do not have power and authority of inspectors, neither are they ranked as inspectors or integrated into the inspection system. Their link with the inspection is the MOST Inspectorate, although the VARANS Director General issues individual inspection orders to VARANS inspectors, which enable them to undertake inspection.

VARANS need to address outsourcing (i.e. use of Technical Support Organizations and/or consultants) for specific areas of expertise, since it does not currently have the capacity or competence to cover all relevant regulatory functions.

3.2 STAFFING AND TRAINING OF THE REGULATORY BODY

Background

Staffing

The current staff of VARANS is distributed as follows (altogether they are 63):

| Administration and Personnel Division | |
|--|----|
| Licensing Division | |
| Legislation and Information Division | |
| The Agency's Inspectorate | |
| Nuclear Control Division | |
| Nuclear Safety Division | |
| International Cooperation Division | |
| Technical Support Centre for radiation safety and emergency response | 13 |

There are two types of employment defined by the Art 5 of the Ministerial Decision No. 2248/QD-BKHCN of 10 October 2008. These types of employment are: regular staff employed by the Ministry and the contracted staff. Art. 7 of the same Decision defines sources of incomes, which are:

- From the State budget;
- From fees and charges obtained from licensing which are retained in accordance to the laws;
- From the business and related service activities;
- From other sources in accordance with the laws: such as sponsorships, aids, loans, gifts.

The ratio between regular and contracted staff in VARANS is approximately 50:50. Actually the contracted staff get their income also from different projects assigned to MOST, including those from the Master Plan. The financial means obtained from fees and charges are negligible.

VARANS has two locations, one is in the centre of the Hanoi, the other is about 8 km to the northwest from the main office.

Staff turn-over (fluctuation) is normal, i.e. within expectations for the administration, although income (salary and other opportunities for additional income) is better in the research and science sector. Bearing in mind that VARANS was established in 2003, the staff are relatively young and they have not yet accumulated substantial experience. The number of staff about to retire is not big, thus the knowledge maintenance due to retirement does not seem to be a problem.

VARANS has staff capable of performing regulatory reviews and assessments as well as evaluating reviews and assessments performed for it by consultants. However, VARANS capability in the area of nuclear safety is limited and still under development. The number of staff performing radiation safety assessments is only 10 while on average 600 licenses are issued per year (among the 600 licenses, there are about 100 licenses for operating radiation facilities). There is a plan for human resource development for the licensing division, and the safety assessment for the research reactor licensing involves the participation of the VARANS Scientific Council.

At DOSTs, the number of staff and equipment used for regulatory activities are limited and in most DOSTs they do not meet requirements for discharging their responsibilities. Often DOST staff do not reach the same level of understanding in radiation safety as VARANS staff.

Training

At present, the Government is developing projects in the Master Plan to provide training for personnel of the regulatory body, and to improve and enhance the competence of state management. The Director General, with all three Deputy Directors General, were responsible for preparing such a project. It has not yet been approved by the Minister, but the approximate assessed figures (not based on a thorough analysis) show that about 50 people are needed to perform radiation protection activities, while an additional 50-100 people are needed to work on regulation and inspection of research reactor and nuclear safety and NPP in the near future.

There is no approved training programme for the regulatory body staff.

Staff performing review and assessment have degrees in nuclear physics or nuclear technology or environmental techniques. VARANS staff receive domestic training at different graduate and post-graduate courses (MSc, PhD) in the country, and they are also sent abroad. Attending IAEA courses is a regular practice. More than 200 participants have taken part in IAEA courses and other events in the last three years. More detail about available training programmes is in Chapter 8 "Education and Training".

Other organizations which provide appropriate competence as well as training are the Institute for Nuclear Science and Techniques, the Nuclear Research Institute, the Ho Chi Minh Nuclear Centre, the Ha Noi University of Technologies.

Example of inspector's training

Persons appointed to the inspection rank must fully meet the following criteria (ref. Article 31 Law on Inspection):

- Having university degree;
- Having State management and legal knowledge;
- Specialized inspectors must also have professional knowledge of their respective specialized branches;
- Having professional inspection skills (attending 3 month course);
- -Having been engaged in inspection work for at least two years, for persons newly recruited into the inspection branch (excluding probation period); for officials and State employees transferred from other agencies or organizations to State inspection agencies, they must have been engaged in inspection work for at least one year.

Comments

Staffing

VARANS need qualified and knowledgeable staff. For instance, VARANS cannot meet the annual inspection goals (frequency of inspection), which were set in line with the IAEA recommendations, even by cooperating with the DOST inspectors.

The majority of VARANS staff are not government officials and are covered by a labor agreement to work for VARANS. Therefore this situation makes staff working on a labor agreement in an inferior position and this may be a reason for staff to leave VARANS.

Although the VARANS organizational structure to a certain extent meets the functional requirements as depicted in Table 1 above, challenges do exist within VARANS and the DOSTs regarding the number of competent staff. The staff of the DOSTs are responsible for a wide range of activities, and conducting oversight of radiation protection practices and facilities are not their main function. Consequently, they frequently do not have the technical skills necessary to conduct regulatory oversight without additional training, which is provided by VARANS.

Available infrastructure needs to be reviewed if it meets the responsibilities assigned to VARANS because it seems it is not sufficient (i.e. premises are rather small and in two locations, measuring equipment needs redundancy, vehicles need to be arranged beforehand, and software (computer codes to perform assessment) is needed).

Training

For VARANS staff a relatively simple training programme could be established on a regular basis, paying attention to the new employees that need to receive training and education appropriate for their work. It is advisable taking into account the current tradition (practice) of attending established courses for a specific post. This programme should be at least annually reviewed by the VARANS management to see if the programme goals have been met.

The qualification process for becoming an inspector at VARANS does not guarantee that the inspector will receive enforcement authorization when carrying out inspections in the field of

radiation and nuclear safety. The qualification process only prepares the potential inspector in the manner in which inspections are carried out.

3.3 ADVISORY BODIES TO THE REGULATORY BODY

Background

The VARANS Director General has appointed a Scientific Council to advise him on different issues (strategy, policy, licensing) within the scope of VARANS' responsibilities. Members are not paid for the work but receive meeting fees.

There are also advisory bodies to the Government/Prime Minister.

- The National Council for Nuclear Safety, Art. 9(2),
- -Council for Atomic Energy Development and Application, Art. 9 (1).

There is also the State Council for Assessment mentioned in Article 47(2)(i) and Article 48 (2)(i). This Council produces a report for the Prime Minister about different stages of projects, which were filled in by the applicants (for instance, about a proposal for nuclear power plant construction or for site approval).

The Government is going to establish the National Council for Nuclear Safety to provide expert advice to the Prime Minister in the field of nuclear safety, while the decision about its establishment is still in draft. The Council for Atomic Energy Development and Application was designated to promote nuclear energy, but is still not established.

Comments

The VARANS Scientific Council is reasonably effective in its operation, but it needs to be expanded to include members knowledgeable in nuclear safety.

Attention should be paid in order that the National Council for Nuclear Safety, when it comes into effect, does not relieve VARANS from making decisions and recommendations.

3.4 RELATIONS BETWEEN THE REGULATORY BODY AND THE OPERATOR

Background

Informal relations between the regulatory body and the operator are mainly influenced by the exchange of information at conferences, seminars and meetings, but this process is random and it depends on personal relations. The regulatory body also tries to meet the demand for training and exercises from the licensees by organizing appropriate events for them.

The IRRS team members who visited licensees reported about correct relations between the operator and the regulator, and inspectors were given the necessary support needed to carry out their work. On the other hand it was also noted that some operators were not satisfied with competence shown by the regulator's representatives. This issue may stem from the fact that the licensee's expectations were simply too high.

Comments

The regulatory body is active in promoting a frank, open and formal relationship with the operator. Meeting licensee's requests is a positive practice, but it should not interfere with the operator's prime responsibility for safety, as well as independence from the operator.

Mutual respect is gained also from the informal relations, which are not governed by the administrative procedure. In addition, high levels of regulatory competence can contribute to improving the mutual relations between the regulatory body and the operator.

3.5 INTERNATIONAL COOPERATION

Background

Vietnam has made a political commitment to implement the Code of Conduct on the Safety and Security of Radioactive Sources, and the Code's supplementary guidance on Import/Export.

Vietnam is a party to:

- Nuclear Nonproliferation Treaty;
- Safeguards Agreement;
- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Comprehensive Test Ban Treaty;
- Bangkok Treaty (Weapons Free Zone in SE Asia); and

Vietnam has signed the Additional Protocol (AP) to the Safeguards Agreement and is considering becoming a party to the following instruments:

- Convention on Nuclear Safety;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Convention on Physical Protection of Nuclear Materials (CPPNM);
- Vienna Convention on Civil Liability for Nuclear Damage.

Comments

Good international relations are important in contributing to the regulatory body to making sound and justified decisions. Nevertheless, Vietnam should be more proactive in meeting current obligations such as establishing a contact point from the Convention on Early Notification (see recommendation in Ch. 6) and as a country with the intention to start with nuclear power it would be beneficial to join the CNS and the Joint Convention.

ORGANIZATION OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

GS-R-1, para 4.1 states "The regulatory body's reporting line in the governmental infrastructure shall ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation-related technologies, or those responsible for facilities or activities."

ORGANIZATION OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R10 **Recommendation:**

MOST should ensure that the reporting lines of its bodies charged with regulatory functions preserve the independence of regulatory decision making from those bodies charged with promotional activities. The same principle should be applied to other relevant Ministries involved in regulatory activities.

R11 Recommendation:

The Government should ensure that the National Council for Nuclear Safety, when advising the Prime Minister and when reviewing and assessing reports made by VARANS, does not relieve VARANS of its responsibility for making decisions and recommendations.

(1) **BASIS:**

GS-R-1, para 4.2 states "If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated."

R12 **Recommendation:**

The Government should ensure that the various regulatory authorities appropriately coordinate their regulatory activities at the national level, including the relevant Councils of the Prime Minister, and also at the provincial level.

(1)**BASIS:**

GS-R-1 Para 4.3 states" If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants..."

S8 Suggestion:

In those areas in which VARANS is not entirely self sufficient, mechanisms and resources should be provided for VARANS to use external services. Accordingly, they should develop criteria for authorization of external consultants and ensure their independence from the operator.

(1)**<u>BASIS:</u>**

GS-R-1 Para 4.3 states: "... Whoever may provide such advice or assistance, arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized."

G1 Good practice:

VARANS use of international peer review teams and services is a good

ORGANIZATION OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

practice.

(1) **BASIS:** GS-R-1 Para 4.6 states "The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities."

S9 <u>Suggestion:</u>

Thorough analysis of staffing and qualification needs should be done and this should be reflected in a VARANS management document.

The staffing and competence issues should be systematically addressed regularly at least once a year and corrective actions should be adopted.

(1) **BASIS:** GS-R-1 Para 4.7 states "In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes..."

S10 Suggestion:

VARANS should establish a training programme for its staff on an annual basis paying attention that new staff receives adequate training and address the areas where there is a lack of expertise, e.g. establish on the job training in medical area for inspectors.

BASIS:

GS-R-1 Para 4.1 states "The regulatory body...shall be provided with adequate resources...to discharge its responsibilities."

BASIS:

GS-R-1 Para 4.8 states "Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants."

R13 Recommendation:

The regulatory body should be provided with the necessary staff with the necessary skills to meet its statutory responsibilities, including staff who are capable of performing safety assessments for the scope of radiation/nuclear infrastructure which exists in the country.

(1) BASIS:

GS-R-1 Para 4.11: ...National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfill safety obligations and to promote cooperation.

ORGANIZATION OF THE REGULATORY BODY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

G2 Good Practice:

VARANS is very engaged in the framework of international cooperation to gain as much experience as possible. It cooperates with, and has concluded bilateral agreements with, some countries that have developed nuclear power programmes worldwide and in the region. These activities support and complement the statutory requirement to incorporate international best practices and experience into regulatory decisions.

4. ACTIVITIES OF THE REGULATORY BODY

4.1 **AUTHORIZATION**

4.1.1 Authorization of industrial and research facilities and activities

Background

63 DOSTs issue licenses for the operation of X-ray diagnosis machines;

The MOST Minister issues licenses for:

- Accelerators:
- Industrial and research irradiation facilities;
- Teletherapy sources.

(VARANS reviews applications and prepares, submits draft license, renewal license or refusal letter).

Also, VARANS issues:

- Other specific licenses
- Registration of Services in supporting the Nuclear Energy Field;
- Certificate of Radiation Workers.

GS-R-1 5.2

Article 72 of the Law on Atomic Energy no. 18/2008-QH12: provides that organizations, individuals possessing radioactive substances or radioactive waste of radioactivity greater than the exemption level, radiation equipment of capacity higher than the notification level, source materials, nuclear material, and nuclear equipment shall notify VARANS. Article 73 provides that a licence is required for organizations and individuals who carry out radiation practices except when exempt.

RAISVN (Regulatory Authority Information System Vietnamese) is established based on the RAIS (Regulatory Authority Information System) provided by the IAEA. This programme includes 3 main modules:

- The module to support web-based authorization with tracking the movement of radiation sources:
- The module for inspection;
- The module to retain the national database of radioactive sources, radiation facilities, radiation practices, individual dose, inspection. The database includes data provided by VARANS and 63 Provincial Departments of Science and Technology.

GS-R-1 5.3

Prior to the granting of an authorization, the applicants are required to submit a detailed safety assessment report appropriate to the facility, activity or practice. As required in Section III, IV, V in Chapter II of the Circular No. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology. Section VII of this Circular and Article 19 of the Law

on Atomic Energy no. 18/2008-QH12 specifies the principal contents of safety assessment report.

Applications for authorization are reviewed and assessed by VARANS in accordance with Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology. A written procedure for handling the applications for registration certificate, licence for radiation related practice promulgated by the Decision no. 117/QD-ATBXHN dated on 17 October 2006; and Articles 75 and 76 of the Law on Atomic Energy no. 18/2008-QH12. This information is also required in (Vietnamese) the Official Letter no. 134 BKHCN-ATBXHN dated 23 Jan 2009 by the Minister of MOST and this provides authorization procedures in line with the Law on Atomic Energy no. 18/2008-QH12.

Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology guiding declaration and authorization of radiation-related practices does not use a risk based approach to consider the potential magnitude and nature of the hazard presented by the radiation facility and practice. However, for some specific activities, the radiation safety assessment is required to include complementary information as listed in item 2 of Section VII, Chapter II of the Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology.

Article 74 of the Law on Atomic Energy no. 18/2008-QH12 provides for the authorization duration to be based on the magnitude and nature of the radiation source's potential hazard.

GS-R-1 5.4

VARANS issues guidance to the operator on the format and content of documents to be submitted in support of an application for authorization, as specified in Appendix III and Appendix IV of Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology guiding declaration and authorization issuance for radiation-related practices. Detailed information required in support of authorization requests is also provided in (Vietnamese) the Official Letter no. 134 BKHCN-ATBXHN dated 23 January 2009 by the Minister of MOST providing authorization procedures in line with the Law on Atomic Energy no. 18/2008-QH12.

The operator is required to submit within an agreed time scale all information that is specified and requested by the Regulatory Body. Section XV, Chapter II of Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology guiding declaration and authorization issuance for radiation-related practices specifies that: Within 5 working days of receiving the application, the Regulatory Body shall notify the applicant of information required to be supplemented. If that information is not submitted within 30 days of notification (based on the postmark), the Regulatory Body may refuse to issue the authorization and does not have to return the application.

Several stages of authorization are only applied to nuclear facilities, where separate licences are issued for discrete stages. Those licences include: licence for construction, licence for comissioning licence for operation, licence for modification, licence for nuclear fuel conversion (for nuclear reactor), license for decommissioning. Those licences are specified in the Articles 38, 41, 47 of the Law on Atomic Energy no. 18/2008-QH12.

The Law on Atomic Energy no. 18/2008-QH12 and the Circular no. 05/2006/TT-BKHCN dated 11 January 2006 by the Ministry of Science and Technology guiding declaration and authorization issuance for radiation-related practices do not required separate licences for

discrete stages. On the contrary in some cases a licence is issued for several activities for example import, export and transportation of radioactive sources. When several discrete stages of authorization are involved, each stage is subject to review and assessment, with account taken of feedback from the previous stages, as prescribed in Article 43 of the Law on Atomic Energy no. 18/2008-QH12.

GS-R-1 5.5

Following the review and assessment and in granting an authorization, VARANS may impose conditions and limitations on the operator's activities as appropriate. These conditions are listed on page 2 of the Licence. The licence for operating the research reactor clearly states the limits and conditions for its operation.

VARANS formally records the basis for granting or refusing an authorization and this information is communicated to the applicant in the case of refusing the authorization.

Clearly defined procedures for any subsequent amendment, renewal, suspension or revocation of an authorization have not yet been fully developed. However:

- Decree No. 51 on sanctions against administrative violations specifies that together with the suspension of license, individuals, organizations shall take measures to remedy consequences.
- Item 2, Article 79 of Law on Atomic Energy prescribes that organizations, individuals that have their licenses revoked for violation of safety and security provisions may only be considered for re-issuance twenty four months after the license is revoked.

GS-R-1 5.6

There are requirements for the timely submission of applications for renewal or amendment of authorizations:

- Renewal of licence: Item 2, Article 78, Law on Atomic Energy specifies the time for application for renewal of licence.
- Amendment of licence: Item 1, Article 78, Law on Atomic Energy specifies that organizations and individuals that wish to have their licences modified shall send their application to competent state agencies.

VARANS ensures that the review and assessment for the amendment and renewal of an authorization are commensurate with the potential magnitude and nature of the hazard. Item 3, Article 78, Law on Atomic Energy specifies dossiers, process and procedures for modifying and extending licenses.

Comments

Applications for authorization should be reviewed and assessed using clearly defined procedures. All current written procedures are for handling the applications for registration certificates or licenses for radiation related practice.

Article 72 of the Law on Atomic Energy no. 18/2008-QH12 provides that organizations, and individuals possessing radioactive substances or radioactive waste of radioactivity greater than the exemption level, radiation equipment of capacity higher than the notification level,

source materials, nuclear material, and nuclear equipment shall notify the agency as required in Para 3 of Article 22. Possess is not one of 'radiation practices' as defined in Article 18. Ownership and transfer is also not one of 'radiation practices' as defined in Article 18. Since possessesion, ownership and transfer are not defined under Article 22, this means that it is not controlled by license. It is advisable that VARANS should control these types of practices in 'license conditions' issued under Para C of Article 22. As required in GS-R-1 Para 5.2, these activities alternatively may be authorized in general to be performed in strict accordance with detailed technical regulations.

Under the Para 3 of Article 22, VARANS is responsible for establishing and updating the state control system of radioactive sources and nuclear material. Since X-ray equipment is also controlled by license (refer to Para 2(b) of Article 77), an inventory system for X-ray equipment needs to be developed.

The IAEA has developed RAIS 3.1 Web and it is available for Member States. It is advisable that VARANS translate this new version rather than develop its own version of RAIS to support web-based authorization.

The processes for authorizing of industrial and research facilities could be improved and made more effective by ensuring that the processes are commensurate with the potential magnitude and nature of the hazard presented by the radiation facility and practice.

Several discrete stages of authorization should be used for other significant practices, not only nuclear facilities.

Clearly defined procedures for any subsequent amendment, renewal, suspension or revocation of an authorization have yet to be fully developed.

ACTIVITIES OF THE REGULATORY BODY:

AUTHORIZATION OF INDUSTRIAL AND RESEARCH FACILITIES AND ACTIVITIES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1 5.2 states that "... alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations ...".

R14 Recommendation:

Activities of possession, ownership and transfer should be included in the detailed technical regulations.

BASIS:

GS-R-1 5.3 states that "[the] detailed demonstration of safety (...) shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures."

ACTIVITIES OF THE REGULATORY BODY:

AUTHORIZATION OF INDUSTRIAL AND RESEARCH FACILITIES AND ACTIVITIES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R15 Recommendation:

VARANS should improve their procedures for the handling and assessment of applications for registration certificate, license for radiation related practice. This should include technical criteria for detailed demonstration of safety.

S11 <u>Suggestion:</u>

VARANS should evaluate the use of RAIS 3.1 Web rather than developing its own version of RAIS to support web-based authorization.

(1)**BASIS:**

GS-R-1 5.4 states that "the regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization".

R16 **Recommendation:**

The requirement for authorization of radiation-related practices should be commensurate with the potential magnitude and nature of the hazard presented by the radiation facility and practice.

Several discrete stages of authorization should be considered for other practices, not only nuclear facilities.

(1)**<u>BASIS</u>**:

GS-R-1 5.6 states that "any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure."

R17 Recommendation:

VARANS should develop clearly defined procedures for any subsequent amendment, renewal, suspension or revocation of an authorization. This should include technical criteria for detailed demonstration of safety.

4.1.2 Authorization of medical facilities and activities

Background

According to Art.73(1) and Art.18 of the Law on Atomic Energy, all radiological medical practices require notification to the regulatory body in Vietnam.

There are currently no exempt medical practices. MOST specify a list of radiation work involving the use of radioactive sources and radiation equipment for which licences are not required (Article 81 item 1b).

Authorization of radiotherapy and nuclear medicine practices is carried out by VARANS or MOST. The 63 provincial offices of DOST authorize only diagnostic X ray practices, i.e. CT scanner, interventional radiology, OPG dental equipment, conventional X ray apparatus, fluoroscopy and mammography in their province.

Licenses for radiotherapy have a validity of 5 years and those for diagnostic radiology and nuclear medicine, 3 years (Art. 74 (6), (7) of the Law on Atomic Energy).

Technical information is required to be submitted by the applicant for a license, including a radiation safety assessment report in accordance to Article 19 of the Law on Atomic Energy.

Circular No.05/2006/TT-BKHCN guides the procedures of notification, registration and license issuance to radiation-related activities and also provides the detailed requirements on the format and content of the documents to be submitted by the operator. Generic procedures have been developed for licensing medical facilities.

As provided for in Articles 77, 78 & 79 of the Law on Atomic Energy, the regulatory body is able to impose conditions on the scope of radiation activities that can be carried out by the licensee. However, in the case of medical practices, implementation of imposing conditions on the licensees' activities is waiting for detailed regulations to be issued by the Ministry of Health (Art. 33(2)(b) Law on Atomic Energy).

Licensees may request amendments to the license. The process to request an amendment to request licence conditions are specified in Circular No.05/2006/TT-BKHCN.

Comments

There is no distinction between the processes used for authorizing different types of medical practices (i.e.: no risk based/graded approach). For example, interventional radiology and diagnostic X ray are authorized in the same manner, even though the radiation doses to patients may be very different.

Regarding licensing of radiotherapy and nuclear medicine practices, MOST will normally issue the license for these types of facilities that require detailed assessment. The decentralization of authority in issuing radiation safety registrations and licenses is reflected in Decision No. 2314 /QĐ-BKHCN which gives a list of radiation safety registrations and licenses issued by VARANS. However, this Decision does not explicitly specify which licenses for medical facilities should be issued by VARANS.

While procedures have been developed in accordance with Circular No.05/2006/TT-BKHCN, they are not prioritized according to the relative complexity of each medical practice. Applicants are not required to include within the license application a specific detailed demonstration of radiation protection of the patient.

The Regulations required by Art 33(2)(b) of the Law on Atomic Energy, when implemented, should enable the regulatory body to impose license conditions in the field of radiological protection of patients.

ACTIVITIES OF THE REGULATORY BODY: AUTHORIZATION OF MEDICAL FACILITIES AND ACTIVITIES RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

BASIS:

S-R-1 5.3 states that ".....The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented.....".

R18 Recommendation:

A graded approach should be implemented for the authorization of radiological medical practices.

S12 **Suggestion:**

To facilitate the graded approach to licensing, medical practices could be considered to be four distinct areas: Radiotherapy, Nuclear medicine, Interventional radiology and Diagnostic radiology. These four areas could then be further subdivided according to the relative risk.

(1)**BASIS:**

GS-R-1 5.5 states that "...At a certain stage in the authorization process, the regulatory body shall take formal actions which will result either:

(1) the granting of an authorization ... ".

R19 **Recommendation**:

MOST and VARANS should establish a formal procedure determining which medical practices will be licensed by MOST and which will be licensed by VARANS.

4.1.3 Authorization of the research reactor

Background

Chapter V of the Law on Atomic Energy is dedicated to nuclear facilities. It contains common provisions for all nuclear facilities, including nuclear research reactors, nuclear power plants, facilities for uranium enrichment and nuclear fuel fabrication, facilities for storage, handling and disposure of spent nuclear fuel:

- Documents to be included in application for site approval;
- The principle of necessary compliance of selection site, construction, modifications of operation or scope and scale of nuclear facilities, with national technical standards;
- The obligation to submit a safety analysis report when applying for permit of construction, modifications of operation scope and scale, termination of operation, operating research reactors and operating nuclear power plants;
- The obligation to submit a safety assessment report when nuclear facilities apply for license or renewal of license for conducting radiation practices, except for operating research reactors and operating nuclear power plant;
- Provision for decommissioning and decontamination of nuclear facilities.

Additional specific provisions are given for nuclear research reactors:

- Documents to be included for permit of construction;
- Obligation to obtain a permit for operation testing before operation testing;
- Obligation to submit to VARANS a report of the operation testing and safety analysis report;
- Responsibility of VARANS to conduct assessment of the report on results from operation testing and safety analysis report, before making a proposal to the Ministry of science and technology in regard to the issuance of permit for operation;
- Responsibility of the Ministry of science and technology to issue the permit of construction and the license for operation.

VARANS recently renewed the licence of the DALAT research reactor.

Three phases appeared in the process of licensing, as listed in Appendix X.

The former license of Dalat research reactor expired March 2009, facing a risk of operation without authorization. To respond to that, MOST has extended through a letter sent to Dalat the term of the former license until the end of the administrative process for review and assessment of the application finalized in February 2009, without any date mentioned in the letter. The Atomic Law brings since January 2009 the obligation for the operator to submit his application 180 days before expiration. To avoid the 2009 case, when writing new regulations about licensing processes, VARANS should take into account the experience to make some provision either to begin its processes for review before 6 months or for limited extension of the license if the review and assessment of the renewal application requires it.

No guidance on the format and content of documents to be submitted by the operator of applications for authorizations in the field of research reactors has been issued.

The atomic law defines more or less implicitly several types of authorization for research reactors granted by MOST:

- Site approval;
- Construction permit;
- Commissioning;
- Operation license;
- Modification of scope and scale of the installation.

In addition, the decommission plan has to be approved by VARANS.

The modification of operation scope and scale of nuclear facilities has to comply with national technical standards, according to article 37 of the Law on Atomic Energy. A safety analysis report is required when applying for permit for such modifications, under article 39 of the Law on Atomic Energy.

Since 2006, MOST has only granted 2 authorizations for modification of DALAT research reactor:

- Replacement of the control system in 2006;
- Modification of fuel characteristics from HEU to LEU in 2007.

The processes followed by VARANS are not documented, but they were similar as for the renewal of the licence, except that:

- MOST did not appoint a special committee. Then VARANS transferred the report and proposed authorization directly to the Minister of Science and Technology;
- The VARANS committee was composed of VARANS Staff and external experts, including foreign experts (IAEA consultants).

There is no definition of the term "modification" in the current legislation and no process is in place to deal with modifications which have an impact safety. The practice is that only the modifications of the installation with very big impact request an authorization from the regulatory body (only 2 in many years).

Neither the legislation nor the Dalat license includes any provision about incident or abnormal event reporting. The operator reports an event only on request by VARANS (only a few cases in many years).

The Dalat licence does not include any provision for environmental monitoring or limits for releases in the environment. No requirements or regulations are in place to regulate theses items. However, a Circular on occupational and public exposure control, which now is being drafted, will take this into account.

Comment

VARANS should take benefit from the recent experience to document the processes to renew a license, firstly in internal VARANS documentation (procedures, guidance) and then include requirements in the legislation and regulation. In particular, safety criteria to review and assess the safety reports have to be developed in the regulation (see also chapter 4.2 on review and assessment).

The circular issued in 2006 concerning guidance on "declaration and authorization issuance of radiation-related practice" (circular 05/2006/TT – BKHCN) and the VARANS DG-decision "promulgating procedures for handling registration and license applications for radiation activities" do not apply to nuclear facilities so that no legal document besides the law exists, i.e. no regulation, procedure or guidance for licensing nuclear facilities.

A set of detailed regulations, clearly defined procedures and guidance documents have not yet been developed to establish a comprehensive process to issue, amend and revoke authorizations for nuclear facilities.

Provisions for regulating releases in the environment and for environmental monitoring requirements have to be included.

No specific actions are identified regarding the licensing of research reactors in the proposed action plan, so that the latter has to be completed.

ACTIVITIES OF THE REGULATORY BODY: AUTHORIZATION OF THE RESEARCH REACTOR RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

GS-R-1 §3.3 states that "In order to discharge its responsibilities (...), the regulatory body

ACTIVITIES OF THE REGULATORY BODY: AUTHORIZATION OF THE RESEARCH REACTOR RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- shall establish a process for dealing with applications, such applications for the issuing of an authorization,

shall establish a process for changing conditions of authorization".

(2)**BASIS:**

GS-R-1 §5.3 states that "[the] detailed demonstration of safety (...) shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures."

BASIS:

GS-R-1 §5.4 states that "the regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization".

(4)**<u>BASIS</u>**:

GS-R-1 §5.6 **states that** "any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure."

(5)**<u>BASIS</u>**:

GS-R-1 §5.5 states that "authorization, which, if appropriate, imposes conditions or limitations on the operator's subsequent activities".

R20 Recommendation:

VARANS should develop a set of detailed regulations, clearly defined procedures and guidance documents to establish a comprehensive process to issue, amend and revoke authorizations for nuclear facilities. The regulation process should ensure that all aspects of safety, including limitation of releases of radioactive material in the environment and environmental monitoring, are covered.

BASIS:

GS-R-1 §5.6 **states that** "any subsequent amendments…of the authorization shall be undertaken in accordance with clearly defined and established procedures".

R21 **Recommendation**:

The regulation should provide criteria to define the modifications of nuclear facilities subjected to a review and assessment and to authorization by the regulatory body, with the potential magnitude and nature of the associated hazard being taken into account.

4.2 REVIEW AND ASSESSMENT

4.2.1 Review and assessment of industrial and research facilities and activities

Background

GS-R-1 §5.7

Chapter IV of the Law on Atomic Energy requires that radiation facilities submit a safety assessment report of radiation facilities which includes operating accelerators, radioisotope production, and irradiation facilities. Review and assessment is done in two section radiation safety and nuclear safety and it covers (list from article 18 and article 34) among other things:

- Accelerator
- Irradiators
- Producing, processing radioactive substances
- Storing and utilizing radioactive substances

The list of radiation practices given in article 18 of law is covered through Decision Promulgating procedures for handling registration and license applications for radiation activities (117/QD-ATBXHN dated 17 October 2006). This includes a requirement for a verification plan, based on potential magnitude and nature of hazards, that contains details about review and assessment.

GS-R-1 §5.8

VARANS do not have a separate circular or procedures for review and assessment but it is covered under Circular 05/2006/TT BKHCN dated 11 January 2006 by MOST guiding declaration and authorization issuance for radiation related practices. The assessment principles and associated criteria to some extent are also given in the annex of the circular. This annex defines the review and assessment principles and some associated criteria for facility, activities and practices under VARANS oversight. The radiation practices under article 18 of the law require the submission of a safety assessment report whose content is also given in article 19, while radiation facilities given in article 34 requires the submission of SAR under article 35 of the law which specifies the content.

GS-R-1 §5.9

Circular 5, requires that a detail verification plan needs to be develop for each activity, facility or practice under VARANS oversight.

GS-R-1 § 5.10

VARANS does not prepare a programme of review and assessment, however, the verification plan is prepared in such a way that it covers all aspects of the review and assessment programme to some extent.

GS-R-1 § 5.11

The Law on Atomic Energy defines, in its Article 42, that safety of modifications of operation or scope and scale of research reactors has to be monitored by VARANS. However, procedures to ensure that safety related modifications are subject to review and assessment

commensurate with the potential magnitude and nature of the hazard presented have not yet been defined.

Comments

VARANS should develop a well defined procedure to ensure that review and assessment is performed in accordance with potential magnitude and nature of the hazard of the practice.

Well defined procedures shall be developed to ensure that review and assessment is performed in accordance with potential magnitude and nature of the hazard of the practice. These procedures shall state and make available to the operator the principles and associated criteria on which decisions are based.

VARANS has to develop procedures to ensure that safety related modifications are subject to review and assessment commensurate with the potential magnitude and nature of the hazard presented.

ACTIVITIES OF THE REGULATORY BODY:

REVIEW AND ASSESSMENT OF INDUSTRIAL AND RESEARCH FACILITIES AND ACTIVITIES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1 §5.7 states that "Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity."

(2)**BASIS:**

GS-R-1 §5.8 states that "In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgments and decisions are based."

R22 Recommendation:

Well defined procedures for industrial and research facilities and activities should be developed by VARANS to ensure that review and assessment is performed in accordance with potential magnitude and nature of the hazard of the practice. These procedures should state and make available to the operator the principles and associated criteria on which decisions are based.

(1) **BASIS**:

GS-R-1 § 5.11 states that "Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated

ACTIVITIES OF THE REGULATORY BODY:

REVIEW AND ASSESSMENT OF INDUSTRIAL AND RESEARCH FACILITIES AND ACTIVITIES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

hazard being taken into account."

R23 Recommendation:

VARANS should develop procedures for industrial and research facilities and activities to ensure that safety related modifications are subject to review and assessment commensurate with the potential magnitude and nature of the hazard presented.

4.2.2 Review and Assessment of Medical Facilities

Background

GS-R-1 5.7-5.11

General procedures for assessment of license applications are in place (Decision No. 117/QD-ATBXHN promulgating Procedures for Handling Registration and License Applications for Radiation Activities), but they are not specific to each type of medical practice (i.e.: no graded approach).

MOST, VARANS and DOST have specific units that deal with the assessment of applications for license. The procedures allow for on-site verification of information in the application as part of the assessment process.

Requirements of assessment of any modification to safety related aspects of a facility or activity are included in Art. 35 (4) of the Law on Atomic Energy.

Comment

The assessment unit of the regulatory body reviews the safety assessment that is submitted by the applicant. However, the assessment units sometimes ask the Technical Support Center for advice.

The potential to allow on-site verification as part of the review and assessment process is a strength of the implementation of the system.

There is a possible potential conflict of interest, as the Technical Support Centers may have performed the safety assessment on behalf of the applicant. In addition, the Technical Support Centers that provide support to the applicants are part of VARANS, MOST, and/or DOST and they are issued with a certificate by MOST (see also Chapter 1 on "Independence of the regulatory body").

ACTIVITIES OF THE REGULATORY BODY: REVIEW AND ASSESSMENT OF MEDICAL FACILITIES RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

GS-R-1 5.7 states that "Review and assessment shall be performed in accordance with ...the potential magnitude and nature of the hazard associated with the particular facility or activity."

R24 Recommendation:

The review and assessment process should be based on a graded approach i.e.: one that takes into consideration the potential magnitude and nature of the hazard, and for medical practices the processes should include specific considerations for the protection of patients.

4.2.3 Review and Assessment of Research Reactor

Background

Safety of the research reactor is regulated through Law18/2008/QH12. MOST is responsible for licensing of research reactor, while review and assessment as well as inspections are performed by VARANS. The requirements for licensing, review and assessment and inspections are drafted by VARANS but approved by MOST. Article 8 of Law`18/2008/OH12 assigns the review and assessment function to VARANS; however, the National Nuclear Safety Council can review and assess the verification reports by VARANS. The safety objectives, principle and concepts of defence in depth are mostly given in Law 18/2008/QH12. Article 41 of the Law also requires a submission of application dossier for permit of construction and operation of nuclear research reactor. At present the regulatory oversight for the research reactor is given by MOST along with VARANS. MOST is responsible for licensing while VARANS performs review, assessment and inspections. The licensing process is elaborate and involves formation of a 'Committee on Safety' by the DG of VARANS to assess the review of SAR by VARANS staff. Article 41 of Law 18/2008/QH12 has many high level requirements, including the requirement for submission of SAR, which constitutes the prime basis for regulatory decision in licensing the nuclear installation and the requirements against which it is licensed and inspected. The content of SAR establishes requirements to be met in the preparation, submission and evaluation of the information included in SAR. Requirements on the format and contents of SAR will be developed after the promulgation of the Decree providing detailed guidance for the implementation of the Law on Atomic Energy.

Article 26 of Law 18/2008/QH12 lays down responsibilities for managers of licensed organization and licensee conducting radiation practices, but neither MOST nor VARANS have explicitly defined in their requirements that the prime responsibility for safety of research reactors over its lifetimes lies with the licensee. This suggests a lack of effective separation of promoting and regulating. There is not much evidence of the existence of a quality management programme for the research reactor.

The research reactor at Dalat has an operation license which states that only staff having radiation worker certificates may operate and repair the nuclear reactor. The research reactor

has shift supervisors and reactor operators. However, an interview with VARANS indicated that MOST or VARANS have not established a syllabus of training/retraining or for examination of shift supervisors and reactor operators other than that is required in Article 28 of Law 18/2008/QH12 which is general in nature.

Comments

GS-R-1 §5.7

Chapter V of Law 18/2008-QH12 requires a site evaluation and safety analysis report for nuclear facilities which includes research reactors, power, plants, uranium enrichment, fuel fabrication and storage, handling and disposal of spent fuel. However, detailed requirements for the review and assessment processes are not defined, although review and assessment is performed in accordance with the stage in the regulatory process and the potential magnitude and nature of hazard. However, there is some subjectivity involved, which needs to be reduced.

GS-R-1 §5.8

VARANS do not have a detailed document specifying the principles and associated criteria on which judgment and regulatory decision are made for research reactor practice. The assessment principles and associated criteria to some extent are given in Law 18/2008/QH12 but there is a need for detail specification for effective implementation of review and assessment process.

GS-R-1 §5.9

According to the authorization process, the DG of VARANS, on receiving the application from the licensee, asks the relevant department of VARANS to prepare a verification plan. This circular requires that a detail verification plan needs to be develop for review of the research reactor. The plan contains resources and schedule; however, this is not shared with the operators. Although the submission of SAR is required, which constitutes the prime basis for regulatory decisions in licensing the nuclear installation and the requirements against which it is licensed and inspected, it was noted that SAR was not reviewed as intended. There is limited understanding of the application of review of SAR in the regulatory decision making process. It appears that both VARANS and MOST have overlooked the need to develop detailed requirements for the format and content of SAR and also VARANS seems to lack the capability for making an integrated assessment of SAR. Although the SAR submitted by Dalat contains a chapter on site characteristics including geology, seismology, metrology, topography, hydrology and population, background interviews with VARANS reviewers indicated that they have no knowledge of site characteristics or its evaluation. This seems to suggest the lack of capacity for review of site characteristic in VARANS.

GS-R-1 § 5.10

VARANS do not prepare a programme of review and assessment, however, the verification plan is prepared in a way that it covers the aspects of the review and assessment programme to some extent but does not follow development of research reactor from initial site selection to closure.

GS-R-1 § 5.11

Article 42 of the Law allows VARANS to monitor modifications of the research reactor, although VARANS has not issued any procedure indicating the renewal process and subsequent requirement for review and assessment of modification. However, in practice VARANS does review the safety related modification to the extent possible, and also have established through operation license Ref. No dated 4 September 2009 that "all modification of reactor core configuration must be notified to VARANS. All modification of characteristics of reactor specified at Appendix 1 and modification relating to radiation and nuclear safety must get permission of MOST".

ACTIVITIES OF THE REGULATORY BODY: REVIEW AND ASSESSMENT OF RESEARCH REACTOR RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1 §5.7 states that "Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity."

R25 Recommendation:

VARANS should define a review and assessment process taking into account the different stages e.g. the design, construction, commissioning, operation and decommissioning of research reactor.

(1)**<u>BASIS</u>**:

GS-R-1 §5.8 states that "In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based."

R26 Recommendation:

VARANS should develop detailed documents specifying the principles and associated criteria on which judgment and regulatory decisions are made for research reactor and make them available to the operators.

(1)**BASIS:**

GS-R-1 §5.9 states that "A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission…shall be performed by the regulatory body…."

R27 Recommendation:

VARANS should develop capacity for review and assessment of technical submission to determine whether the research reactor complies with the relevant safety objectives, principles and criteria.

(1)**<u>BASIS</u>**:

GS-R-1 §5.10 states that "The regulatory body shall prepare its own programme of review and assessment of the facilities and activities

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under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."

R28 Recommendation:

VARANS should develop a detailed programme for review and assessment of research reactor facility so as to follow the development of research reactor from initial selection of site through design, construction, commissioning and operation, to decommissioning and closure.

(1)**BASIS:**

GS-R-1 §5.11 states that "Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account."

R29 Recommendation:

VARANS should define the modification process in the review and assessment so that any modification to safety related aspects of research reactor shall be subjected to thorough review and assessment, taking into account the potential magnitude and nature of associated hazard.

4.3 INSPECTION AND ENFORCEMENT

4.3.1 Inspection and Enforcement of Industrial, Research and Medical Facilities

Regulatory Body to carry out Inspections

Background

Section 11(a) of Decree No. 28/2008/ND-CP, Defining the functions, Tasks, Powers and Organizational Structure of the Ministry of Science, dated 14 March 2008, grants authority to MOST to carry out various functions in the area of atomic energy, of which is the authority to inspect the implementation of programmes and projects on the use of atomic energy.

Article 9 of the Decree No. 87/2006/ND-CP, on the Organization and Operation of the Science and Technology Inspectorate, dated 28 August 2008, provides the tasks and authorities of general department inspectorate, where VARANS is an agency of MOST.

The regulatory body has the authority to carry out inspections, and this is governed by Circular no. 10/2006/TT-BKHCN "Guides on Inspection specializing in Radiation Safety and Control" dated 17 May 2006.

The Law on Inspection, No. 22/2004/QHI I, promulgated on 24 June 2004, prescribes the organization and activities of inspections at the national and provincial levels.

Governmental Decree No. 51/2006/ND-CP on Sanctions against Administrative Violations in the field of Radiation Safety and Control, dated 19 May 2006, was initially proclaimed to implement the Ordinance on Radiation Safety and Control. Although the Ordinance was voided by the implementation of the Law on Atomic Energy on 1 January 2009, this decree remains in effect until it is replaced by a new Decree on administrative penalty which is planned for proclamation in 2009.

Comment

There currently exists a sufficient regulatory framework and the necessary guides for the carrying out of inspections and enforcement at industrial and research facilities. However, much of this framework pre-dates the implementation of the Law on Atomic Energy and therefore may not be currently suitable. In addition, some of these documents, such as Circular No. 10, were adopted directly from IAEA documents and have not been adapted to the system of laws and the regulatory framework of Vietnam. Some work is currently underway to address this issue but resources are limited to complete all required documentation.

Regulatory Body to inspect all areas

Background

Article 14 of the Law on Atomic Energy describes the responsibilities for formulating and approving programmes for atomic energy development. The responsibility of each respective Ministry for the various programmes for atomic energy is detailed in this Article. The Ministry of Science and Technology is given the responsibility to establish the general programme for development and applications of atomic energy.

Articles 68 through 70 describe supporting service for the application of atomic energy, the conditions for an application and certification. All such organizations and individuals who conduct the prescribed supporting services must register with the Ministry of Science and Technology.

Circular No. 10/2006/TT-BKHCN, dated 17 May 2006, clearly provides that the scope and application of inspection specializing in radiation safety control are those within the State management scope of radiation safety in control of the Ministry of Science and Technology.

Comment

Within the current legal framework only MOST, through the system of MOST Inspectorate, VARANS Inspectorate and DOST inspectorate, is responsible for the inspection of nuclear activities and facilities. Item 3 of Article 14 of the Law on Atomic Energy describes the responsibility for inspections.

VARANS is provided with clear direction on the nuclear activities and facilities for which it has the authority to conduct inspections.

Purposes of regulatory inspection and enforcement

Background

Through the provisions of Circular no. 10; MOST, VARANS and the DOSTs are able to ensure that the main purposes of inspections and enforcement are met. The provision of this Circular enables VARANS to examine most areas listed in GS-R-1 section 5.13.

Following an inspection, the inspectors prepare a report, which is given to senior management. In this report, they summarize the inspection and propose suggestions to management regarding further actions for implementation. Senior management at VARANS is then responsible for deciding on which further actions will be pursued.

In the event of generic safety issues, VARANS has several options available to it in order to provide feedback from the inspection process to the overall regulatory control. VARANS management can issue an official letter to some or all facility operators asking them to address specific safety issues. With support from VARANS management, VARANS staff can also organize meetings and workshops with facility operators relating to specific nuclear activities or facilities to discuss ways of improving safety. One such workshop on industrial radiography is being planned for November 2009. Finally, VARANS staff can affect changes in the regulatory approach through either changes in the law, which is a long process, or through the application of new Circulars. Either of these courses of action will require the support of management at VARANS.

In general, VARANS staff makes proposals following each inspection. As noted, the decision on when to implement these proposals rests with VARANS senior management.

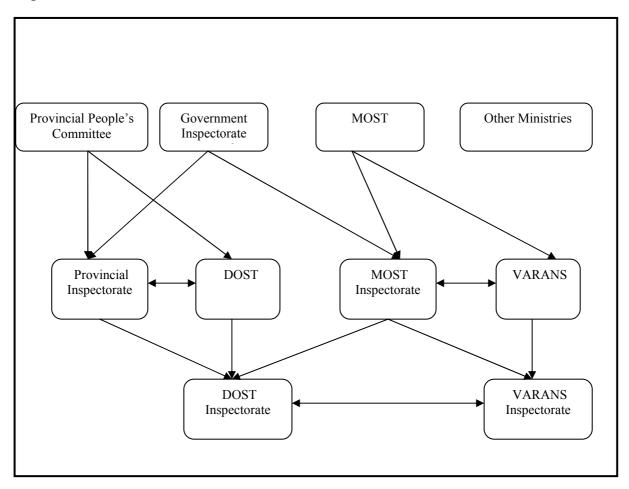
Comment

There are several mechanisms for lessons learned and common safety issues to be communicated to other operators and suppliers as well as the regulatory body as may be required.

Planned and systematic inspection programme

Background

Fig. 3. Interaction between the various groups involved in conducting radiation safety inspections.



The annual planning process for inspections begins in November of each year with VARANS selecting a list of facilities for which it intends to conduct inspections in the coming year. Appendix I of Circular No.10 specifies the frequency of radiation safety and control inspections for various nuclear activities and facilities. It does not provide inspection frequencies for nuclear power or nuclear research reactors. The inspection frequency is provided for each listed practice and it appears that there is some graded approach to the frequency of inspections, based on the risk posed by the practice. All nuclear activities and facilities are inspected at least once, every three years.

The decision on which facilities to inspect is also somewhat based on the results of the inspection programme from the previous year. For example, in 2009 the inspections were focused on the following areas, as a result of inspections that were carried out in 2008:

- import and export;
- radiography;
- nuclear medicine;
- portable gauges;
- oil industry;
- irradiators;
- x ray generating equipment; and,

radiation sources.

Once VARANS has identified a list of facilities that it would like to inspect in the coming year, it sends a letter with a list of the local facilities for each province to the respective DOST. VARANS and DOST may exchange opinions for cooperation to co-organize inspection missions to some facilities.

The MOST inspectorate approves the annual inspection plan proposed by VARANS. To carry out individual inspection missions, the Director General of VARANS will sign the decision on establishment of the inspection mission.

In a similar fashion, each DOST sends its proposed inspection plans to the MOST Inspectorate. It should be noted that each DOST may inspect more facilities than those they inspect with VARANS inspectors. While DOST is authorized to issue license for medical X ray machines, it can perform inspections to any radiation facility and radiation practices within its locality.

Once all of the proposed inspection plans have been received at the MOST Inspectorate, including those from VARANS and each provincial DOST, the MOST Inspectorate reviews all the proposed inspection plans and ensures that they are coordinated and can be carried out. If there is a disagreement between the plans, then the MOST Inspectorate will convene a meeting to resolve the difficulties.

Once the overall plan has been approved by the MOST Inspectorate, formal approval is given by the Chief Inspector of MOST, under authority given in Article 26 of the Law of Inspections. It should be noted that the Minister of MOST also has authority to sign decisions to inspect but this is rarely exercised. The authority of the Minister is only used in the event of an accident or major event. The MOST inspectorate approves the annual inspection plans proposed by VARANS and 63 DOSTs. VARANS has the list of those facilities for which VARANS will carry out inspections.

Comment

VARANS has a planned and systematic inspection programme, although the process is long and complex. Furthermore, it would appear that substantial cooperation has to be obtained from a number of different agencies at both the national and provincial level in order to carry out planned inspections.

The planning for inspections does take into account the nature of the hazard and the potential magnitude of the hazard associated with a facility or activity by basing the proposed inspections on a prescribed inspection frequency and also on the results obtained from the ongoing inspection programme. Consequently, there is good feedback from the results of the inspection programme into the planning for the future inspections.

Announced and Unannounced Inspections

Background

The Law on Inspection allows Ministerial inspectors to carry out announced inspections. Articles 30 and 31 of the Law on Inspection stipulate the requirements for persons designated as Inspectors. Article 32 of this law describes 'Inspection Collaborators' as persons who are not inspectors but have professional knowledge related to the inspection.

Article 34 of the law allows for announced and unannounced inspections to be carried out. Announced inspections must be carried out in accordance with the approved plan. Unexpected inspections may only be carried out as a result of violations of the law or other regulatory requirements or upon receiving information from persons.

Comment

The process for announced inspections is very long and planned far in advance. While this should ensure that the resources are available to conduct the proposed inspections, it also does not allow for flexibility for changing the plan as situations may dictate. In principle, VARANS has to follow the plan. However, in case of necessity, VARANS can perform special inspection or the checking to gain necessary information or to verify the information received from other sourses.

Furthermore, while some unannounced inspections are allowed, the criteria for conducting such inspections are very restrictive and solely reactive. VARANS should be allowed some latitude in conducting such inspections where the circumstances dictate. Such inspections enhance the overall regulatory control by introducing an element of uncertainty for operators. The regulatory programme is enhanced when operators perceive that an inspection is possible at any time. In addition, conducting more unannounced inspections would allow VARANS to continually adjust to changing situations and responding to changes in priorities.

Inspections following abnormal occurrence

Background

The Law on Inspection, No. 22/2004/QHI I, promulgated on 24 June 2004, prescribes the organization and activities of inspections at the national and provincial levels. Article 34 of the law allows for unannounced inspections to be carried out as a result of violations of the law or other regulatory requirements or upon receiving information from persons.

In 2008, VARANS staff carried out approximately 120 inspections of which 115 inspections were in the plan for that year. The remainder was unplanned inspections carried out for specific reasons.

Facility operators are required to send a report to the Director General of VARANS following any abnormal occurrence. The Director General then decides who within VARANS will respond to the issue. If the Director General considers that a sufficient need exists, then the Inspection Division at VARANS will be involved to conduct follow-up. However, to ensure a rapid response, the local DOST can also be used for this function. Normal times for making such responses following receipt of a report are approximately 2-3 days, although it can be immediate if warranted.

Comment

VARANS does not carry out inspections in all cases where an abnormal occurrence has occurred. While some unplanned inspections are carried out, it is not clear whether these were responding to abnormal events. Given the lack of regulatory guidance on the requirements for reporting of abnormal events by operators, it is likely that most abnormal events are not investigated.

Utilization of the local DOST to conduct such inspections is a good way to ensure continued local cooperation and to expedite response to an event. This is a good and effective use of resources.

Inspection reports

Background

In Vietnam, inspection reports comprise more than the conclusions and findings of the inspection. The inspection report comprises all documents associated with that inspection. The time limits between the initiation of an inspection and the preparation of the conclusions are prescribed in the Law on Inspections.

When a planned inspection is to be carried out, a letter is sent to the facility in advance by the VARANS Director General to announce the decision to conduct the inspection.

The inspection team leader then sends a letter to the facility to specify:

- the time and date of the inspection;
- the proposed scope of the inspection;
- a request for a written report on the status of operations in the facility;
- a list of documents that the facility has to prepare for the inspection;
- a list of persons who should be available to work with the inspection team;
- a request for in the management of the facility to be present at the inspection; and,
- a request to provide an escort for the inspection team.

The inspection team leader also sends a letter to the local DOST to inform them of the upcoming inspections in the area.

Inspectors arrive at the facility and assemble in a meeting room to ensure that all persons who are involved in the operation of the facility are at the opening meeting. At the commencement of the inspection, the team leader declares that the inspection is under way and identifies the names and titles of all persons on the inspection team. In addition, the scope of the inspection will be announced, as the inspection will be limited to this stated scope. As noted previously, Vietnamese law limits the number of inspections at any given facility to a maximum of one per year.

Inspections usually begin with a review of the documentation that was requested in the letter sent by the team leader. Following the documentation review, the inspection team will review the operation and other technical components of the facility. Once the inspection team has completed the on-site evaluation, the inspection is concluded for that day. The inspection team will usually meet off site to discuss the findings from that inspection. Later that day or the next, the inspection team will return to the facility to review any additional issues that arose as a result of their discussions following the inspection the previous day. This is an opportunity to ask additional questions and follow-up on issues identified in the inspection.

To close the inspection, all persons who were interviewed by or met with the inspection team are invited to the closeout meeting. At this time, a report is presented to the management using the prescribed form, including space for describing the findings of the inspection, the conclusions of the inspection, any enforcement measures that are required, any recommendations made by the inspection team and the response by the senior management of the facility to the inspection findings. The report is signed by both a senior manager from the

facility in the inspection team leader. All parties involved in the inspection receive a copy of the report, including VARANS, DOST and the facility operator.

Comment

The regulatory body has a very comprehensive process for the preparation of reports of the inspection activities and findings. Throughout the inspection, there is considerable discussion back and forth between the operators and the inspection team regarding particular findings or conclusions. Both the inspection team and the operators have sufficient opportunity to make their positions on these issues. Providing copies of the inspection report at the conclusion of the inspection ensures that operators maintain a sense of awareness regarding the outcome of the inspection and provide immediate feedback to the operator and the facility staff. This prompt feedback is helpful to operators and the immediate interaction with the inspection team ensures that the regulatory requirements are clearly communicated.

Range of enforcement actions

Background

Decree No. 51 sets out the scope of administrative penalties, the sanctioning principles and the forms and consequences of sanctions. This Decree also identifies the various violations and the proposed penalties. In addition, the operator may be compelled to rectify the noncompliance by carrying out specified actions, including decontamination, restoration, recovery and other such methods.

Following an inspection, VARANS Inspectorate provides a summary and general information of the inspection. Recommendations for enforcement actions or any timelines that are proposed by the team leader for implementation of the corrective actions will be given in the inspection report made at the witness of the operator. The proposed enforcement actions and the timelines for their implementation are based in large part on the expertise of the team leader for the inspection, with input from the other team members.

Comment

Decree 51 does allow the regulatory body to take enforcement action in the event of noncompliance with administrative requirements, as defined in the Decree. Furthermore the enforcement actions allow for some latitude that can reflect the seriousness of the noncompliance. A variety of enforcement options are available to the regulatory body, including warnings and penalties. However, withdrawal of the authorization is only permitted for up to six months. There could be situations where withdrawal of the authorization should be for longer periods or even permanent. The limit for the withdrawal of the authorization of six months is unduly restrictive. Furthermore, the withdrawal of authorizations is an enforcement action that is rarely taken.

There is sufficient provision in the current Decree to require the operator to carry out remedial measures as may be necessary.

However, the proposal for enforcement actions at medical facilities is complicated by the additional pressure to maintain health services to the local population. The regulatory enforcement in the field of medical facilities should be discussed and coordinated amongst MOST, VARANS, the DOSTs and the Ministry of Health.

Background

Pursuant to the Law on Inspections, at the conclusion of an inspection a report is presented to the facility operator using the prescribed form, which describes the findings of the inspection, the conclusions of the inspection, any enforcement measures that are required and any recommendations made by the inspection team. While issues related to operation or protection of the facility are provided with timelines for correction, typically no timeline is provided for the remediation of issues of minor safety significance.

Comment

This system for resolving deviations from or violations of, requirements or unsatisfactory situations which have minor safety significance is widely used and therefore is appropriately implemented by VARANS. In practice, facility operators generally carry out most remediation efforts within one year following the inspection with any uncompleted issues the subject of the following inspection.

Ability to curtail activities

Background

Decree No. 51 specifies that in addition to any other administrative penalty, the operator may be compelled to rectify the noncompliance by carrying out specified actions, including decontamination, restoration, recovery and other such methods. Furthermore, the operator can be made to forfeit the use of radioactive materials for a period of up to six months.

Comment

There is a sufficient range of administrative sanctions available to the regulatory body to ensure that the operator applies an effective remedy to the item of noncompliance. The regulatory body may compel the operator to take specific actions including restoration, renovation, destruction, excavation and decontamination in order to rectify the situation and restore normal order. As noted previously, the regulatory body should be allowed to remove the authorization for periods longer than six months, up to and including permanent removal of the authorization to deal with the most serious issues of noncompliance.

Potential to suspend or revoke authorization

Background

Article 4, item 2 of Decree No. 51 specifies that in addition to any other administrative penalty, the operator may be compelled to rectify the noncompliance by carrying out specified actions, including decontamination, restoration, recovery and other such methods. The time limit for implementing such measures is not specified.

Comment

There are sufficient sanctions available to the regulatory body to compel an operator to carry out remedial actions as may be necessary. However, clarification should be provided that such action should be taken promptly. Prompt remediation of items of noncompliance,

through the measure specified, is the most effective means of restoring regulatory control and ensuring public safety and protection of the environment.

Enforcement decisions in writing

Background

Article 28 of Decree No. 51 specifies that enforcement decisions must be made in writing.

Comment

There is sufficient provision for enforcement decisions to be made in writing.

Potential for field decisions determined

Background

Article 28 of Decree No. 51 provides the procedures for issuing sanctions for administrative noncompliance. The procedures involve identifying the violation and notifying the responsible authorities. Decree No. 51 does provide a list of noncompliance issues for which sanctions may be carried out.

Following an inspection, VARANS Inspectorate provides the summary/general information of the inspection to VARANS management. Recommendations for enforcement actions or any timelines that are proposed by the team leader for implementation of the corrective actions will be given in the inspection report made at the witness of the operator. The recommendations for enforcement actions are based on the input from the inspection team and rely on the knowledge and experience of the inspection team leader.

Comment

The potential for inspectors of VARANS to carry out field decisions regarding sanctions is not clear. Inspectors must have definitive guidance on the limits to their authority and such authority should be extended to allowing immediate, independent actions to be taken particularly in the event of serious items of noncompliance. Inspectors are reluctant to take enforcement actions as they can be held responsible under the terms of the Law on Inspections.

Field decisions in a timely manner

Background

Article 28 of Decree No. 51 provides the procedures for issuing sanctions for administrative noncompliance. The procedures involve identifying the violation and notifying the responsible authorities.

Following an inspection, VARANS Inspectorate provides the summary/ general information of the inspection to VARANS management. Recommendations for enforcement actions or any timelines that are proposed by the team leader for implementation of the corrective actions will given in the inspection report made at the witness of the operator. Only MOST Inspectorate and DOST inspectorate are authorized to perform the enforcement actions which are proposed by VARANS in its inspection report.

However, VARANS inspectors may telephone the Chief of Inspectorate to report and request direction in the event of a serious issue with immediate consequences. The Chief of Inspectorate would then direct what action should be taken. However, this approval may not be immediate.

Comment

This formal process, involving reporting and recommending action, does not allow immediate action, suited to the urgency of the situation. Although the inspectors may telephone the Chief of Inspectorate, the provisions of Article 28 of Decree No. 51 still seem to include specific time requirements, thus precluding immediate action.

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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1, para 5.15 states that "Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity."

S13 <u>Suggestion</u>:

VARANS should be provided with a legal document that specifies clear guidelines that allow for non-reactive, unannounced inspections, at the discretion of VARANS.

(1) BASIS

GS-R-1, para 5.16 states that "In addition to routine inspection activities, the regulatory body shall carry out inspections at short notice if an abnormal occurrence warrants immediate investigation."

R30 Recommendation:

VARANS and DOST should have a more formal, defined process to conduct inspections following the reporting of abnormal occurrences and other incidents, based on the risk posed by the event. Conducting unplanned inspections should not be limited to situations where violations are known to have occurred.

(1)**BASIS:**

GS-R-1, para 5.18 states that "... there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization."

R31 Recommendation:

The regulatory body should be provided with the authority to withdraw an authorization for a period of greater than six months, as may be

ACTIVITIES OF THE REGULATORY BODY:

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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

necessitated by the severity of the noncompliance.

S14 **Suggestion**:

The regulatory body should ensure that development continues to proceed on the Decree on administrative penalty in accordance with Law on Atomic Energy, as identified in task 1.1.2 of the Proposal of Action Planned for Regulatory Body - Vietnam, 2009.

(1)**BASIS:**

GS-R-1, para 5.19 states that "... and the period of time permitted for taking remedial action."

S15 <u>Suggestion</u>:

VARANS should provide specific timelines in which all remedial actions must be taken following the reporting of deviations or violations of minor safety significance on inspection reports. Where the facility cannot carry out the necessary actions in the time period allowed, the facility should report to VARANS on the reasons for failing to respond so that VARANS can decide on the appropriate regulatory follow-up action.

(1)**BASIS:**

GS-R-1, para 5.23 states that "The extent of the authority of the regulatory inspectors to take on the spot enforcement actions shall be determined by the regulatory body."

R32 Recommendation:

MOST, VARANS and the DOSTs should determine the extent of the authority of the regulatory inspectors to take on the spot enforcement actions.

(1)**<u>BASIS</u>**:

GS-R-1, para 5.24 states that "... so that necessary actions are taken in a timely manner..."

S16 Suggestion:

MOST, VARANS and DOST inspectors should be provided with a legal document which describes the sanctions and timeliness of the application of those sanctions, which can be imposed by the inspector without further consultation. Where such approval is not possible to be given to the inspector in the field situation, the same information should be framed so

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that immediate action can be taken once the appropriate level of approval has been secured

(1)**<u>BASIS</u>**:

RS-G-1.5 2.21 states that "The Regulatory Authority should establish and publish an enforcement policy, both to encourage compliance and to correct non-compliance. Such a policy should be part of the general regulatory infrastructure established to meet the principle requirements of the BSS. This policy should include specific examples related to non-compliance in relation to medical exposures and the resulting enforcement action by the Regulatory Authority."

S17 **Suggestion:**

The regulatory enforcement policy in the field of medical facilities should be discussed and coordinated among MOST, VARANS, DOSTs and the Ministry of Health and its implementation should be clearly established in the forthcoming regulations that the Ministry of Health will issue in compliance with the requirement 33 (2) (b) of the Law on Atomic Energy.

(1) **BASIS**:

GS-R-1, para 4.7 states that "In order to ensure that the proper skills are acquired and that adequate levels of competence the regulatory body shall ensure that its staff members participate in well defined training programmes"

R33 Recommendation:

VARANS should develop specialized on the job training for its inspectors and DOST inspectors of medical facilities.

S18 **Suggestion:**

For the implementation of the on-the-job training, VARANS should make arrangements with a teaching hospital in order to allow the inspectors to be trained by specialists in the medical uses of radiation, e.g. medical physicists, medical specialists, medical technologists.

4.3.2 Inspection and Enforcement of the Research Reactor

Background

Article 8 of Law no. 18/2008/QH12 allows VARANS to conduct inspection and checking of the research reactor. Article 26 of same Law allows inspectors to conduct examination and inspection and the operating organization is required to provide necessary information in full upon request of regulatory body. The subsequent details of scope, purpose, rights of inspected

organization, role and responsibilities of inspectors and collaborators of inspection are covered under Law of Inspection (No. 22/2004/QH11).

Regulatory Body to inspect all areas

Background

GS-R-1 para 5.12 requires that inspection and enforcement activities shall cover all areas. VARANS during inspections satisfy itself that the operator of the research reactor is in compliance with the conditions of license and regulatory requirement. However, enforcement power lies with MOST.

Comment

VARANS cover all areas of regulatory inspection in the research reactor under its purview, although inspection of the research reactor involves DOST inspectors.

Purposes of regulatory inspection and enforcement

Background

Through the provisions of Law No. 18/2008/QH12, VARANS is able to ensure that the most purposes of inspections for research reactor are met, however, power for enforcement lies with the MOST.

Comment

VARANS, through inspection, ensure that operating licensee condition is met and the research reactor is managing safety in a proper manner.

Planned and systematic inspection programme

Background

GS-R-1 para 5.14 requires the establishment of a planned and systematic inspection programme and the plan should take account of the potential magnitude and nature of the hazards. The plan for inspection of the research reactor is made in advance and is part of the annual inspection plan, which is approved by MOST. While inspections may be carried out solely with the authority of the Director General of VARANS, it is not the normal practice without the approval of the MOST Inspectorate.

Comment

VARANS has not developed a planned and systematic inspection programme for the research reactor. However, they do have an annual plan which includes the inspection of the research reactor. This inspection is done along with DOST inspectors. Furthermore, it would appear that substantial cooperation has to be obtained from a number of different agencies at both the national and provincial level in order to carry out planned inspections. So far, the checklist for inspection of the Dalat research reactor has not yet been developed while checklist for inspection of radiation facilities and practices is already available.

Background

GS-R-1 para 5.15 requires VARANS to conduct both announced and unannounced inspection of the research reactor. The Law 18/2008/QH12, and the Law on Inspection No. 22/2004/QHI I promulgated on 24 June 2004, allows VARANS to carry out inspection of the research reactor. Articles 30 and 31 of the Law on Inspection stipulate the requirements for persons designated as Inspectors. Article 32 of this law describes 'Inspection Collaborators' as persons who are not Inspectors but have professional knowledge related to the inspection. Article 34 of the law allows for announced and unannounced inspections to be carried out. Announced inspections must be carried out in accordance with the approved plan. However, checking, which is essentially an unannounced inspection, can only be carried out in reaction to a known violation or the information of a person. There was no evidence to suggest that VARANS can perform unannounced inspection of research reactor, except in a reactive situation.

Comment

VARANS should have the authority to conduct unannounced inspections which are not reactive in nature. The regulatory body should be allowed some latitude in conducting unannounced inspections which would enhances the effectiveness of the inspection programme and would allow VARANS to continually adjust to changing situations and responding to changes in priorities in the research reactor.

Inspections following abnormal occurrence

Background

GS-R-1 para 5.16 requires that, in addition to routine inspection activities, inspections should be carried at short notice if an abnormal occurrence warrants immediate investigation. Article 8 of The Law 18/2008/QH12 allows VARANS to carrying out inspection and checking in research reactor, according to interview with DG of VARANS this checking is in case of abnormal occurrence. VARANS, therefore, in addition to routine inspection also carry out inspections at short notice if an abnormal occurrence warrants immediate investigation.

Comment

It is not clear that the VARANS carries out inspections in all cases where an abnormal occurrence has occurred in research reactor. While some unplanned inspections are carried out, it is not clear whether these were responding to abnormal events. Given the lack of regulatory guidance on the requirements for reporting of abnormal events by operators, it is likely that most abnormal events are not investigated, although the reporting of abnormal event in research reactor on annual basis license conditions for research reactor issued by VARANS, but this does not provide sufficient time to conduct inspection or take remedial action.

Inspection reports

Background

GS-R-1 para 5.17 requires that inspectors prepare reports of their inspection and findings. VARANS inspection reports comprise more than the conclusions and findings of the inspection. The report is signed by both a senior manager from the facility in the inspection team leader. All parties involved in the inspection receive a copy of the report, including VARANS, DOST and the research reactor.

Comment

VARANS issue inspection reports with finding, conclusion and recommendations. However, there is no database system for the tracking and trending of inspection findings which would assist in inspection planning. Now development of such a system is under way via RAISVN.

Enforcement

Background

GS-R-1 para 5.18 requires that regulatory body can take enforcement action commensurate with seriousness of non-compliance. VARANS do not to have the power for enforcement actions, this can only be taken by MOST, however, VARANS under Article 8 of Law 18/2008/QH12 can recommend the MOST to suspend research reactor following unsafe conditions.

Comment

It seems that in the absence of enforcement power for VARANS inspectors for the research reactor, VARANS effectiveness of an inspection has the potential to be affected unless timely enforcement action by MOST, which has enforcement power, is ensured.

Process for minor violations

Background

GS-R-1 para 5.19 requires the regulatory body issue a written warning or directive to the operator in case of deviation from, or violation of, requirement or unsatisfactory conditions. Such power is with MOST.

Comment

The authority to issue written warning or directive is with the MOST, which is also responsible for operation of research reactor. It is an issue of potential conflict of interest and regulatory independence, and for this see recommendation in Chapter 1 on Legislative and Governmental Responsibilities.

Ability to curtail activities

Background

GS-R-1 para 5.20 requires that in the event of a deterioration in the level of safety or event of serious violations in the research reactor which, in the judgment of the regulatory body, pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail activities and take action necessary to restore an adequate level of safety. In document review and discussion with VARANS, it was indicated that no such provision exist in legal document for VARAN to take such action immediately. The inspectors can only report to MOST which then can take some action if deemed necessary.

Comment

The enforcement authority is with MOST, which includes VAEI which is also responsible for operation of research reactor. There is an issue of potential conflict of interest and regulatory independence and for this see recommendation in Chapter 1 on Legislative and Governmental Responsibilities.

Potential to suspend or revoke authorization

Background

GS-R-1 para 5.21 requires that in the event of continued, persistent or extremely serious non-compliance, or a significant release of radioactive material to environment due to serious malfunction or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke authorization. Article 8 of Law 18/2008/Qh12 only allows VARANS to recommend to MOST to suspend research reactor operation in case unsafe conditions are suspected. Article 4, item 2 of Decree No. 51 specifies that in addition to any other administrative penalty, the operator may be compelled to rectify the noncompliance by carrying out specified actions, including decontamination, restoration, recovery and other such methods. The time limit for implementing such measures is not specified.

Comment

The enforcement authority is with MOST, which includes VAEI that is also responsible for the operation of the research reactor. This is an issue of potential conflict of interest and regulatory independence and for this see recommendation in Chapter 1 on Legislative and Governmental Responsibilities.

Enforcement decisions in writing

Background

GS-R-1 para 5.22 requires that all enforcement decisions shall be confirmed to operators in writing.

Comment

VARANS does not have any such enforcement power and this is done by MOST, which is also responsible for operation of the research reactor.

On Spot Decision by Inspectors

Background

GS-R-1 para 5.23 and 5.24 requires that regulatory inspectors should take on the spot enforcement action if required, where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in timely manner; information shall be transmitted immediately if the inspector judge that the health and safety of workers or public are at risk or the environment is endangered.

Comment

VARANS inspectors do not have powers for on the spot decision regarding sanctions in such situation they have to call the DG of VARAN who in turn then call the MOST, there is no definitive guidance of transmission of information to regulatory body to take account of urgency of situation.

ACTIVITIES OF THE REGULATORY BODY: INSPECTION AND ENFORCEMENT OF THE RESEARCH REACTOR RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1 § **5.14 states that** "The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility ore activity."

R34 **Recommendation:**

VARANS should develop a planned and systematic inspection programme and procedures for research reactor which should take account of the potential magnitude and nature of hazard associated with different stages of research reactor.

(1)**BASIS:**

GS-R-1, section 5.15 states that "Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity."

S19 **Suggestion:**

VARANS should be provided with a legal document that specifies clear guidelines that allow for non-reactive, unannounced inspections, at the discretion of the VARANS in research reactor.

(1)**BASIS:**

GS-R-1 § **5.17 states that** "Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."

R35 Recommendation:

VARANS should make the database system for the tracking and trending of inspection findings readily available to all inspectors for use as a trending tool for research reactor and for assisting in inspection planning.

ACTIVITIES OF THE REGULATORY BODY:

INSPECTION AND ENFORCEMENT OF THE RESEARCH REACTOR RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

GS-R-1, section 5.18 states that "... there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization."

BASIS:

GS-R-1, section 5.24 states that "... so that necessary actions are taken in a timely manner..."

R36 Recommendation:

MOST and VARANS should ensure effective coordination so that enforcement actions can be taken in a timely manner commensurate with the potential nature and hazard pose to workers, public or the environment.

4.4 DEVELOPMENT OF REGULATIONS AND GUIDES

4.4.1 System of regulations and guides

Background

The hierarchy of regulations and guides in Vietnam is described in details in chapter 1, together with the legislative framework.

5 types of legally binding documents are used to regulate atomic energy in Vietnam:

- Law.
- Decrees by the Government,
- Decisions by Prime Minister,
- Circulars by Ministries,
- National Technical Regulations,
- Technical standards, which become legally binding when referred in legal documents or in licenses.

The Law on the Promulgation of legal documents, promulgated on 3 June 2008, provides details on the process to issue the 4 first legally binding documents. The law on Standards and Technical regulations promulgated on 29 June 2006 gives provisions for issuance of the two last documents.

Law on Atomic Energy

At the highest level is the Law on Atomic Energy, which was passed on 3 June 2008 and came into effect on 1 January 2009.

The Law on Atomic Energy was prepared in accordance with the Vietnam constitution and law adoption processes, now specified in the Law on the Promulgation of Legal Documents (No. 17/2008/QH12) which was also passed on 3 June 2008. To begin the process for the development of the Law on Atomic Energy, the National Assembly passed the law plan in

2002 and authorized the Ministry of Science and Technology (MOST) to proceed. MOST established a drafting committee in 2002 which was chaired by the Minister of MOST. On the drafting committee, there was participation by VARANS, VAEI, legal department from MOST and other relevant Ministries, such as MONRE, MOIT, MOH and MOJ. A representative from VARANS was the Secretary of this Committee since 2006, prior to that it had been a representative from VAEI.

The Committee took the IAEA handbook on nuclear law as a reference and also sought input from other countries in the development of the draft law, most notably from experts from Japan and the United States. Experts from other countries, such as Australia and South Korea, assisted under the umbrella of the IAEA. It should be noted that the external consultation include a 16 day website publication for comments from the public.

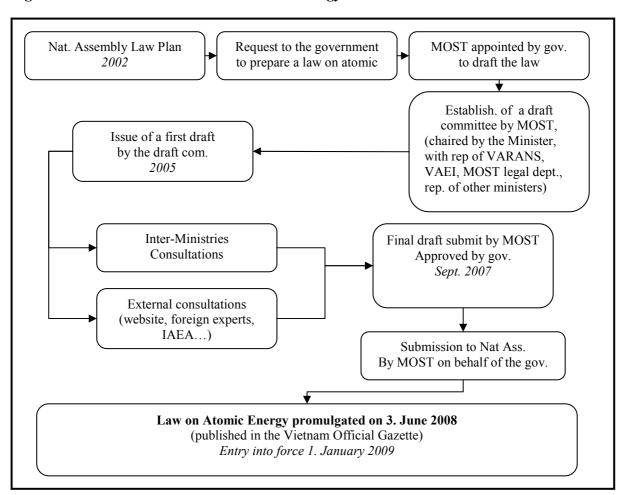


Fig. 4. Process to issue the Law on Atomic Energy

The first draft of the Law on Atomic Energy was sent to other agencies in Vietnam for comments in 2005.

Government approval to proceed with the law was obtained in September 2007 and final approval by the National Assembly was obtained in June 2008, after submission by MOST on behalf of the government. Following promulgation, the Law on Atomic Energy was published in the official government gazette, replacing the former Ordinance on radiation safety and control. An ordinance, which is under a law in hierarchy of norms, is issued by the Standing Committee of the National Assembly to temporally adopt legal provisions before issuing a law.

Decrees in the field of nuclear energy

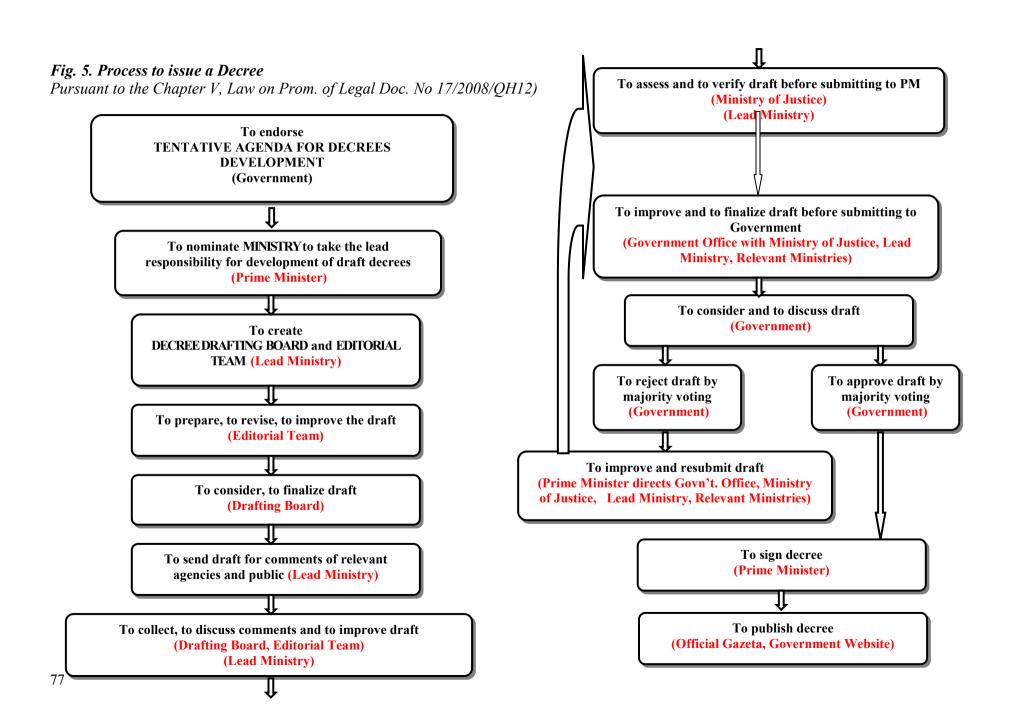
When the responsibilities are clearly assigned by law, like in article 33 of the Law on Atomic Energy, assigning MOST the responsibility to provide detailed regulations and guidelines in specified areas, no decree is needed.

Decrees issued by the government are needed to provide detailed guidelines on the implementation of laws (or ordinances) and to specify tasks, authority and organizational structures of Ministries or Ministry-agencies, if these responsibilities are not already mentioned in the law.

Three Decrees are required to implement the Law on Atomic Energy:

- Decree on sanctions against administrative violations;
- Decree providing Details and Guidance for the Implementation of some articles in the Law on Atomic Energy, which includes the following chapters:
 - Master plan for nuclear energy;
 - Human resource development;
 - o Ensuring safe conditions for radiation workers;
 - o Radiation measurement and calibration:
 - o Detecting and managing orphan sources;
 - Safety control during transit of radioactive material;
 - o Licence requirement for nuclear-powered vessels;
 - o Cooperation mechanism for control of import/export of radioactive material;
 - Environmental monitoring;
 - o Identification of nuclear incident levels (similar to INES);
 - o Communication with mass media;
 - o Fees and charges for licensing; and,
 - o Insurance requirements for occupational and liability.
- Decree on nuclear power plants.

These two first decrees have been drafted many times and should be soon submitted by the first minister, according to the following process:



The two decrees, which were planned to be developed in 2009, should be finally issued in 4th quarter 2009 and will replace the following decrees:

- Governmental Decree n°50/1998/ND-CP detailing the implementation of the ordinance on radiation safety and control;
- Governmental Decree n°51/2006/ND-CP on the sanctions against administrative violations in the field of Radiation Safety and Control.

The provisions of the last two decrees remain valid as long as they are not against the law and as the new decrees are not issued. Another decree will remain valid after adoption of the new decree:

- Governmental Decree n°87/2006/NC-DP on the organization and operation of the science and technology inspectorate.

The draft Decree on nuclear power plant was prepared by MOIT with VARANS as part of the drafting board and, for the draft Decree on sanctions; this was drafted by the MOST inspectorate in close cooperation from VARANS. The draft Decree on nuclear power plant as supported by MOIT has completed work by the drafting board and the draft has been sent to other Ministries for comment. The Decree will be issued in November as this Decree seems to have a higher priority with the government.

Decisions of the Prime Minister in the field of nuclear energy and related Regulations

Decisions are taken by the Government at the level of the Prime Minister to lead, manage and coordinate the actions of ministers and of minister-agencies.

In the field of nuclear energy, the major decisions are the following:

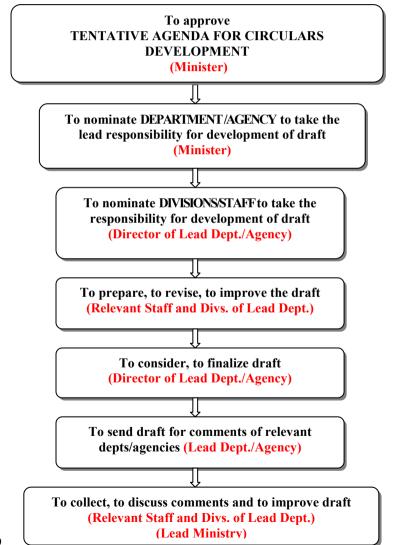
- Decision n°115/2007 on issuing regulations on ensuring the security of Radioactive sources, which will be replaced by a MOST Circular;
- Decision n°146/2007 for the recovery and handling of orphan radioactive sources, which is to be revised and to be included in the drafting Decrees and Circulars;
- Decision on nuclear control (Drafting under development).

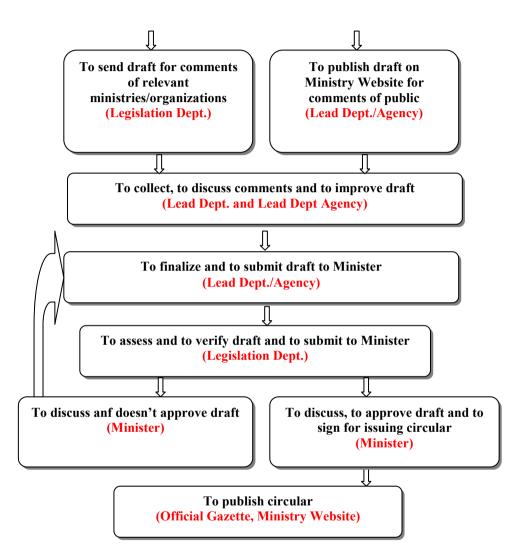
Circulars

A **circular** is a legal document issued by ministers and is used to provide guidelines on the implementation of legal documents, as laws, ordinances, decrees or decisions by the Prime Minister. It can also bring legally binding technical standards when the responsibility to issue such standards is assigned to a ministry through a legal document. Joints circulars can also be issued by several ministries.

The issuance of Circulars is based on an annual planning exercise that includes input from all departments and agencies in a given Ministry. The initial step involves preparing an annual plan of the Circulars to be issued. VARANS contributes to the MOST Circular plan through internal discussion. Once approved, the Circular plan is presented to MOST for incorporation into its overall plan for Circulars with the decision to include a Circular into the plan based on its necessity.

Fig. 6. Process to issue a Minister Circular (Pursuant to Article 68, Chapter V, Law on Promulgation of Legal Document No 17/2008/QH12)





Once the Minister has approved the Circular plan, the lead agency for the Circular (generally VARANS in the field of nuclear energy) proceeds to draft the document.

An assessment committee appointed by the Minister has then to review the proposed Circular. If accepted, the Circular is proclaimed by the Minister.

The very simple process, which doesn't include external consultation, guarantees a limited time scale for issuing such a circular.

The following numbers of Circulars drafted by VARANS have been issued:

- 3 circulars in 2006;
- 3 circulars in 2007;
- 0 circular 2008; and
- 10 are in the 2009 MOST circular plan (of which 3 are for nuclear power plant).

The sudden increase in the number of Circulars in 2009 is due to the new Law on Atomic Energy which requires quicker implementation of several provisions.

The 7 proposed radiation safety Circulars in 2009 providing provisions for nuclear activities except NPP are:

- notification and licensing for radiation practices except operation of nuclear power plant;
- regarding fees and charges;
- regarding safe transport, eventually replacing Circular 14;
- for occupational and public radiation exposure safety;
- *for the safe management of radioactive waste;*
- regarding emergency response in nuclear and radiation incidents; and,
- regarding radiation protection in medical facilities in a joint Circular to be issued with MOH.

These circulars will not all be issued in 2009.

The three proposed Circulars on nuclear safety for nuclear power plants issued by MOST are being prepared by VARANS, which has the regulatory authority. These proposed Circulars concern sitting, basic design safety and guidance on performing Probabilistic Safety Reviews.

National Technical regulation

According to law on standards and regulation promulgated on 29 June 2006, "Technical regulation" means stipulations on the limitation of the technical characteristics and management requirements that goods, services, processes, environment and others in socio-economic activities need to satisfy in order to ensure hygiene, safety and health of human, to protect animals and vegetation and the environment; and to protect national interests and security, benefits of consumers and other essential needs. Technical regulation shall be issued by the competent State authority in writing for compulsory application.

Technical regulations issued by Ministers are considered as legally binding by law. The process includes the following major steps:

- Drafting by the drafting agency (VARANS in the case of Nuclear or Radiation Safety);
- Internal consultancy of relevant agencies;
- External consultancy (experts, foreign consultants, public etc.);
- Review from MOST Directorate on Standards and Quality (technical committee TC85 on Nuclear Energy);
- Review from MOST Legal Department;
- Approval through a Decision of MOST Minister or on behalf of the MOST Minister.

There has not been any National Technical Regulation adopted in the field of Atomic Energy until now. But VARANS is now planning to draft a set of National Technical Regulations, putting for instance some parts of Minister Decisions adopted in the former administrative processes in the new kind of documents.

Other non-legally binding regulatory documents

National Technical Standards are drafted only by MOST through a complex process not specific for nuclear energy, involving a very long consultation of the MOST department for standards and quality.

Twenty-six technical standards have been adopted in the field of radiation safety or transport safety. The lengthiness of the process could be one of the reasons for the lack of any technical standards in the field of nuclear safety. The technical standards are not legally binding except in two cases:

- o If any legal documents refers to them (ex article 34 of Law on Atomic Energy provides that "the construction or modification of operation scope and scale of radiation facilities shall be complied with national technical standards";
- o If they are mentioned in licenses.

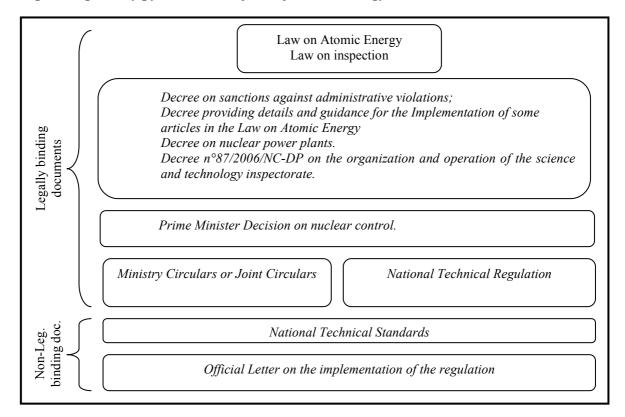
Official Letters are issued by a Minister or VARANS-DG to give guidelines on the implementation of the regulation.

Directives, which can be issued by ministers, are non-legally binding documents to give policy orientations on the regulation to be developed. The directive n°13/2006 gives instruction to the administration to strengthen the State Management on Radiation Safety and Radioactive Source Security.

4.4.2 Framework for more detailed conditions and requirements, development of guides

Vietnam is currently renovating its entire regulatory framework in the field of atomic energy. The regulatory pyramid planned is the following:

Fig. 7. Regulatory pyramid in the field of atomic energy



Currently, VARANS is preparing the annual plan for 2010 and is also preparing three and five year plans in accordance with direction from the government. The plan is being prepared by VARANS divisions.

Following approval by the DG of VARANS, the master plans must go to MOST through the legal department of MOST. Once reviewed and combined with other plans from within MOST, the plan is finalized and MOST signs off on the plan for all agencies within MOST. Ultimately it is the decision of the Minister to issue the annual plan.

For instance, the following Minister Decisions adopted in the former Legislative processes will be progressively integrated either in circulars or in National technical regulations:

- Decision n°17/2007 on the issuance of radioactive sources categorization complying with security requirements;
- Decision n°38/2006 on Fees and Charges from radiation Safety and Control Management activities and their usage;
- Decision n°2314/2005 on the Decentralization of authority in issuing Radiation Safety Registration and Licences.
- Decision n° 117/2006 on licensing procedures;
- Decision No. 483 on Establishing and Issuing Organization and Operation Regulations of the Inspectorate Vietnam Agency for Radiation and Nuclear Safety
- Decision No. 1112 on Adjustment of the Organizational Structure of the Vietnam Agency for Radiation and Nuclear Safety;
- Decision No. 3616/2004/ on the Issuance of the Regulations on Safety and Sanitation of Foods preserved by Irradiation;

- Decision No. 32/2007/ on Issuance of Regulation on Testing X -ray Equipment for Medical Diagnosis.

Comments

A system is in place in Vietnam to issue regulations, technical standards and guides of a non-mandatory nature on how to comply with the regulation. The action 6.1 of the action plan is dedicated to improve the several processes. This action has to be detailed for further implementation.

VARANS pays due attention to IAEA Safety Standards and has the will to take into account internationally recognized standards and recommendations. To achieve this, more external consultancies and bilateral cooperation could be very helpful, especially with countries having already operating NPP.

The scope of the regulation to issue or to revise is very broad and the staff dedicated to this task is limited. A three year plan is now under the process of drafting by VARANS before approval by MOST. This plan assesses the need and the possible input from foreign legislations or from IAEA standards to develop the needed documents. This plan should be a very useful management tool. But to become a national strategy plan for developing regulation in the fields of nuclear and radiation safety, the plan has to include clearer prioritization between the different regulations needed and the resources to be employed for the tasks. A big challenge for VARANS is to develop a detailed set of regulations and technical standards for nuclear facilities (research reactors, NPP, waste facilities, etc.) but the regulation on other radiation practices have also to be reviewed and completed.

VARANS should also pay due attention to the implementation of the regulation being developed, and will have to develop guides of non-mandatory nature on how to comply with the regulation. Efforts will also be necessary to inform all interested parties on the issuance of new regulations. A specific action could be added in the action plan regarding these two last items, in addition to the action 7.2.

4.4.3 Comments from interested parties

Background

The law on the promulgation of legal documents, promulgated on 3 June 2008, provides clear and detailed provisions to collect comments form concerned agencies or organizations on draft legal documents. Comments can be received from all interested parties, including individuals. For drafting decrees, Article 61 of the law states for instance that "In the course of developing draft decrees, the lead drafting agency shall have to organize for the collection of comments and ideas from ministries, Ministry-equivalent agencies, Government-affiliated agencies, and target groups that are directly affected by the document in question. The full text of the draft decree should be posted on the website of the Government or that of the lead drafting agency at least for 60 days for agencies, organizations and individuals to submit their comments and ideas."

The law on standards and technical regulations, promulgated on 29 June 2006, defines in its articles 15 and 31 the rights of organizations, individuals participating in

development of national standard. Any organizations or individuals can make comments on plans or programmes for development of national standards or regulations, make a draft proposal to the Ministry of Science and Technology or provide comments on draft standards or national technical regulations.

Minimum times for publication of draft on internet are stated in the law.

Comment

The processes to adopt legally binding documents include quite advanced provisions to take comments from all interested parties.

ACTIVITIES OF THE REGULATORY BODY: DEVELOPMENT OF REGULATIONS AND GUIDES RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1 §3.3 states that "The regulatory body shall ensure that its regulatory principles and criteria are adequate and valid, and shall take into consideration internationally endorsed standards and recommendations".

(2)**BASIS:**

GS-G-1.4 § 3.1 states that "A systematic approach should be adopted for the production of regulations and guides, and the regulatory body's quality management should cover these activities".

BASIS:

GS-G-1.4 § 3.26 states that "The regulatory body should follow a consistent procedure for establishing, revising and revoking regulations and guides"

S20 Suggestion:

The draft plans on the development of regulation should be completed to become a National Strategy for the production of regulations and guides and for the revision of existing ones, covering all fields of nuclear safety and radiation safety controlled by VARANS. This strategy should include the following elements:

- determination of the need for the new regulations or the revision of the existing documents, including all relevant information;
- *setting the priority for development of the regulations;*
- determination of the scope of the proposed regulations or revisions;
 and
- determination of the resources to be employed, depending on the resources available and on the time-scale for the preparation and establishment of regulations and guides.

ACTIVITIES OF THE REGULATORY BODY: DEVELOPMENT OF REGULATIONS AND GUIDES RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

• the necessary time for implementing the new regulations.

S21 **Suggestion:**

VARANS should review this national strategy, taking account of good international practices and with broad consultation, to ensure that it covers all important areas and to help defining priorities.

(1)**<u>BASIS</u>**:

GS-R-1 §5.28 states that "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties".

G3 Good practice:

The processes to issue legal documents in the field of nuclear energy include comprehensive provisions to take comments from all interested parties into consideration.

4.4.4 Development of regulations and guides for industrial and research facilities

Background

Decision No. 115/2007/QD-Ttg on issuing Regulations on Ensuring the Security of Radioactive Sources, issued 23 July 2007 by the Prime Minister sets out regulations on ensuring the security of radioactive sources.

Directive No. 13/2006/CT-BKHCN on Strengthening the State Management on Radiation Safety and Radioactive Source Security, issued 7 June 2006, directs VARANS to effectively conduct the State management on radiation and nuclear safety and control into a special attention to inspections on security measures in radiation facilities.

Regulations for the recovery and handling of orphan radioactive sources, were promulgated in accompaniment with Decision No 146/2007/QD-TTg dated 4 September 2007.

Comment

There currently exists a sufficient regulatory framework and guides for licensing and for the carrying out of inspections and enforcement at industrial and research facilities. However, much of this framework pre-dates the implementation of the Law on Atomic Energy and therefore may not be currently suitable. In addition, some of these documents, such as Circular No. 10, were adopted directly from relevant IAEA documents and have not been adapted to the system of laws and the regulatory

framework of Vietnam. Some work is currently underway to address this issue but resources are limited to complete all required documentation.

4.4.5 Development of regulations and guides for medical facilities

Background

The following legal documents are the main instruments for regulating medical exposures:

- 1. Law on Atomic Energy promulgated by the National Assembly;
- 2. Decree No. 50/1998/ND-CP by the Government detailing the implementation of the Ordinance;
- 3. Decree No. 51/ND-CP-2006 by the Government providing for the sanctioning on the field of radiation safety and control;
- 4. Circular No. 05/2006/TT-BKHCN by the Ministry of Science and Technology guiding the procedures in reporting, granting licenses and registers;
- 5. Joint Circular No. 2237/1999/TTLT-BKHCNMT-BYT dated 28/12/1999 of the Ministry of Science and Technology and the Ministry of Health guiding the implementation of Medical Radiation safety;
- 6. Circular 10/2006/TT-BKHCN Guides on Inspection specializing in Radiation Safety and Control.

Those legal documents do not address the BSS requirements regarding radiological protection of patients (Appendix II).

Article 33 (2) (b) of the Law on Atomic Energy specifies that the Ministry of Health is responsible for providing detailed regulations on the control of medical exposures. As of October 2009, these regulations have not been provided.

VARANS has collaborated in developing a number of non-mandatory guides in the medical area:

- Vietnam Standard TCVN-6869:2001 promulgated by the Ministry of Science and Technology for Radiation Protection – Medical Exposure – General Provisions. This standard is the one that introduces in the regulatory framework of Vietnam the requirements of the Appendix II of the BSS but with the character of recommendations;
- Vietnam Standard TCVN-6561:2001 promulgated by the Ministry of Science and Technology for Ionizing Radiation Safety at medical radiology centers;
- Vietnam Standard DLVN 40/1999 Co-60 teletherapy equipment. Methods and means for verification;
- Vietnam Standard DLVN 41/1999. X-ray general diagnostic radiography and direct fluoroscopy. Methods and means for verification;
- Vietnam Standard DLVN 42/1999. X-ray intensifier fluoroscopy. Methods and means for verification;
- Vietnam Standard DLVN 43/2000. Computerized Tomography. Methods and means for verification.

Comment

Regulations and guidance in the area of medical activities, issued before the Law on Atomic Energy require review and possible revision. MOST and MoH should develop a plan to review and revise the existing regulations and guidance for consistency with the new Law.

There is a lack of practice-specific guidance, i.e. there are no guides for interventional radiology, radiotherapy, nuclear medicine, diagnostic radiology for providing information to the operators of medical facilities for the implementation of radiation protection and quality assurance programmes in each practice.

ACTIVITIES OF THE REGULATORY BODY: DEVELOPMENT OF REGULATIONS AND GUIDES FOR MEDICAL FACILITIES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1, 5.27 states that "Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary.";

GS-R-1, 5.28 states that "in developing regulations and guides, the regulatory body shall take into consideration, comments from interested parties and the feedback of experience..."

R37 Recommendation:

Regulations and guides for each specific medical practice should be developed by MOST, VARANS and the Ministry of Health, as appropriate.

S22 Suggestion:

The relevant professional societies should be involved at an early stage during the development of those regulations and guides.

4.4.6 Development of Regulations and Guides for the research reactor

Background

Although there is a need for more detailed requirements to regulate research reactor activities, neither MOST nor VARANS has issued any as yet. At present, the regulatory oversight for research reactor is given by MOST along with VARANS. MOST is responsible for licensing while VARANS performs review & assessment and inspections. More details about licensing of research reactors are given in chapter 4.1.3.

VARANS recognizes that a big challenge for improving the regulation is to issue a set of regulations and technical standards to provide safety objectives, safety criteria for licensing and for review and assessment of nuclear facilities, in order to implement

the Law on Atomic Energy, the Decrees and the circulars (see Chapter 4.1.3 on authorization of research reactors and 4.2 on review and assessment).

The Dalat license conditions indicate that quality assurance programme needs to be issued and submitted to VARANS no later than 1 June 2010, but the regulation doesn't include any provision in this field.

Comments

A high priority should be given to develop detailed regulation in the field of nuclear safety, including safety objectives and criteria. Requirements regarding quality assurance programme, environmental protection, ageing management programme and decommissioning programme have to be included. The actions 5.1, 6.1, 6.3, 6.4 have then to be detailed and completed.

As stated in GS-G-1.4, the development of any particular regulation for nuclear facilities will involve a balance between the need for flexibility, to permit easy adaptation of the regulation to developing circumstances and technology, and the need to include detailed requirements, to facilitate determination of whether the requirements have been met. Performance based regulations specify primarily the overall safety objectives. A prescriptive regulation is more specific than a performance one and states how to achieve safety. A regulatory system should include both types of regulations, striking an appropriate balance between performance based and prescriptive regulations, to match the anticipated workload and the skills of the regulatory body's staff. Before working on very detailed regulations and technical standards, VARANS should benchmark the different systems existing in other countries to develop his regulatory approach, and not only IAEA general recommendations, as proposed in action 6.2 of the action plan.

ACTIVITIES OF THE REGULATORY BODY:

DEVELOPMENT OF REGULATION AND GUIDES FOR THE RESEARCH REACTOR

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

GS-G-1.4 § **3.13 states that** "the development of any particular regulation will involve a balance between the need for flexibility (…) and the need to include detailed requirements".

S23 Suggestion:

VARANS should benchmark the different existing regulatory system regarding nuclear facilities to develop its own regulatory approach, with an appropriate balance between performance based and prescriptive regulations, before developing detailed regulations and standards.

5. CONTROL OF MEDICAL EXPOSURES

5.1 REGULATIONS

Background

In the Vietnamese regulatory system, the BSS requirements for the control of medical exposures (Appendix II) have been included into the Vietnam Standard TCVN-6869:2001 "Radiation protection – Medical exposure – General provisions", issued by the Ministry of Science and Technology.

As it is a non-mandatory document, several requirements are still not implemented.

The Article 33 (2) b) of the Law on Atomic Energy establishes that the Ministry of Health shall be responsible for providing detailed regulations and guidance on the control of medical exposure.

These regulations have not been provided yet, but the Ministry of Health has developed an action plan for making available those regulations during the year 2010.

Comment

Even if there are no specific enforceable regulations addressing the BSS requirements on medical exposures, some requirements included in the general legal and regulatory framework are applicable to the control of medical exposures (e.g. Arts. 18, 19 and 20 of the Law on Atomic Energy).

5.2 RESPONSIBILITIES FOR MEDICAL EXPOSURE

Background

BSS §II.1 − II.3

TCVN 6869: 2001 Section 4.1 a) & b) require licensees to ensure that each medical exposure is prescribed by a medical practitioner and assign medical practitioners the main responsibility for overall patient safety in the prescription and delivery of the medical exposure.

Compliance with this requirement is verified by the Vietnamese regulatory body through inspection and verification of the signed treatment charts.

Comment

The process of authorization does not require the applicant to submit a formal statement assigning responsibility for overall patient safety to a medical practitioner.

Background

TCVN 6869: 2001 4.1 c) establishes that licensees shall ensure that medical and paramedical personnel are available as needed

Comment

In addition to the requirement in Art. 75 c) of the Law on Atomic Energy, provisions on the adequate staffing levels for the different medical practices are waiting for the regulations that shall be provided by the Ministry of Health, according to Art. 33 (2)(b) of the Law on Atomic Energy.

Background

Article 27 of the Law on Atomic Energy requires that radiation workers are trained with specialized knowledge and professional skills. Medical practitioners and paramedical personnel receive specific training in radiation protection. The syllabuses for the courses on radiation protection in medical practices are expected to be more focused on radiological protection of patients after implementation of the regulation to be completed by the Ministry of Health in 2010.

TCVN 6869: 2001 4.1 d) establishes that licensees shall ensure that requirements for medical physics availability and their involvement in calibration, dosimetry and QA aspects will be met.

A significant shortage of these qualified experts in Vietnam impedes compliance with this requirement.

Comment

At present there is not any programme in Vietnam for building competence in medical physics and formal means for accrediting qualifications of medical physicists are not implemented.

Background

Practitioners are required to promptly inform the licensee of any deficiencies or needs regarding protection and safety of patients (TCVN 6869: 2001 4.3, and Art.27 of the Law on Atomic Energy).

5.3 JUSTIFICATION OF MEDICAL EXPOSURES

Background

BSS §II.4-II.9

The BSS requirements on justification are established in TCVN 6869: 2001 5.1 to 5.6.

Implementation of the justification principle is waiting for appropriate regulations of the Ministry of Health (Art. 33 (2)(b) of the Law on Atomic Energy).

5.4 OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURES

Background

BSS §II.10 – II.27

Operational requirements for optimization of protection for medical exposures are established in the TCVN 6869: 2001 6.2.1 a) and b).

The only measures implemented for verifying compliance with these requirements are observation of working procedures during inspection. Enforceable requirements on the availability of clinical protocols (choice of radiopharmaceutical, quality image, appropriate dose) containing details on radiological protection of patients are not yet implemented.

Requirements on the design of equipment and facilities of the Standards are established in the TCVN 6869: 2001, 6.1.

Compliance with these requirements is verified during the process of authorization.

Comment

For improving compliance with the requirements of the BSS on the design of medical equipment, more cooperation and coordination among regulatory bodies and the MoH is required. At present, MoH is involved in the process of approving new equipment to be purchased by medical centres, without enough consultation with the regulatory bodies (MOST, VARANS, DOST) to ascertain if the equipment meets design requirements for authorization.

Background

Implementation of the requirements on calibration is made through the SSDL of the Institute of Nuclear Science and Technology that is part of the Vietnam Atomic Energy Institute.

Comment

It is understood that the SSDL of Vietnam can respond to the present demand.

Background

Requirements on quality control of equipment, particularly in x-ray diagnostics are being implemented through the use of external technical support services authorized by VARANS.

Comment

A possible conflict of interests could take place since there is no formal independence among those technical support services (TS Centres of VARANS, VAEI of MOST, technical support centres of DOST) and the Vietnamese regulatory bodies.

Background

There is no implementation of internal QA programmes for each medical facility.

Requirements on clinical audits, clinical dosimetry, use of diagnostic reference levels, dose constraints for patients undergoing biomedical research and comforters and carers are not implemented.

5.5 MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

Background

BSS §11.28

The (TCVN 6869: 2001(9).) adopts the maximum activity for I-131 recommended by the International Basic Safety Standards. Compliance with this requirement is verified through inspection.

5.6 INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

Background

BSS §II.29- II.30

These requirements of the Standards are established in the Art. 20 of the Law on Atomic Energy and in the TCVN 6869: 2001 10.1) and 10.2), and their compliance is verified through inspection, interviews with the RPO and the pertinent personnel of the facility and revision of the technical documentation.

5.7 RECORDS

Background

BSS §II.31– II.32

The requirements of the Standards are established in TCVN 6869: 2001 11.1) and 1.2). As enforceable regulation for implementation of the control of medical exposure is not yet provided, compliance with this requirement is only partially verified through inspection.

RADIATION SAFETY IN MEDICINE: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

GS-R-1, para 5.26 (to implement BSS Appendix II) states that "The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations."

R38 **Recommendation:**

The Government should ensure the provision of the regulations which are necessary for implementing the Standards according to the requirement in Art.33 2 b) Law on Atomic Energy and their timely issuance.

RADIATION SAFETY IN MEDICINE: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S24 **Suggestion:**

VARANS should assume a proactive role in fostering the cooperation among the Vietnamese regulatory authorities and the Ministry of Health providing sound information on the risks derived from the lack of regulatory control of medical exposures and offering assistance in drafting the regulations that allow to implement the requirements of the Standards.

(1) BASIS:

GS-R-1, para 6.17 (to implement BSS II. 1(c)) states that "...Government and, as appropriate, concerned organizations shall therefore pay attention to, and provide for, among other things, the following:

(1) training and education;..."

R39 **Recommendation:**

The Government through the appropriate authorities should develop a comprehensive programme for providing adequate and specific training at least to the following persons:

- Physicians who are responsible for individual justification and conducting the exposures
- Radiation technologists or equivalent staff and other relevant health professionals.

R40 Recommendation:

The Government, through the appropriate authorities, should develop a national strategy for building competence in the Medical Physics area and establish formal means for accrediting qualifications.

(1)**BASIS:**

BSS para 2.27 states that "Guidance levels for medical exposure shall be established for use by medical practitioners..."

R41 Recommendation:

The Government, through the appropriate bodies, should expand the programmes under development for performing comprehensive surveys of patient doses with special focus on CT and interventional radiology, and to engage professional societies in developing and implementation of Diagnostic Reference Levels (DRLs).

6. EMERGENCY PREPAREDNESS AND RESPONSE

6.1 GENERAL REQUIREMENTS

6.1.1 Basic Responsibilities

Background

The main legal provisions regarding emergency preparedness and response are contained in the Law on Atomic Energy in Chapter X. In Art.83 the Law authorizes the MOST to collaborate with other ministries and provincial level to develop national radiological emergency plan (NREP). The NREP comprises both nuclear and radiation emergencies. There are also two other types (levels) of emergency plans, i.e. facility and provincial. Art. 84 describes responsibilities of licensees, which may be institutions or individuals, in case of emergency. In the same Article the responsibilities of the following institutions are stipulated:

- Provincial People's Committees
- -MOST
- National Committee for Search and Rescue
- Ministry of Defense
- Ministry of Public Security
- Ministry of Foreign Affairs
- Ministry of Public Health.

Basic requirements for the contents of the nuclear and radiation emergency plans are in Art. 83, but the emergency plans except for the facility operators do not exist. MOST intends to develop guidance for writing emergency plans by the end of 2009. It is planned that provincial emergency plans for seven provinces will be developed by the end of 2010 and then writing of NREP shall follow.

A routine inspection according to the practice and procedure involves also verifying if emergency preparedness procedures are in place.

Comments

The coordinating role for developing NREP has been given to MOST, but effectively this coordination duty is delegated to VARANS, which would need to establish a good working relation with the representatives of other ministries and a strong support from Minister of Science and Technology.

A system for threat categorisation, as described in GS-R-2, para 3.6, is not in place. Application of threat categorization system and later on determining adequate (commensurate) emergency planning and response measures as described in IAEA EPR-Method 2003 guidance.

There was no information about dedicated emergency preparedness inspections or that this item would be addressed in the emergency plan.

6.1.2 Assessment of Threats

Background

VARANS claims that some sort of threat assessment has been performed in the framework of the preparation of seven provincial emergency plans. The criteria would be population in the vicinity of the site, activity and isotope composition, number of sources at one site, etc. The inventory showed 373 sources with the activity above 50 Ci. There is also a construction site for a Chinese NPP (Fangchanggang) about 60 km from the Vietnamese border.

Comments

A threat assessment for all radioactive sources and practices and Vietnam seems to be a prerequisite for any emergency planning.

6.2 FUNCTIONAL REQUIREMENTS

6.2.1 Establishing Emergency Management and Operations

Background

There are no emergency plans, neither national nor provincial, in place, which would describe emergency management and operation. Art. 86 of the Law on Atomic Energy stipulates that all response measures (i.e. emergency plan implementation) shall be in line with the provisions of the Law on Emergency.

Comments

The management structure should be clearly described in the emergency plan. The present interim management and operations structure, as discussed with the counterparts, was described as the interaction between organizations. The management of emergencies should be in line with the incident command system (ICS), which is built around five major components: command, planning, operations, logistics and finance/administration. In small scale incidents/emergencies, one person, the incident commander, may manage or perform all of the components. Large-scale incidents/emergencies usually require that each component is set up separately. Each of the primary ICS sections may be divided into smaller functions as needed.

6.2.2 Identifying, Notifying and Activating

Background

Art. 84 of the Law requires the licensee to report the incident and the incident place to the superior agencies, organizations, the local People's Committee, local police, VARANS and MOST. Also the same article deals with the informing the foreign countries and the designated authority is MOST, which should collaborate with the Ministry of Foreign Affairs to provide this information. VARANS as the designated

Convention on Early Notification Contact Point does not operate round-the-clock, neither its officers are accessible 24-hrs a day.

Comments

VARANS has not established a State notification network/system which operates round-the-clock to enable VARANS being accessible at any time. Once this is established VARANS needs to inform licensees whom they should send the notification and what information the notification should contain

Vietnam has not established a national contact point operating round-the-clock.

Scrap Metal

Vietnam has made an effort to establish control over scrap metal at scrap collectors, as well as at processing facilities by passing a decree requiring performing radiation measurements of scrap metal shipments. The difficulty is that radiation detectors have not been procured and the decree practically has not yet been enforced. The measurement of scrap metal shipments is an important measure to find lost ("orphan") radioactive sources, but the regulator must be aware that the licensee should be adequately "stimulated" to report and handover found sources to the appropriate radioactive waste storage. This measure would prevent found sources from being lost again (become "re-orphaned").

6.2.3 Taking Mitigatory Action

Background

In principle, the operators are responsible for taking mitigatory actions within the facility and this is inspected during inspections as well as assessed in the licensing process. VARANS would provide expert advice in most of the emergency cases if requested, especially to the first responders. Art. 84(4) requires from VARANS to provide support and mobilize its resources and means to mitigate incidents.

Comments

Since in Vietnam there are operators of threat category III and IV sources only, the team did not identify any facility at which a potential emergency scenario would comprise a transient situation (i.e. an emergency whose classification can change over time as the situation changes, since the status of an emergency can be a complex time-dependent process). The only exception may be the research reactor, which the worst possible accident would be uncovered core (but the reactor has no potential for melting down the core). The uncovered core would produce very high dose rates in the reactor building especially in the vertical direction, which is unshielded. All probable radiation emergency scenarios in Vietnam would require radiation measurements to assess the situation prior to recovery of the source and decontamination of an area if needed. The only exceptions would be a spill of radioactive liquid, and a source caught by fire or an explosion involving a radioactive source.

6.2.4 Taking Urgent Protective Action

Background

This item is not applicable for off-site actions since in Vietnam there are not any installations with protective actions planning zones around them. In case of installations of threat category III at which the arrangements to ensure safety of all persons on site are needed, the operator shall address this in its emergency plan or procedures, which need to be submitted when applying for a license.

Comments

The regulatory authority decided to also include intervention levels and operational intervention levels in the future documents for the sake of completeness and in case in the future such installations will be built, e.g. nuclear power plants.

6.2.5 Protecting Emergency Workers

Background

The VARANS is aware of the issue of protecting emergency workers, but no provisions are in place.

Comments

Protecting emergency workers has not yet been considered and it should be addressed by the authorities as well as the employers of potential emergency workers (e.g., MOST, DOST; hospitals, medical centers, police, and fire brigades).

In general, the incident commander is responsible for giving on-the-scene instructions to emergency workers. However, this person cannot act alone (not being fully competent in radiation protection issues), and may require expert advice by the radiation protection staff about the application of the emergency workers' turn-back limits.

6.2.6 Assessing the Initial Phase

Background

Responsibility for the assessment of the initial phase of an emergency rests with the operator and these assessments are addressed in their emergency plans and evaluated and inspected by VARANS. In addition, VARANS is capable of providing expert advice, as well as measurements with its Technical Support Centre in case of an emergency, e.g. dose rate, contamination, identification of radionuclides, gamma spectroscopy, and recovery of unshielded sources.

Comments

The default operational intervention levels (OILs) are to be devised to make an estimate, based on measurements, if the generic intervention levels are exceeded during a nuclear accident. Since there are no nuclear power plants currently in Vietnam, it is unlikely that the OILs would be exceeded and that countermeasures

would need to be introduced. The only exception may be agricultural countermeasures, which are considered in Chapter 6.2.8.

6.2.7 Keeping the Public Informed

Background

Art. 82 of the Law stipulates the Government shall specify the announcement in the public media in case of incident, while Art. 84 requires Provincial People's Committees to inform the local media about the incident in the local area. Art. 85 of the Law requires that mass media provide objective information to the public. The team learned that Prime Minister and the commander in charge of response can designate spokespersons to provide the information to the public, but it is questionable, if any spokesperson can meet requirements for such a job.

Comments

However, the Law just assigns responsibility to the Government, but it is not determined who should actually prepare this information. There is no instruction or procedure how this information will be prepared (sources of primary information, frequency of preparation, template), nor procedures for interaction with media in a public information centre (PIC). See EPR-Method 2003 for further guidance. Providing consistent and timely information to the public requires not only persons qualified to provide such information, but also continuous work with the media to build mutual trust and partnership between journalists and spokespersons. Since Vietnam is still developing its radiation emergency response capability, it is not surprising that public information issues have not yet received sufficient attention.

6.2.8 Taking Long Term Protective Actions

Background

Environmental radiation monitoring in case of an emergency is not addressed in any procedure, e.g. where, how (sampling method and transport to the measuring device), throughput (number of measurements/day).

In the event of an emergency, the decision-making mechanism regarding agricultural countermeasures and food consumption has not yet been determined.

Comments

The adoption of national intervention and action levels for agricultural countermeasures may be a good initial step. Next, the responsibility for decision-making should be assigned to the appropriate authorities, e.g. Ministry, responsible for agriculture or food.

6.2.9 Conducting Recovery Operations

Background

Recovery operations after a major radiological emergency are not addressed in any documents, neither strategy or principles or relevant authorities tasks were envisaged.

Comments

Conducting recovery operations is a demanding task after a nuclear disaster, which needs tremendous resources. In a more realistic case, when the authority is faced with the legacy of past activities, the main challenges besides performing decontamination to bring the dose levels to the so called levels "acceptable for living on contaminated areas" are reassuring population that the risks are acceptable. It is advisable to develop these dose rate levels in advance to provide public with the fact that these doses were justified and optimized and are not just ad-hoc levels of "some group of experts", which may change from day to day.

6.3 REQUIREMENTS FOR INFRASTRUCTURE

6.3.1 Organization

Background

The national, as well as provincial, emergency response organisation is under establishment. The draft schemes of distribution of function or responsibilities do exist, but these have not been agreed between all stakeholders. These schemes have not been developed to assign responsibilities to individual positions neither have they been developed for different levels of emergency response (i.e. for different types of events or emergency classes).

Comments

It is important that the responsibilities of each organisation, as well as the individual positions within each operating and response organisation, are well understood and are clearly assigned in the emergency planning documents.

6.3.2 Plans and Procedures

Background

The emergency plans as required by the Law (Art. 83) are not in place except for the operators. Also adequate procedures on national and provincial level in line with the responsibilities as they will be described in the future emergency plans have not yet been developed.

Comments

It is an essential requirement to have the NREP in place in order to establish an interim radiation emergency response capability. Many inputs are required before the NREP is finalized. One important input is the threat assessment, which defines the scope of the NREP. In addition, documents regarding the planning basis and concept of operations are needed to write the NREP.

It is not necessary to postpone writing of emergency response procedures until the plans are finished, but the procedures need to be harmonized with the tasks, as required by the respective plans before the procedure becomes effective.

6.3.3 Logistical Support and Facilities

Background

There are about 20 gamma spectrometers in the country, but the proficiency in taking measurements has not been reported. The VARANS Technical Support Centre gamma spectrometrists have taken part in the IAEA inter-comparison measurements and the results were good.

A national early warning system consisting of gamma measuring stations sending on line measurements to a central location does not exist.

The task to identify facilities which can play a role during an emergency has not been accomplished, except for coordination of on-site response actions which is the responsibility of the operator. e.g.: these are facilities for coordination of: provincial and national response actions, public information, off-site monitoring, medical response, etc.

The Technical Support Center of VARANS (TSC) has been assigned a role in emergency response as its scope of jurisdiction is the whole country. The TSC has experience in carrying out radiation measurements, e.g. dose rate, radionuclide detection, neutron detection, gamma spectrometry, because it carries out these measurements regularly for external customers. Equipment has also been procured to carry out tasks in the area of emergency response. This equipment comprises protective clothing for the team members, various tongs for grabbing a source, two lead containers to store sources, marker rope, labels, etc. The TSC team is not experienced in decontamination and this job should be done by others (e.g VAEI). The transport means are not readily available and there is no procedure to carry out intervention in case of emergency.

Comments

During preparation of the NREP, a thorough analysis should be performed to confirm whether the tools (protective clothing, instruments, vehicles, communication means, computes, software) are sufficient and adequate (e.g., some items are perishable, such as protective clothing, electronic personal dosimeters, and communications equipment). It is better to rely on instrumentation in regular use, rather than instrumentation stored in a warehouse.

The TSC staff are knowledgeable and dedicated but they need to be organized to carry out emergency response duties. An appropriate procedure would substantially improve the emergency preparedness of TSC, i.e. a procedure describing how to get ready and pack up the equipment which is placed in different rooms in the building. Attention should be paid to items such as batteries, communication means, extension cords, battery chargers, notebooks, pencils, boxes to pack up equipment, which is normally in use, etc.

6.3.4 Training, Drills and Exercises

Background

The arrangements for specific training for radiation emergency response are still in the preparatory phase, because the plans and procedures are not in place. It was reported that training in the emergency preparedness is a subject on some radiation protection courses, as well as knowledge gained by attending regional IAEA courses on emergency preparedness and response.

It was reported that exercises such as searching for a lost source and decontamination are conducted. In the last three years there were such exercises every year (2007 – orphan source in Hanoi, 2008 – contamination with broken sealed source in Hanoi, 2009 – orphan source in Dalat). However, annual or multiannual exercise programmes addressing various emergency response objectives have not been developed, neither is there any information about taking part in international emergency exercises. VARANS reported that they conduct exercises for the operators and they also evaluate the exercises.

Comments

The staff have a very good general knowledge, and regularly update this knowledge through IAEA training courses and other training events or exercises. It has to be noted that a specific training syllabus for radiation emergency response, including among other details the communication and coordination between various stakeholders, without prior developing emergency procedures has not yet been designed or conducted.

The scope and objectives of exercises are substantially limited since procedures do not exist, except for the operator's exercises. It is rather unusual that the regulator is organizing exercises for the operator.

Drills and exercises are an important element of emergency preparedness and are an indicator of how well the whole emergency response system was conceived and implemented. Thus, the emergency plans and other documents should adequately address the scope and planning of exercises.

6.3.5 Quality Assurance Programme

Background

A Quality Assurance programme for emergency preparedness and response does not exist.

Comments

During the preparation of the emergency plans, arrangements and contracts should be concluded to ensure the availability and reliability of equipment and services. The Quality Management System may ensure higher reliability, but this system can only be integrated with radiation emergency preparedness and response after the interim emergency response capability has been established.

(1)**<u>BASIS</u>**:

GS-R-2, para. 3.2-4, 5.13 states that "...[The State] shall ensure that [the regulatory body and response organizations] have the necessary resources and that they make preparations and arrangements to deal with any consequences of [a nuclear or radiological emergency] in the public domain, whether the [nuclear or radiological emergency] occurs within or beyond national [borders]. These preparations shall include the actions to be taken both in and after an emergency."

.... "It is presumed that the State will have determined in advance the allocation of responsibilities for the management of interventions in emergency exposure situations between the [regulatory body], national and local [response organizations] and [operators]...The coordinating authority shall ensure that the functions and responsibilities of operators and response organizations as specified in these requirements are clearly assigned and are understood by all response organizations, and that arrangements are in place for achieving and enforcing compliance with the requirements.

5.13 Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies...«

R42 Recommendation:

VARANS should write a National Radiological Emergency Plan and the task should be finished in a reasonable timeframe.

(1) BASIS:

GS-R-2, para. 3.15 states that "The nature and extent of emergency arrangements [for preparedness and response] shall be commensurate with the potential magnitude and nature of the [threat] ... associated with the facility or activity." (Ref. [10], para. 6.4.) The full range of postulated events shall be considered in the threat assessment."

R43 Recommendation:

Threat assessment shall be performed by VARANS for all radioactive sources and installations in Vietnam for the full range of postulated events taking into account their probability of occurrence.

BASIS:

GS-R-2, para. 3.6 states that "For the purposes of the requirements nuclear and radiation related threats are grouped according to the threat categories shown in Table I. The five threat categories in Table I establish the basis for developing generically optimized arrangements for preparedness and response."

R44 Recommendation:

The threat categorization as required in GS-R-2, para. 3.6, should be addressed and applied whenever needed.

(1)**<u>BASIS</u>**:

GS-R-2, para. 3.4 states that "....The coordinating authority shall ensure that the functions and responsibilities of operators and response organizations as specified in these requirements are clearly assigned and are understood by all response organizations, and that arrangements are in place for achieving and enforcing compliance with the requirements.."

Good Practice:

VARANS recognized that good knowledge of counterparts is essential for the effective and efficient work in the group. Therefore, VARANS plans to provide basic training on radiation protection and emergency preparedness for the provincial officials, who will take part in the working group, which is going to draft provincial radiological emergency plan.

(1)**<u>BASIS</u>**:

GS-R-2, para. 4.25 states that "Declaration of a particular class of emergency at a facility or practice in threat category I, II, III or IV shall promptly initiate the appropriate level of co-ordinated and pre-planned emergency response on and off the site. The responsibilities and initial response actions of all response organizations shall be defined for each class of emergency."

R45 Recommendation:

An emergency classification system should be in place which would enable prompt initiation of co-ordinated and pre-planned emergency response on and off the site.

(1) BASIS:

GS-R-2, para. 4.71 states that "...arrangements shall be made for promptly assessing the results of environmental monitoring and monitoring for contamination on people in order to decide on or to adapt urgent protective actions to protect workers and the public, including the application of operational intervention levels (OILs) with arrangements to revise the OILs as appropriate to take into account the conditions prevailing during the emergency."

R46 Recommendation:

For the sake of consistency with international standards, the operational intervention levels (OILs) should be adopted by VARANS and

arrangements for their implementation made.

(1)**BASIS:**

GS-R-2, para. 4.89 states that "For areas with activities in threat category V arrangements shall be made for taking effective agricultural countermeasures, including restriction of the consumption, distribution and sale of locally produced foods and agricultural produce following a release of radioactive material. These arrangements shall include: default OILs for environmental measurements (such as dose rates due to deposition and deposition densities) and food concentrations; the means to revise the OILs; timely monitoring or ground contamination in the field; the sampling and analysis of food and water; and the means to enforce agricultural countermeasures."

S25 Suggestion:

Responsibilities for decision-making regarding agricultural countermeasures and food consumption in the event of an emergency should be clearly addressed in the national emergency plan. Also sampling procedures for food, crops, and agricultural soil in the event of an emergency should be included in the appropriate procedure and the measuring capabilities designated.

(1)**<u>BASIS</u>**:

GS-R-2, para. 4.10 states that "Arrangements shall be made for the implementation of a command and control system for the response to a nuclear or radiological emergency."

R47 Recommendation:

All relevant organizations should take part in the development of emergency response management and operations organization, and implement a command and control system for adequate response to a nuclear or radiological emergency.

(1)**BASIS:**

GS-R-2, para. 4.16 states that "Notification points shall be established that are responsible for receiving emergency notifications of an actual or potential nuclear or radiological emergency. The notification points shall be continuously available to receive any notification or request for assistance and to respond promptly or to initiate an off-site response."

R48 Recommendation:

VARANS should initiate the establishment of a network of notification points across the country that includes radiological emergencies.

S26 **Suggestion:**

This network can be used to receive notification and to initiate the offsite response to an emergency of any type (conventional, nuclear or radiological).

(1) BASIS:

GS-R-2, para. 4.29-30 states that "The State shall make known to the IAEA and to other States, directly or through the IAEA, its single warning point of contact responsible for receiving emergency notifications and information from other States and information from the IAEA."

R49 Recommendation:

Vietnam should establish its Early Notification Contact Point in line with the IAEA requirements, including the operation of communication system (ENAC) and taking part in the exercises/tests aimed at testing the system.

(1)**BASIS:**

GS-R-2, para. 4.57 states that "Arrangements shall be made to designate as emergency workers those who may undertake an intervention...".

BASIS:

GS-R-2, para: 4.59 states that "Those persons who may be called upon as first responders shall be informed of the risks of radiation exposure and the meanings of radiation signs and placards."

BASIS:

GS-R-2, para: 4.60 states that "National guidance that is in accordance with international standards shall be adopted for managing, controlling and recording the doses received by emergency workers. This guidance shall include default operational levels of dose for emergency workers for different types of response activities..."

R50 Recommendation:

Emergency workers should be designated and informed about risks of radiation exposure in advance and dose limits for emergency workers should be adopted.

(1) BASIS:

GS-R-2, para.4.82 states that "All practicable steps shall be taken to provide the public with useful, timely, truthful, consistent and appropriate information throughout a nuclear or radiological

emergency."

R51 Recommendation:

Public information should be addressed in the future documents, i.e. national and provincial emergency plan and relevant procedures. The staff responsible for preparation of press releases should be designated in advance. In addition, the information pathways should be described, outlining which media information should be sent, by which means (facsimile, e-mail, telephone), and identifying the responsible person to authorize and send out this information.

(1) BASIS:

GS-R-2, para. 5.21 states that "The operating and response organizations shall develop the necessary procedures, analytical tools and computer programs in order to be able to perform the functions specified to meet the requirements for emergency response."

R52 Recommendation:

All emergency response organizations should begin developing procedures for radiological emergency response.

(1) **BASIS:**

GS-R-2, para. 5.25 states that "Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the appropriate functions. These items and facilities shall be selected or designed to be operational under the postulated conditions."

R53 Recommendation:

The NREP preparation by VARANS and other organizations should include a thorough analysis to determine whether the available resources meet the needs of emergency response, including scenarios anticipated by the threat assessment.

BASIS:

GS-R-2, para. 5.22 states that "Procedures, analytical tools and computer programs to be used in performing functions to meet the requirements for emergency response shall be tested under simulated emergency conditions and shall be validated as correct prior to use."

R54 Recommendation:

VARANS should develop a procedure to activate the Technical Support Centre staff in case of an emergency, send its staff to the scene and carry

out a response (could be for different scenarios/events). This procedure needs to be exercised before it comes into effect.

(1)**BASIS:**

GS-R-2, para. 5.31 states that "The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the required functions. The operator and the response organizations shall make arrangements for the selection of personnel."

R55 Recommendation:

After the provincial and national emergency plans and procedures are developed, VARANS should assist other organizations to prepare and conduct an emergency preparedness training programme. For first responders, this requirement can be met earlier.

$(1) \qquad \qquad \textbf{BASIS:}$

GS-R-2, para 5.36 states that "The performance of exercises at facilities in threat category I, II or III shall be evaluated against established response objectives that demonstrate that identification, notification, activation and other initial response actions can be performed in time to achieve the practical goals of emergency response."

R56 Recommendation:

All relevant organizations should take part in testing their emergency response capabilities in an exercise. The exercise should be thoroughly analyzed, and lessons learned should be integrated to improve the emergency response capability.

(1)**BASIS:**

GS-R-2, para 5.37 states that "The operator of a facility, practice or source in threat category I, II, III or IV and the off-site response organizations shall establish a quality assurance programme, in accordance with international standards, to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the functions..."

R57 Recommendation:

The response organizations should include provisions for establishing and maintaining the required quality assurance programme for radiation monitoring instrumentation and other equipment.

7. CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES

7.1 REGULATORY BODY HAS APPROPRIATE MEASURES

Background

Article 22 of the Law on Atomic Energy specifies the security measures that are required to be taken by facility operators who possess radioactive sources.

Article 25 of the Law on Atomic Energy requires that the categorization and treatment of disused radioactive sources comply with national technical standards. However, there are no national technical standards regarding disused radioactive sources. At this time, facility operators are required to store the disused sources at their licensed location or make arrangements for their return to the manufacturer, until such time as a national storage facility has been created. Where these measures are insufficient or the facility operator does not have storage capability for the disused sources, the Ministry of Science and Technology has issued a letter requiring the Nuclear Research Institute at DALAT to accept disused sources from these operators.

Article 26, item 4 requires all operators of facilities to organize for the implementation of guidelines and procedures on safety and security.

Article 30 prescribes measures to be taken with respect to the handling of lost, illegally transferred, abandoned or undeclared radioactive sources. The Article requires that any such situations be reported immediately to the People's Committee, the local police or VARANS. Where such reports are received, the Article provides clear responsibilities for taking specific actions.

Article 65 prescribes the requirements for the import or export of radioactive material, including corrective actions if appropriate authorization is not obtained prior to carrying out the activity. In most cases, the required corrective action is for the facility operator to apply for the necessary authorization.

Decision No. 115/2007/QD-Ttg on issuing Regulations on Ensuring the Security of Radioactive Sources, issued 23 July 2007 by the Prime Minister sets out regulations on ensuring the security of radioactive sources. These regulations set out:

- to whom the regulations apply;
- definitions for the purposes of these regulations;
- the principles for radioactive source security;
- the assignment of radioactive sources to security groups;
- the requirements for each of the security groups;
- the responsibilities for using, storing, and transporting each security group of sources;
- responsibility for reporting in case of radioactive source loss;
- responsibilities of the Ministries; and,
- handling violations.

Although this Decision was issued pursuant to the Ordinance on the Radiation Safety and Control, which is no longer in force, this Decision remains valid until replaced as planned in 2009.

Directive No. 13/2006/CT-BKHCN on Strengthening the State management on Radiation Safety and Radioactive Source Security, issued 7 June 2006, directs VARANS to effectively conduct the State management on radiation and nuclear safety and control and to pay special attention to inspections on security measures in radiation facilities.

Comment

The Law on Atomic Energy provides a good starting point for subsequent work to be carried out on the Code of Conduct. However, most of this Law still needs to be implemented through Decisions, Decrees and Circulars, and other legal instruments.

Decision No. 115 provides a good basis for beginning work on the Code of Conduct as it does include sufficient provisions for the use, storage and transport of the various security groups chosen by Vietnam.

In one area, the Group A radioactive sources, the regulatory body has worked with the US DOE to assist facilities in enhancing the security particularly for hospitals and irradiation facilities. The security upgrades for most of these facilities have been completed and include cameras, intrusion detection and the development of security plans by the facility operator.

Article 25 of the Law on Atomic Energy requires that the categorization and treatment of disused radioactive sources comply with national technical standards. However, there are no national technical standards at this time regarding disused radioactive sources. At this time, facility operators are required to store the disused sources at their location or make arrangements for their return to the manufacturer, until such time as a national storage facility has been created. Where this is not possible, such sources can be stored at the Nuclear Research Institute at Dalat which is mandated to accept them.

Through the control provided under Decision No. 115, there is sufficient direction to provide the starting basis for a security culture. However, operators need to understand the basis for this requirement and the regulatory body must communicate this information. The Decision must be implemented in a practical manner so as to respect the security requirements as well as the operational limitations faced by the operator.

The concept of safety culture is not well established in Vietnam, as the work philosophy is not based on an industrialized point of view. The regulatory body will have to address this issue through continued, consistent communication with operators and the general public on the concept of a safety culture. This undertaking will likely require coordination across Ministry lines. Information on the requirements for a safety culture may be found in Section 2.5 of IAEA Safety Requirements No. GS-R-3.

7.2 EFFECTIVE NATIONAL LEGISLATIVE AND REGULATORY SYSTEM

Background

Many of the requirements in this area are covered in other sections of the report and will not be repeated here. Only those provisions specific to the Code of Conduct will be reported here.

In addition to the provisions specifically outlined in the Law on Atomic Energy, regulations for the recovery and handling of orphan radioactive sources, promulgated in accompaniment with Decision No 146/2007/QD-TTg dated 4 September 2007, specify the range of activities, responsibilities and authorities for managing orphan sources. These Regulations also include provisions for the recovery of orphan sources in order to regain regulatory control.

Comment

The national legislative and regulatory system of control over the management and protection of radioactive sources provides a sound basis to meet the requirements of the Code of Conduct.

The regulations for managing orphan sources, as part of Decision no. 146/2007/QD-TTg, are particularly descriptive and detailed.

7.3 PROVISION OF FACILITIES AND SERVICES

Background

Many of the requirements in this area are covered in other sections of the report and will not be repeated here. Only those provisions specific to the Code of Conduct will be reported here.

Although there are legal requirements for reporting of abnormal events, an operator can report the event to either VARANS, DOST or the local police. VARANS will normally receive reports from the local police or DOST if radiation is involved. If the event is serious, VARANS can send a team to the facility using staff from the Technical Support Center. Personnel from the Center would be responsible for finding and retrieving lost sources. These personnel have received source recovery training in the past and have received updated training in 2007 and mid-2009. The team has played an important role in responding one incident of a lost source in 2006. The source was recovered. The affected area was cleaned up and rehabitated. This showed the effectiveness of VARANS in such situation. Personnel have access to two kits, supplied by the US DOE, for the recovery of lost sources and additional supplies are placed at additional locations in the country to expedite response.

Comment

In combination with other aspects of the function and structure of the regulatory body, it appears that there are sufficient and appropriate facilities and services available to, and used by, the persons who are authorized to manage radioactive sources.

7.4 ADEQUATE TRAINING

Background

Many of the requirements in this area are covered in other sections of the report and will not be repeated here. Only those provisions specific to the Code of Conduct will be reported here.

VARANS staff has not received training on the implementation of the Code of Conduct, other than having been provided with a copy of the document.

Training for police and other emergency responders on the discovery of an orphan source has been limited to advising these personnel to isolate the area and notify VARANS. While there is no formal training programme for emergency responders, contact information is provided through the website and specified in licenses. It is also possible for the emergency responders to contact DOST who will then in turn contact VARANS.

Comment

VARANS should provide training for its staff on the implications of the Code of Conduct and its implementation. VARANS staff will be responsible for advising on implementation of the Code and for evaluating the measures taken to comply with the Code. Therefore, it is essential that comprehensive training on all aspects of the Code of Conduct be provided to VARANS staff.

VARANS should consider additional training for police and other emergency responders who will be the likely first contact with an orphan source upon its discovery. While the system in its current form does work, police and other emergency responders need further information in order to assure consistent response in all parts of the country.

7.5 NATIONAL REGISTER OF RADIOACTIVE SOURCES

Background

Decision No. 17/2007/QD-BKHCN on the Issuance of Radioactive Sources Categorization complying with Security Requirements, issued 31 August 2007, sets up four security Groups:

- Group A sources radioactivity ratio greater than 1000;
- Group B sources radioactivity ratio of 1 to 1000;
- Group C sources radioactivity ratio of 0.01 to 1;
- Group D sources radioactivity ratio less than 0.01;

where the radioactivity ratio of a radioactive source is the quotient of the activity of the radioactive source over the "D value" of activity specific to the various radionuclide. The "D values" are base activity levels for each radionuclide and are consistent with those provided in the Code of Conduct.

These security groups are based on IAEA-TECDOC-1355, Security of radioactive sources - Interim guidance for comment, which was issued in June 2003.

As a result of a lost source incident in 2006, the government requested that VARANS establish a national registry of radioactive sources. To achieve this objective, VARANS has implemented the RAISVN software as the national registry of all radiation sources and the software Tracker, is used for control of imports and exports.

The RAISVN software is a national registry of all radiation sources, not just those in Groups A and B, and also allows for some data evaluation to be carried out, based on specific industries and licensed activities. Information on radioactive source inventories is input by the licensing staff at the time that an application is received from a facility operator. Further updates to the information are carried out as a result of information obtained from inspection reports. At present, licensing staff have updated the information in RAISVN.

The verification of the information in RAISVN versus actual inventory of an operator is also carried out during inspections which are conducted either by VARANS staff or DOST staff. In most situations where a mismatch between the national registry and the inventory of an operator occurs, the reason is the receipt by the operator of a radioactive source that is not on the existing license. In such circumstances, the operator is asked to apply for the appropriate license to allow for possession of the radioactive source. While in theory the operator could be issued a fine for the contravention of the legal documents, the VARANS normally achieves compliance by requesting the application for a license.

Comment

The RAISVN software information may not be compatible with that of other States due to the use of four groups rather than the five categories prescribed in the Code of Conduct.

The issue arises in Group B which has a wider range of activity ratios than the corresponding Categories in the Code of Conduct. Functionally, in this implementation, Group B encompasses Categories 2 and 3 from the Code of Conduct.

The regulatory body should update Decision No. 17/2007/QD-BKHCN in order to make the Groups consistent with the Categories of the Code of Conduct.

7.6 PROMPT REPORTING OF LOSS OF CONTROL

Background

No incidents have occurred where there was potential for any transboundary effects associated with the loss of control of a radioactive source.

Comment

In the event of the loss of control of a radioactive source which could have transboundary effects, VARANS needs to be able to promptly notify neighbouring States and the IAEA. Such prompt reporting has helped other States to reacquire control over such sources where they have been transported to another State. In addition, such notification provides time for the State to activate its emergency response system, as may be necessary.

7.7 PROMOTE AWARENESS OF ORPHAN SOURCES

Background

Regulations for the recovery and handling of orphan radioactive sources, which were promulgated in accompaniment with Decision No 146/2007/QD-TTg dated 4 September 2007, specify the range of activities, responsibilities and authorities for managing orphan sources. These Regulations also include provisions for the recovery of orphan sources in order to regain regulatory control. The regulations include provisions for dissemination of information to promote awareness across other Ministries and other persons likely to encounter orphan sources.

Scrap metal dealers are required by the Regulations to have a radiation meter to detect orphan sources and stray radioactive material. However, most scrap metal dealers are small business owners and do not have the resources to purchase this equipment.

Comment

The regulatory body has begun an education process with scrap dealers and has hosted a workshop with people involved in scrap metal recycling to provide some information on radiation source types and signs associated with radioactive sources. The intention is to enhance awareness of these potential hazards as this information is distributed at these meetings. No other outreach is carried out in this area. Further education of this group should be considered. Education of this group, usually the first to detect such sources, will help reduce the likelihood of these sources going undetected.

7.8 REUSE AND RECYCLING

Background

The regulatory body does not provide any specific direction on the reuse and recycling of radioactive sources. A new Circular on managing disused radioactive sources, in the context of overall radioactive waste management, is being drafted.

Comment

The regulatory body must provide guidance to operators and other persons who use radioactive sources to ensure that the principles of reuse and recycling are well understood. It is not clear that a new Circular on disused radioactive sources will address this issue. This proposed new Circular was to have been issued in 2009 but has been delayed to next year.

7.9 SAFETY AND SECURITY OF SOURCES AT ALL STAGES

Background

Vietnam has no domestic capacity for the manufacturer of sealed radioactive sources. All radioactive sources used or stored in the country are imported by the operator, under license by the regulatory body.

A storage facility for the storage of disused sources is currently under consideration for siting but no timetable has been set for its construction.

Decision No. 115/2007/QD-Ttg on issuing Regulations on Ensuring the Security of Radioactive Sources, issued 23 July 2007 by the Prime Minister sets out regulations to ensure the safety and security of radioactive sources by users.

Comment

Through the application of the Law on Atomic Energy and Decision No. 115, there is sufficient information provided to users of radioactive sources regarding the requirements for their use, storage and transport.

7.10 IMPORT/EXPORT FOR CATEGORY 1 & 2 SOURCES

Background

Each licence for import or export may be issued for one or more radiation sources, provided that the application by the operator specifies the number of sources. As of 29 September 2009, VARANS has issued 105 import licences in 2009, usually for 2-3 radioactive sources each. In the same period, VARANS has issued 5 export licences for a total of 81 radioactive sources. Most exports of radioactive sources are for those radioactive sources which are of no further use. Vietnam does not have any domestic capacity to manufacture sources and as a result there is no import of sources associated with the return of the sources to the manufacturer.

In addition to RAISVN, a separate system, called Tracker (supplied by the US DOE), is helping to establish a connection between licensing division of the regulatory body and the customs personnel at ports of entry. Using the Tracker system, the licensing staff of the regulatory body will be able to verify import and export activities associated with radioactive sources. In addition, it is also intended to allow the customs personnel to verify that the recipient is authorized to carry out the activity of import or export of the radioactive sources. Further efforts will be undertaken to integrate both Tracker and RAISVN software in the future.

Comment

While specific licenses are required for each import or export activity, there is no reporting to either the importing State, neither is there provision for prior notification for VARANS for imports. When VARANS issues a license to export a radioactive source it should ensure prior notification is sent to the corresponding regulatory body of the importing State. Similarly, VARANS should receive notifications from exporting States, prior to the activity being carried out. This will ensure that each State involved in a transaction can confirm that the intended recipient is authorized for the possession and import of that radiation source.

7.10.1 Import consent if recipient authorized

Background

Importing of sources into Vietnam requires specific licensing for this activity. Facility authorizations do not cover importation of radioactive sources. Therefore,

when an operator requires the importation of a source they must apply to the regulatory body for a specific license to carry at this activity. The application will include information on the source material, activity and intended storage location. This applies to all imports of radioactive sources.

Comment

The importation of sources into Vietnam is adequately controlled through this system of specific licensing.

7.10.2 Export consent if recipient authorized

Background

Exporting of sources from Vietnam requires a specific license for each activity although each license may comprise more than one source to be exported. However, the timing of each export under that license is not provided to VARANS. While information on the export of radioactive sources is provided following the completion of the activity, VARANS does not ensure that the intended recipient is authorized to possess the source.

Comment

VARANS must set up a system to receive information about pending exports, prior to their completion, so that VARANS may properly assure the recipient is authorized to receive the radioactive source. Such a system will require interaction with the regulatory body of the importing State.

7.10.3 Authorization under exceptional circumstances

Background

All importation or exportation of radioactive sources requires licensing by the regulatory body. This ensures that all sources are managed in a safe and secure manner. If there is no license for either import or export of radioactive sources, the activity is halted by customs personnel and VARANS is notified. The facility operator will be requested to apply for the appropriate license before the activity can resume.

Comment

The control of all importation or exportation of radioactive sources provides sufficient control and precludes the need for authorization under exceptional circumstances.

7.10.4 Re-entry of disused radioactive sources

Background

Vietnam has no domestic capacity for the manufacture of radioactive sources. Therefore, there is no provision for the reentry of disused radioactive sources for return to a manufacturer. Article 12 of the Law on Atomic Energy prohibits the importing of radioactive waste.

Comment

Since no operator in Vietnam manufactures radioactive sources, there is no requirement for the reentry of disused radioactive sources.

7.11 TRANSPORT CONTROLS

Background

Circular No. 14/2003/TT-BKHCN, on the Safe Transport of Radioactive Material, issued on 11 July 2003, prescribes requirements for those persons undertaking transport that is consistent with international requirements.

In addition, Article 9 of Decision No. 115 prescribes some requirements for the transport of Group A radioactive sources. Article 12, for the transport of Group B radioactive sources, refers to Article 9 for the requirements for transport.

Comment

Based on the requirements of Circular No. 14, there is sufficient assurance that the transport will be conducted in a manner consistent with the relevant international standards.

7.11.1 Transport controls during transit

Background

The provisions of Circular No. 14/2003/TT-BKHCN apply also to shipments in transit through Vietnam.

Comment

Based on the requirements of Circular No. 14, there is sufficient assurance that the transport while in transit will be conducted in a manner consistent with the relevant international standards.

CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

Code of Conduct, §7 (b) states that "Every State should, in order to protect individuals, society and the environment, take the appropriate measures necessary to ensure... the promotion of safety culture... with respect to radioactive sources."

R58 Recommendation:

The regulatory body, in conjunction with other Ministries, should begin the promotion of safety culture within the country.

CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

Code of Conduct, §10 states that "Every State should ensure that adequate arrangements are in place for the appropriate training of the staff of its regulatory body, its law enforcement agencies and its emergency services organizations."

R59 Recommendation:

VARANS should make arrangements to provide training to its staff for the implementation of the Code of Conduct. Such training should be sufficient to allow the required staff to evaluate proposals made by facility operators to achieve compliance with the Code.

Recommendation:

VARANS should undertake a programme of outreach for police and other emergency responders to ensure that they clearly understand their actions upon the discovery of, or reporting of, an orphan source. This information should include contact information for persons who are available to respond to such events.

$(1) \qquad \qquad \textbf{BASIS:}$

Code of Conduct, §11 states that "For the purpose of introducing efficiency in the exchange of radioactive source information between States, States should endeavor to harmonize the formats of their registers."

R61 Recommendation:

Decision No. 17/2007/QD-BKHCN should be updated to reflect the Law on Atomic Energy and revised to include categorization of the sources as provided in the Code of Conduct. This should be done in accordance with the IAEA Safety Guide RS-G-1.9.

(1)**<u>BASIS</u>**:

Code of Conduct, §12 states that "Every State should ensure that information concerning any loss of control over radioactive sources, or any incidents, with potential transboundary effects involving radioactive sources, is provided promptly to potentially affected States through established IAEA or other mechanisms."

CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R62 Recommendation:

The State should establish a process whereby notification may be made in the event of a situation with potential transboundary implications. The process should include prompt, complete notification of the potentially affected neighbouring States and also provide notification to the IAEA.

(1)**<u>BASIS</u>**:

Code of Conduct, §13 (b) states that "Every State should... encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources."

S27 <u>Suggestion</u>:

VARANS should conduct more outreach with scrap metal dealers to ensure they understand the implications of the discovery of an orphan source. In addition, the Government should consider ways of mitigating the costs for scrap metal dealers to obtain the necessary monitoring equipment.

(1) BASIS:

Code of Conduct, §14 states that "Every State should encourage the reuse or recycling of redirect resources, when practicable and consistent with considerations of safety and security."

R63 Recommendation:

VARANS should expedite the development of the new Circular regarding radioactive waste management, including the management of disused sources. VARANS should also ensure that guidance is provided to all facility operators regarding the reuse and recycling of radioactive sources.

(1) BASIS:

Code of Conduct, §23 states that "Every State involved in the import or export of radioactive sources should take appropriate steps to ensure that... transfers of radioactive sources in Categories 1 and 2 of Annex 1 of this Code take place only with prior notification by the exporting State and, as appropriate, consented by the importing State in accordance with their respective laws and regulations."

CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R64 Recommendation:

VARANS should establish a process for providing prior notification of any exporting activity to the corresponding regulatory body of the importing State. VARANS should also establish a process for receiving such notifications from any exporting State.

(1)**<u>BASIS</u>**:

Code of Conduct, §25 states that "Every State in tending to authorize the export of radioactive sources in Categories 1 and 2 of Annex 1 to this Code should consent to its export only if it can satisfy its self, insofar as practicable, that the receiving State has authorized the recipient to receive and to possess the source and has the appropriate technical and administrative capability, resources and mandatory structure needed to ensure that the source will be managed in a manner consistent with the provisions of this Code."

R65 Recommendation:

VARANS should set up a system, including prior notification, to ensure that the intended recipient in an importing State is authorized to receive the material.

8. EDUCATION AND TRAINING

8.1 REGULATIONS AND LEGAL BASIS FOR EDUCATION AND TRAINING

Background

Under Article 8(8) of Law on Atomic Energy 2008, VARANS is responsible to organise and coordinate for professional trainings on radiation protection and nuclear safety.

The responsibility for manager of the licensed organization and licensees conducting radiation practices to provide technical training for radiation workers is prescribed in the Article 26(5) of Law on Atomic Energy 2008.

As required under the Article 27(1) of Law on Atomic Energy 2008, the radiation workers need to be trained in specialised knowledge and professional skills on radiation safety.

Individuals who conduct the job of chief engineer of nuclear reactor, shift operator in chief of nuclear reactor, radiation protection officer (RPO), radiation decontamination officer, emergency response officer for radiation incidents, nuclear incidents, nuclear fuel manager, nuclear reactor's operator, operator of accelerator, operator of irradiation equipment using radioactive sources, worker for radioisotope production and industrial radiographer shall obtain certificate for radiation worker as required in the Article 28(1) of Law on Atomic Energy 2008.

Medical physicists and qualified experts are not defined under the law nor their qualifications and training.

The duty for keeping records of staff training is prescribed in Article 29(d) of Law on Atomic Energy 2008.

Comments

VARANS is responsible for organising and coordinating the professional training on radiation protection and nuclear safety. The development of a national strategy for education and training (E&T) in radiation protection and nuclear safety would ensure that national infrastructures are adequate to provide for education and training of specialists in those areas. A comprehensive national strategy would include several stages as follows:

- Analysis of training needs;
- Design of a national training programme in a realistic time frame;
- Development and implementation of a national training programme;
- Evaluation of the effectiveness of the national strategy and its individual components.

The education and training programme should address the following:

• Written procedure for approval of training syllabus, training material and E&T centers.

- Written procedure on certification of radiation workers, RPO and qualified experts in specific practices including qualification, training and experience requirements.
- Written official collaboration agreement on E&T with other training centre (supporting services).

8.2 REGULATORY RESPONSIBILITIES

Background

Licensees are responsible for providing training to their workers.

The following 5 training centre (supporting services) provide training on radiation protection and nuclear safety as required under Article 68(3) of Law on Atomic Energy 2008:

- Center for Radiation Safety and Emergency Response to Radiological and Nuclear Accidents, under VARANS, in Hanoi
- Institute for Nuclear Science and Technology (INST), in Hanoi
- Nuclear Research Institute, in Da Lat
- Ho Chi Minh Center for Nuclear Techniques, in Ho Chi Minh City
- Hanoi University of Technology (HUT), in Hanoi

In 2008, these centres provided 64 training course for 2371 participants.

INST was offering short training on radiation safety (3 days) and practical training (with 13 lectures and 9 experiments) in collaboration with Japan Atomic Energy Agency (JAEA) on radiation measurement (2 weeks) and radiation protection (2 weeks).

Training courses on emergency will be organized this year in collaboration with JAEA. The contents of the course are 2 days basic course on emergency and 5 days advance course on radiation emergency for responders.

The training centre (supporting services) is certified by MOST as required under Article 70 of Law on Atomic Energy 2008, to give training on radiation safety.

Several universities offer education in nuclear science, nuclear physics and nuclear engineering. Master degree and PhD in nuclear engineering and environmental physics course is offered by HUT.

Comments

Under the Article 70 of Law on Atomic Energy 2008, MOST is required to certify the training centre (supporting services) given training on radiation safety. Certification programme for training centre (supporting services) is recommended to accomplish this Article.

Hanoi University of Technology (HUT) is running a Master Degree course on nuclear engineering and environmental physics, a good part of which is about radiation detection and radiation protection and safety. Institute of Nuclear Science and

Technology (INST) has very comprehensive laboratories and equipment for practical training in radiation protection. VARANS should conclude an agreement with INST and HUT to establish a Postgraduate Educational Course (PGEC) master degree course in radiation protection and safety of radiation sources in HUT with parts of the practical training and experimental work placed in INST and VARANS technical support centre.

8.3 EDUCATION AND TRAINING OF REGULATORY STAFF

Background

In nuclear safety, under the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam" as specified in Part IV "Enhancing human resource for nuclear safety oversight", provides a detailed programme and action plan for training the staff for NPP project review.

In radiation safety, VARANS management has greatly increased staffing numbers, but there is not a well-defined training programme for inspectors, assessors and reviewers.

VARANS provides on-the-job training (OJT) to its staff (under the IAEA and bilateral agreement with other countries). VARANS staffs attend local, regional and international training courses supported by various countries (Australia, France, IAEA, Japan, Korea and the US). Some VARANS staffs have participated in the PGEC course in Malaysia. Some have attended IAEA train the trainer courses. VARANS also provides training on radiation protection to Departments of Science and Technology (DOST) inspection and regulatory staff (2 courses per year).

Currently, 2 VARANS staff are attending OJT at IRSN France, 2 master programmes in nuclear engineering at the National Institute for Nuclear Science and Technology (INSTN) France. 2 other VARANS staff will be going for fellowship on inspection of Nuclear power programme (NPP) at the United States Nuclear Regulatory Commission (USNRC).

Comments

In nuclear safety, it is recommended to adopt and implemented the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam".

In radiation safety, VARANS should consider the development of a structured training programme to bridge existing gaps (especially in inspection and review and assessment) in education and training of regulatory staff. The above suggested national PGEC master degree course in HUT in collaboration with VARANS and INST with support from IAEA should be considered to enhance the training of regulators and qualified experts from Technical Support Organizations (TSO). IAEA can provide standard syllabus, standards training material and experts for the course.

Certification programmes for inspectors and assessors need to be developed to ensure competencies of the authority body.

The train the trainer approach is also very useful since inspectors and assessors are also involved in giving a training/lecture on radiation safety. VARANS is also one of recognized training centres (supporting services) on radiation safety.

8.4 EDUCATION AND TRAINING OF WORKERS

Background

Under Article 33(1)(f) of Law on Atomic Energy 2008, MOST is required to provide detailed regulations and guidelines on specialized qualifications, professional skills, and safety related training requirements for radiation workers.

Under Article 27(1) of Law on Atomic Energy 2008, a radiation worker is defined as a person who directly works with radiation, has been trained with specialized knowledge and professional skills and has thoroughly understood regulations on safety.

All radiation workers are required to attend 3 days training prior recognition. Refresher training for 1 day is required every year.

Ongoing refresher training both for radiation workers in general and workers responsible for emergency response are required.

Medical doctors (specialized in radiotherapy, nuclear medicine and diagnostic radiology) and radiographers need to attend 3 days training prior recognition as a radiation worker. Training course material for radiation protection in medical fields is being developed and another course for non-medical purposes is under development too. Medical physicists and qualified experts are not defined under the law nor their qualifications and training.

Under the Article 27(2) of Law on Atomic Energy 2008, RPO is defined as person who has been trained with specialized knowledge and professional skills, has thoroughly understood regulations on safety.

Radiation protection officers are required to attend 3 days training and to sit an examination prior appointment. Appointment of the RPO will be for 3 years and can be renewed. Refresher training is required for 1 day every year.

Comments

The RPO is required to get a license. According to Article 26(2) of Law on Atomic Energy 2008 manager of the licensed organization and licensees conducting radiation practices is responsible to appoint an RPO in accordance with provisions specified by the MOST. The authority and responsibility of the appointed person shall be designated in writing. One RPO is responsible for one licensee.

Special training for RPO in specific practices is needed. Currently the training for RPO is similar as others radiation workers (3 day training with same contents). Training syllabus and training material has not been developed.

Standard training programme (syllabus, material, material, credits hours etc) for RPO need to be developed to be in line with Article 33(1)(f) of Law on Atomic Energy 2008.

Based on the number of practices and sources in Vietnam stated in the Education and Training (E&T) questionnaire for self assessment of training need (see Table 8.1 Number of training courses needed in the next five years), a national training programme in radiation protection can be developed on the following basis:

- Over the next 5 years, there is a need for 5 training courses or programme for qualified experts, 36 training courses for RPO and 100 courses for qualified operators.
- The number of courses is estimated on the basis of average 20 25 participants per course (50 participants per course for operators).
- There is a need for awareness and refresher courses for 250 radiation health professionals (mainly radiologists) which means there is a need for about 10 awareness courses for health professionals.
- Similar number of basic awareness courses is needed for other radiation workers.

The need on average every year is:

Qualified experts: 1 course
 Radiation protection officers: 7 courses
 Qualified operators 10 courses

Health professionals
 Other radiation workers
 2 Awareness or refresher courses
 basic awareness courses

Also there is a need in first 12 months for:

- national train the trainer workshop for the recognized E&T centers
- national training course for safe transport of radioactive material
- national training course on emergency and preparedness.

Table 8.1: Number of training courses needed in the next five years

Based on: the numbers supplied in the questionnaire about education and training, the Total is taken on the basis that all (existing and required) QE and RPO need to be trained, the existing qualified operators are

trained they only need a refresher course and the rest need to be trained.

| Practices using radiation sources | Total number to be trained | | | Number of training courses | | |
|--|----------------------------|------|---------------------|----------------------------|-----|---------------------|
| | Qualified Expert | RPO | Qualified operators | Qualified Expert* | RPO | Qualified operators |
| INDUSTRIAL and RESEARCH | | | | | | |
| Industrial radiography | | 52 | 285 | | 2 | 6 |
| Industrial irradiator facilities (industrial and research) | | 7 | 55 | | 1 | 2 |
| Industrial gauges and well logging | | 139 | 1100 | | 5 | 22 |
| Research activities: use of sealed and unsealed sources | 15 | 24 | 50 | 1 | 1 | 2 |
| MEDICAL | | | | | | |
| Dental radiology (alone) | | | | | | |
| Diagnostic and interventional radiology | 25 | 1250 | 5000 | 1 | 25 | 50 |
| Radiotherapy and brachytherapy | 10 | 20 | 40 | 1 | | 2 |
| Nuclear medicine | 16 | 26 | 52 | 1 | 1 | 2 |
| NUCLEAR AND RELATED IN | NDUSTRY | | | | | |
| Research accelerators or reactors | 1 | 1 | 10 | | | 1 |
| Power reactors | | | | | | |
| Fuel cycle facilities including enrichment, fuel fabrication and reprocessing facilities | | | | | | |
| Isotope production operations and source manufacturing | 1 | 1 | 7 | | | 1 |
| Uranium mines | | | | | | |
| REGULATORY ACTIVITIES | | | | | | |
| Inspectors and reviewer | 18 | | | 1 programme | | |
| OTHER PRACTICES | | | | | | |
| Waste management facility | 1 | 3 | 15 | | | 1 |
| Veterinary Radiology | | | | | | |
| Security equipment (e.g. baggage x-ray, container inspection, etc) | | 21 | 500 | | 1 | 10 |
| Any other | | | | | | |
| Total | | | | 5 | 36 | 100 |

EDUCATION AND TRAINING RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

BSS - SS No. 115 NATIONAL INFRASTRUCTURES states that "National infrastructures must provide for adequate arrangements to be made by those responsible for the education and training of specialists in radiation protection and safety".

(2)**BASIS:**

RS-G-1.4 §4.5 states that "A national strategy for building competence consists of interrelated phases"

- Analysis of training needs;
- Design of a national training programme in a realistic time frame;
- Development and implementation of a national training programme;
- Evaluation of the effectiveness of the national strategy and its individual components.

S28 **Suggestion:**

VARANS should develop national strategy to ensure that national infrastructures are adequate to provide for education and training of specialists in radiation protection and safety. This national strategy consists of several phases: analysis of training needs; design of a national training programme in a realistic time frame; development and implementation of this programme; evaluation of the effectiveness of the national strategy and its individual components.

S29 Suggestion:

The relevant authority should approve the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam" which address education and training in nuclear safety.

S30 Suggestion:

MOST should develop a well defined procedure for certification of E&T centers.

(1)**<u>BASIS:</u>**

GS-R-1 § 4.7 states that " ...the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts.

EDUCATION AND TRAINING RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S31 <u>Suggestion:</u>

VARANS should consider the development of a structured training programme to bridge existing gaps (especially in inspection and review and assessment) in education and training of regulatory staff.

(1) **BASIS:**

BSS - **SS** No. 115 states that "(I) (h) suitable and adequate human resources and appropriate training in protection and safety be provided, as well as periodic retraining and updating as required in order to ensure the necessary level of competence."

S32 **Suggestion:**

VARANS should develop a standard training programme for RPO.

G5 Good practice:

In nuclear safety, under the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam" as specified in Part IV "Enhancing human resource for nuclear safety oversight" provides a detailed programme and action plan for training the staff of the regulatory authority for NPP project review. This draft plan is very comprehensive and sufficient for training regulators is the assessing and reviewing the NPP project.

9. THE MANAGEMENT SYSTEM FOR THE REGULATORY BODY

9.1.1 Management System

Background

Paragraph 4.5 of GS-R-1 requires that "The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."

GS-R-3 defines the requirements for establishing, implementing, assessing and continually improving a management system. GS-R-3 may be used by regulatory bodies as the basis for its management system. GS-R-3 states that the main aim of the management system is to ensure that the organization gives paramount and overriding priority to safety over other demands and that this management system should take account the all requirement for managing the regulatory body.

VARANS has made progress in establishing, implementing and documenting some of its activities, especially in defining functions, tasks and authorities of various department of VARANS through Decision No. 136/QD-ATBXHN that provides for the functions, tasks and authorities of VARANS departments, Decision No. 2248/QD-BKHCN (10 October 2008) by Ministry of Science and Technology to promulgate the VARANS Statute, and Decision No. 483/QD-BKHCN (2 April 2007) by MOST to establish VARANS Inspectorate and to promulgate its Statute. However, there are still many documents to be developed at the VARANS level, especially in taking into account the priority to safety, coherence and integrating requirements from different sources.

Safety Culture: GS-R-3 requires that the management system be used to promote and support a strong safety culture. In VARANS, safety culture is considered to be an important issue and promoting safety culture to be an essential element of a robust safety and security infrastructure but currently there is no mechanism to promote safety culture in VARANS. It should also be noted that VARANS has no processes in place to promote safety culture within regulated organizations.

Grading the application of the management system: GS-R-3 requires that the application of the management system is to be graded, giving due consideration to the potential hazard and consequences in an activity or facility. VARANS's application of management system requirement is not graded clearly but grading is applied to some extent in developing the human resource plan. Each division has its own development plan with clearly stated functions and responsibilities.

Documentation of the management system: GS-R-3 requires that the documentation of the management system include the policy statements of the organization, a description of the management system, the organizational structure, the responsibilities and accountabilities of those managing and performing work and a description of the processes of the work carried out by the organization. GS-R-3 requires that the documentation be understandable to those who use it and that it be made available at the point of use. Documents exist that describe the organizational structure of VARANS, the functions of each division, the roles and responsibilities of each Unit, procedures for the development of regulations and guides, the authorization

process, and guidelines for inspection and enforcement. Some of these documents are the policies that are defined in the Law, but have not been reproduced in lower level document, while others have been developed by VARANS and are authorized by Director General of VARANS. However, the documentation for some processes is not complete, and other activities and processes of VARANS are not documented.

Comment

GS-R-3, para 2.1, 2.8-2.10

While VARANS has made progress in documenting its policies, organizational structure, functions, roles and responsibilities or organizational units, and procedures for some of its activities, VARANS has not formally established a documented management system.

GS-R-3, para 2.5

VARANS does not carry out any activities to promote safety culture within VARANS or within regulated organizations.

9.1.2 Management responsibility

Background

The requirements for management responsibility in GS-R-3 include requirements in relation to: management commitment; satisfaction of interested parties; organizational policies; planning; and responsibility and authority for the management system.

Management commitment: There is an indication of management commitments to establish a management system, but work on formally developing a management system has not commenced, and resources to establish the management system have not been provided.

Satisfaction of interested parties: VARANS has no mechanism to identify its stakeholders or to assess and measure stakeholder satisfaction.

Organizational policies: Senior management of VARANS has developed policies of VARANS that are set out in the Master Plan of VARANS.

Planning: VARANS develops a Master Plan to describe its work plan for each year. VARANS participates in an annual review of existing activities for each Division and staff member and those planned for the forthcoming year. Based on that plan, the regulatory body asks the Minister of MOST for the needed human and financial resources. VARANS can also prepare specific plans to carry out particular projects and will request the necessary resources for these activities.

Responsibility and authority for the management system: Senior management of VARANS has not assigned responsibility for the development and implementation of the management system.

Comment

GS-R-1, para 3.1-3.14

Since a documented management system does not exist, there was little evidence of demonstration of management commitment to continual improvement of management system. Background interview revealed that there has been limited initiative to develop individual and institutional values and defining behavioural expectation for staff of regulatory body. However, senior management tries to instill a culture of professionalism and efficiency.

VARANS have not made any formal efforts for identification of its internal or external stakeholders and therefore any effort to assess and measure their expectation is also missing.

In the absence of a documented management system there was no evidence of development of organizational policies at VARANS level but high level policies are given in Law No 18/2008/QH12.

9.1.3 Resource management

Background

The requirements for resource management in GS-R-3 include requirements in relation to: provision of resources; human resources; and infrastructure and the working environment.

Provision of resources: GS-R-3 requires that senior management determine the amount of resources (staff, infrastructure, office and laboratories, equipment, and financial) necessary, and provide the resources to carry out the activities of the organization, or to establish, implement, assess and continually improve the management system. VARANS did not provide evidence that it has determined what resources are necessary to carry out all of its activities, or to establish the management system.

Human resources: GS-R-3 requires that senior management determine the competence requirements for staff at all levels, and to provide training to achieve the required level of competence. GS-R-3 also requires that senior management are to ensure that individuals are competent to perform their assigned work, and that they understand the consequences for safety for their activities. VARANS did not provide evidence that it has determined the competence requirements for staff at all levels.

Infrastructure and the working environment: GS-R-3 requires that senior management is to determine, provide and maintain infrastructure and working environment for the requirements to be met. VARANS did not provide evidence that it has determined the physical resources that are required to carry out its activities.

Comment

GS-R-3, para 4.1 - 4.5

There was no documented evidence about the level of resources, including staff numbers, office and laboratory space, and working equipment, required by VARANS to carry out its activities and responsibilities.

The competence requirements for staff at all levels and their training programme were not available. There was no formal mechanism for evaluation of effectiveness of training programmes.

9.1.4 Process implementation

Background

The requirements for process implementation in GS-R-3 include requirements in relation to: developing processes and process management, the control of documents, control of products (such as regulations and guidance documents, licences, inspection reports, enforcement notices, public information, annual reports), control of records, purchasing and communication.

The core processes of VARANS include the development of regulation and guides, authorization, review and assessment, inspection and enforcement, and the provision of some technical services, but they are not fully documented. Other processes of VARANS include management processes (e.g. business planning, performance management) and supporting processes (e.g. human resources, purchasing).

Some elements on procedures for the core processes have been developed, such as for authorization, review and assessment, and inspection of the use of radiation sources in industry and medical facilities, and research reactors, but they are general and not facility specific.

Comment

GS-R-3, para 5.1-5.29

While some elements of the processes of VARANS are documented, others are not, such as for authorization, review and assessment, and inspection for research reactors.

9.1.5 Measurement, assessment and improvement

Background

The requirements for measurement, assessment and improvement in GS-R-3 include requirements in relation to: monitoring and measurement; assessment; management system review; non-conformance and corrective and preventive actions; and improvement.

As noted earlier, VARANS reviews the performance of divisions and staff in carrying out the activities of the Master Plan each year. However, the requirements on

management system review are applicable when the management system has been documented.

Comment

GS-R-3, para 6.1-6.18:

In developing its management system, VARANS will need to ensure that the management system provides for management at all levels to evaluate the performance of work and the improvement of safety culture, and that it is monitored and measured to confirm that its processes achieve their intended results, and to identify opportunities for improvement.

ORGANIZATION OF THE REGULATORY BODY: THE MANAGEMENT SYSTEM FOR THE REGULATORY BODY RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GS-R-1, 4.5, GS-R-3 §2.1 states that "A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:

- —Bringing together in a coherent manner all the requirements for managing the organization;
- —Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
- —Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."

BASIS:

GS-R-3, §2.8-§2.10 states that "The documentation of the management system shall include the following:

- The policy statements of the organization;
- A description of the structure of the organization;
- A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;

A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."

R66 <u>Recommendation</u>: VARANS should establish and implement a documented management system that is understandable to all of those who will use it, and make it available to all staff to use.

ORGANIZATION OF THE REGULATORY BODY: THE MANAGEMENT SYSTEM FOR THE REGULATORY BODY RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- S33 <u>Suggestion:</u> VARANS while developing the management system should take account of the graded application of management system and the promotion of safety culture.
- S34 <u>Suggestion:</u> VARANS should include a process to identify its stakeholders and their expectations in the management system.
- S35 <u>Suggestion:</u> VARANS, while developing the processes, should take account of the control of documents, products and records.
- Suggestion: VARANS in developing its management system ensure that it provides for management at all levels to evaluate the performance of work and the improvement of safety culture, and that it is monitored and measured to confirm that its processes achieve their intended results, and to identify opportunities for improvement.

10. SAFETY INFRASTRUCTURE FOR A NATIONAL NUCLEAR POWER PROGRAMME

10.1 INTRODUCTION

The IAEA, based on Member State request, is developing a Safety Standard Guide regarding the development of a safety infrastructure for States implementing a nuclear power programme. The document, which is currently in draft, is DS-424, "Establishing a Safety Infrastructure for a National Nuclear power programme." DS-424 describes the gradual implementation of the IAEA Safety Standards (Actions) beginning with the State's initial consideration of developing a national nuclear power programme (Phase 1) through construction and readiness for commissioning of the NPP (Phase 3).

VARANS, together with other relevant organizations (VAEI, MOIT, EVN and etc), conducted a national self-assessment based on the actions identified in DS424 for phases 1 and 2, and provided the information with regard to development of Vietnam's national nuclear safety infrastructure.

This section of the IRRS report addresses the review that was conducted of Vietnam's progress with respect to safety infrastructure development using DS-424 as a reference (Phases 1 and 2 only). Specifically, the review addressed the Actions expected to be conducted to comply with IAEA Safety Standards by the various organizations (Government, Regulatory Body, Operating Organization, etc.) involved in the development of Vietnam's nuclear power programme during Phases 1 and 2 only. The review included 19 of the 20 areas covered by DS-424 (Preparation for Commissioning is only applicable in Phase 3 and was not addressed.).

The Recommendations and Suggestions identified during this review were based on existing and draft IAEA Safety Requirements (not DS-424) and are thus referenced as the Basis for each, and reflect the level of completion expected at the end of Phase 2 (Ready to Invite Bids for a NPP).

10.2 NATIONAL POLICY AND STRATEGY

Phase 1

Action 1: The government should consider the necessary elements of a national policy and strategy for safety, in conjunction with the fundamental safety objective and principles established in the IAEA Safety Fundamentals.

The Prime Minister of Vietnam issued a Prime Minister Decision in January 2006, identifying the "Strategy for Peaceful Uses of Atomic Energy up to 2020," which includes the development of nuclear power. The Master Plan for implementing the Strategy was approved in a Prime Minister Decision in July 2007. The Ministry of Science and Technology (MOST) has been assigned responsibility for implementing the Master Plan, which consists of 23 separate projects.

Action 2: The government should ensure the coordination among the stakeholders of all the activities of the safety infrastructure development.

The Government (MOST) has been directing the coordination through the following documents:

- "Strategy for peaceful uses of atomic energy up to 2020", which clearly defines responsibilities of relevant Ministries.
- The Master Plan to implement "Strategy for peaceful uses of atomic energy up to 2020". Of the 23 projects specified in the Master Plan, 17 projects have safety implications or are directly related to safety (Projects Nos. 6 14, and 16 23).

The Law on Atomic Energy was issued, effective 1 January 2009, and Decrees, Circulars, Technical Regulations and Standards are being formulated to provide the detailed responsibilities of stakeholders with regard to implementing the law. The existing plan is for VARANS to develop 45 technical regulatory documents before the end of 2011, with an additional 5 being developed by the end of 2012.

Although MOST has the responsibility for coordinating the nuclear programme development it is not clear how the various stakeholders and organizations involved in the nuclear programme development provide input to MOST such that it is able to coordinate the development of all of the applicable organizations at the appropriate time.

Action 3: The government should ensure that the status of the national safety infrastructure is assessed in relevant areas and that radiological aspects are adequately analysed in the environmental impact assessment (EIA).

Initial assessments have been conducted by various ministries in a number of areas as part of their specific projects. However, these assessments were not sufficiently detailed to develop a plan for necessary actions to be taken. Fields that have been assessed to some level include:

- Legal framework
- Organizational system
- Capability of research and development
- Capability to ensure safety, security, and safeguards
- Human resources

General assessments are also included in:

- "The Strategy for peaceful uses of atomic energy up to 2020", in which the national safety infrastructure was assessed. Areas addressed in the Strategy are nuclear power research and development, technical infrastructure, legal framework, human resources, and state management, mechanisms and policies. At present, the national safety infrastructure is only for ensuring radiation safety. The national infrastructure for nuclear safety is at a very early stage of development.
- Vietnam's regulatory body has been assessed twice, in 2003 and 2006, by the International Atomic Energy Agency (IAEA). However, these assessments were only on Radiation Safety (Radiation Safety and Security Infrastructure (RaSSIA) missions).

Between November 2008 and September 2009, the regulatory body for radiation and nuclear safety in Vietnam (Vietnam Agency for Radiation and Nuclear Safety – VARANS) conducted a self-assessment with IAEA support. This was an opportunity for Vietnam in general and VARANS in particular to assess the progress that Vietnam made after the RaSSIA mission in 2006 and more importantly to assess the regulatory and safety infrastructure of Vietnam in preparation for the nuclear power programme.

The requirements for Environmental Impact Assessment are specified in:

- Law on Atomic Energy (Items d and đ Article 38; Item d, Article 41; Article 44; Item 2 Article 47; Item 2 Article 48; Article 52);
- Environment Protection Law (Article 18-23);

The Ministry of Natural Resources and Environment has the responsibility to establish the specific programme for the application for environmental protection. A Decree on nuclear power plants is currently drafted and will define the required content of the Report of Environmental Impact Assessment.

Action 4: The government in cooperation with legislative bodies should take due account of the assessment of the safety infrastructure elements and the fundamental principle of justification when making a decision on whether or not to introduce nuclear power.

The decision on the introduction of nuclear power plan will be based on:

- Research regarding the development of the first nuclear power plant in Vietnam, which has been carried out since the 1990s,
- The Planning on Electricity, which is regularly updated.

The formal decision to move forward with a nuclear programme in Vietnam has not yet been made. A Pre-Feasibility Study (PFS) has been conducted and is with the National Assembly for review and action (November 2009). If the PFS is approved and signed, that will constitute the official approval for continued development of the nuclear programme.

In addition, the Government requires the investor to develop an investment report to submit to the National Assembly for a decision on investment policy as specified in Article 46 of the Law on Atomic Energy. The fundamental principles of justification shall be included in the investment report included in the PFS. Several justifications in the PFS report have already been confirmed by research that has been conducted over time and is regularly updated.

Phase 2

Action 5: The government in cooperation with legislative bodies should establish a clear national policy and strategy for safety in order to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.

A national policy and strategy have been identified as noted in Action 1. However, the Strategy and Master Plan do not include all of the elements addressed in the Safety Fundamentals, SF-1.

Principle 2, Role of Government, addresses an independent regulatory body. The licensing arrangement of the NPP as stated in the Law on Atomic Energy would not meet this Principle.

Principle 3, Leadership and Management for Safety, addresses management systems. This principle would apply to all organizations involved in safety-related activities including design, construction, operation, etc. It is not clear how management system principles will be applied in all of the involved organizations throughout the various ministries.

Principle 4, Justification of Facilities and Activities, addresses that the benefits of facilities and activities must outweigh the radiation risks to which they give rise.

Principle 6, Optimization of Protection, addresses providing the highest level of protection that can be reasonably achieved. It is not clear from the Strategy, Master Plan, or the Law on Atomic Energy what level of safety/risk is acceptable. This specificity may be planned to be addressed during the formulation of specific requirements yet to be developed.

Action 6: The government should ensure that the development of the various elements of the safety infrastructure is adequately coordinated.

See Action 2.

Action 7: The government in cooperation with legislative bodies should ensure identification and progressive allocation of responsibilities to the relevant organizations involved in safety infrastructure development.

In the Law on Atomic Energy:

- Article 7 provides for the State management in the field of atomic energy.
- Article 8 provides for functions and responsibilities of the Agency for Radiation and Nuclear Safety (VARANS).
- Article 9 provides for the roles and responsibilities of the National Council on Development and Application of Atomic Energy and the National Nuclear Safety Council.

However, these provisions are not specific and detailed requirements still need to be formulated.

The Master Plan assigns responsibility for the various 23 projects to individual ministries. The ministries are responsible for developing plans to implement each project (See Action 2).

NATIONAL POLICY AND STRATEGY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

Draft GSR Part 1, Requirement 1 requires that "The government shall establish a national policy and strategy for safety, the execution 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."

R67 Recommendation:

The government should ensure that there is appropriate coordination between the government (Ministries), regulatory authorities (VARANS and others as applicable) and the operating organization (EVN) to assure all fundamental safety principles are addressed in the nuclear safety infrastructure.

S37 **Suggestion:**

As part of the coordination, the government should conduct assessments of all areas that are required to support the national nuclear safety infrastructure that are sufficient in detail to develop national action plans.

10.3 GLOBAL NUCLEAR SAFETY RÉGIME

Phase 1

Action 10: The government should prepare for active participation in the Global Nuclear Safety Regime.

Vietnam has been preparing to participate further in the Global Nuclear Safety and Security Regime.

- At present, Vietnam is actively participating in activities organized or supported by the IAEA, and using the IAEA and international standards as reference for formulating legal documents and technical standards.
- Vietnam is a party to several important international treaties in the field of nuclear energy, including:
 - Treaty on the Non-Proliferation of Nuclear Weapons (NPT);
 - Comprehensive Nuclear Test Ban Treaty
 - Safeguards Agreement (for NPT) with the IAEA;
 - Convention on Early Notification of a Nuclear Accident;
 - Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency;
- The Ministry of Science and Technology has established an inter-ministerial working group, which meets every two months, to study additional international treaties. VARANS is a standing member of the group and is studying relevant international conventions so as to propose to the Government a roadmap for

participation. The following conventions have been reviewed by the committee and recommended to the government for approval:

- Convention on nuclear safety;
- Convention on the Physical protection of Nuclear materials.

The following two conventions are scheduled to be addressed/studied at the next meeting of the inter-ministerial committee:

- Joint Convention on the Safety of Spent fuel Management and on the Safety of Radioactive Waste Management;
- Vienna Convention on Civil Liability for Nuclear Damage.

Additional international treaties and conventions under study include:

- Additional Protocol:
- Paris Convention on the Third Party Liability in the Field of Nuclear Energy;
- Joint Protocol relating to the Application of the Vienna Convention and the Paris Convention; and
- Convention on Supplementary Compensation for Nuclear Damage.

Action 11: The government should begin dialogue with neighbouring States regarding its projects to establish a nuclear power programme.

Vietnam has discussed its nuclear plans with China in conjunction with discussions regarding China's plans to operate nuclear facilities near Vietnam's borders. Detailed discussions with other countries bordering Vietnam have not been conducted.

Action 12: The government and other relevant organizations should establish contact with foreign and international organizations to seek advice on matters related to safety.

The Government has established relationships with foreign and international organizations, including:

- Participating in international treaties, conventions, agreements;
- Agreements on cooperation in the use of nuclear energy for peaceful purposes (See Action 11).

Vietnam actively participates in regional forums such as Association of Southeast Asian Nations (ASEAN), Asian Nuclear Safety Network (ANSN), and Forum for Nuclear Cooperation in Asia (FNCA) and has shared information with neighbouring countries in the region of the plan for the nuclear power plant programme through these organizations and the IAEA.

The Government and relevant organizations and agencies also asked for consultations in nuclear safety for the nuclear power programme, especially from the IAEA.

Vietnam annually exchanges information with electricity companies, and Heads of Asian Power Utilities/Authorities (HAPUA). Vietnam has bilateral cooperation

agreements with 5 countries: Russia, China, the Republic of Korea, India and Argentina and is working on cooperation agreements with other countries such as France, Japan, and USA.

VARANS has established bilateral cooperation agreements with the United States of America, France, Japan, Australia, and the Republic of Korea as follows:

- 1. Bilateral cooperation with the National Nuclear Security Agency (NNSA/US DOE). NNSA assisted VARANS in formulating the Law on Atomic Energy, regulations on ensuring the security of radioactive sources and the regulation on recovery and handling of orphan radioactive sources.
- 2. Bilateral cooperation with US Nuclear Regulatory Commission (US NRC): NRC assisted VARANS in developing an action plan to strengthen capacity of the regulatory body (VARANS), developing the Circular on siting, providing training for staff of VARANS, VAEI, and EVN on nuclear safety in NPP siting and nuclear safety in general.

A training course on organizational structure and staffing for the regulatory body provided by the US NRC is scheduled for later in 2009. Currently NRC is assisting VARANS in formulating regulations on NPP construction, including design requirements.

- 3. Bilateral cooperation with the IRSN France: IRSN provided VARANS with the Code for Analysis of Thermal hydraulics during an Accident of Reactor and safety Evaluation (CATHARE). Two VARANS staff have been trained in using this code.
- 4. Bilateral cooperation with Japan (JNES) for exchange of technical information related to nuclear safety
- 5. Bilateral cooperation with Japan (JAEA) for exchange of technical information in non-proliferation.
- 6. Bilateral cooperation with Australia (ANSTO) for ensuring security of radioactive sources and emergency response.
- 7. Bilateral cooperation with Australia (ARPANSA) for exchange of technical information
- 8. Korea (KINS and KAERI): signed the Memorandums of Understanding on cooperation and exchange of technical information on nuclear safety.

Phase 2

Action 13: All the relevant organizations should continue participation in the Global Nuclear Safety Regime

See Actions 10 - 12.

Action 14: The government in cooperation with legislative bodies should adhere to the relevant international conventions, as identified in Phase 1.

See Action 10. Vietnam is also a party to the Code of Conduct on the Safety and Security of Radioactive Sources and Guidelines on Export and Import Radioactive Sources.

Action 15: All the relevant organizations should strengthen cooperation with countries with advanced nuclear power programmes on matters related to safety.

Vietnam is and has been cooperating with several countries with advanced nuclear programmes such as Russia, France, United States, Japan, and Korea for receiving assistance in training and developing nuclear energy and nuclear safety infrastructure. This cooperation is expected to continue.

GLOBAL NUCLEAR SAFETY REGIME: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1 Requirement 14 states that "The government shall fulfill the relevant international obligations, shall participate in the relevant international arrangements, including international peer reviews, and shall promote international cooperation to enhance safety globally."

- S38 <u>Suggestion</u>: The Government should continue efforts to approve and ratify the appropriate and applicable international instruments associated with the development of a nuclear power programme.
- Suggestion: The regulatory body should ensure that communications are established with all neighbouring countries regarding the development of the nuclear power programme and the sharing of information related to nuclear operating and regulatory experiences.

10.4 LEGAL FRAMEWORK

Phase 1

Action 19: The government in cooperation with legislative bodies should identify all necessary elements of a legal framework for the safety infrastructure, and plan how to structure and develop it.

Vietnam is developing a legal framework necessary for the safety infrastructure, including:

- The Law on Atomic Energy, issued in June 2008;
- Drafting Decrees under the law (in progress);
- A circular on requirements of nuclear safety for siting at PFS stage, issued in 2009;

- Technical regulations (for radiation safety, nuclear safety, safety of transport, radioactive waste management) are in planning;
- Technical standards are in planning.

Relevant legislative agencies have been involved in this process.

Currently, VARANS is developing a roadmap for formulating and issuing legal documents, and coordinating with the General Department of Standards, Metrology and Quality to issue technical regulations and standards in order to ensure nuclear safety for all stages of the nuclear power plant programme. The current schedule is for 45 legal documents to be issued by the end of 2011 and another 5 by the end of 2012.

Action 20: The government in cooperation with legislative bodies should consider the process which needs to be employed to licence nuclear power facilities in the later stages of the programme.

Article 77 of the Law on Atomic Energy specifies the authority and procedures for issuing licenses for operating nuclear power plants.

Approval or licenses for different stages of the NPP programme have been specified:

- Approval for PFS (Article 46 of the Law on Atomic Energy, Circular 13/2009-BKHCN);
- Approval for siting (Article 47 of the Law on Atomic Energy);
- Approval for FS and licence for NPP construction (Article 48 of the Law on Atomic Energy);
- License for commissioning and operation (Article 50 of the Law on Atomic Energy).

Details of these approvals and licenses are not yet developed or approved and are expected to be provided in the Decree on nuclear power plants which is under development.

Phase 2

Action 21: The government in cooperation with legislative bodies should enact and implement essential elements of the legal framework for the safety infrastructure.

Vietnam is in the process of developing relevant legal documents.

Many legal documents in the field of atomic energy have been promulgated, including:

- 1. Criminal Law, 1999
- 2. Environmental Law.
 - Decree No. 21/2008/ND-CP dated February 28, 2008 by the Government. Decree No. 80/2006/ND-CP dated August 09 2006 by the Government, is a

- detailed guide on implementation of some provisions in the environmental law.
- Decree No. 121/2004/ND-CP dated 12/5/2004 by the Prime Minister on handling administrative violations in the field of environment protection. Articles 14, 15, 20 in the Decree are related to radioactive waste transport, handling and management.
- 3. Law on Natural resources and minerals.
 - The Law on Natural resources and minerals was approved by the National Assembly in 1996. Several provisions in this law provide for radiation safety in mining radioactive ores. The law has been revised, amended, and promulgated in 1/10/2005 (The Law No.46/2005/L-QH11) in association with Decrees No. 160/2005/ND-CP, No. 01/2006/ND-CP, and No.07/2009/ND-CP.
- 4. Law on Atomic Energy adopted by the National Assembly on 3/06/2008 at the third session of General Conference XII, 03/06/2008. The law consists of 11 chapters with 93 articles, and came in force on 01/01/2009.
 - Decree No.50/1998/ND-CP dated July 16, 1998 detailing the Implementation of the Ordinance on Radiation Safety and Control.
 - Decree No. 51/2006/ND-CP, dated 19/05/2006, concerning administrative violations in the field of radiation safety and control.
 - Regulation on ensuring the security of radioactive sources promulgated in accompaniment with Decision No.115/2007/QĐ-TTg, dated 23rd July 2007 by the Prime Minister.
 - Regulations for the recovery and handling of orphan radioactive sources promulgated in accompaniment with Decision No 146/2007/QD-TTg dated 4 September 2007 of the Prime Minister.
 - Circular No. 14/2003/TT-BKHCN, dated 11/7/2003, Guiding on radiation transportation safety.
 - Circular No.05/2006/TT-BKHCN, dated 11/1/2006, Guides on declaration and authorization issuance of radiation-related practices.
 - Circular No.10/2006/TT-BKHCN, dated 17/5/2006, Guides on inspection in radiation safety and control.
 - Directive No. 13/2006/CT-BKHCN, dated 7/6/2006, on strengthening the State management on radiation safety and radioactive source security.
 - Decision No.17/2007/QĐ-BKHCN, dated 31/8/2007, on the issuance of radioactive sources categorization complying with security requirements
 - Circular No.13/2009/TT-BKHCN, Guiding on preliminary nuclear safety assessment for site selection for nuclear power plants.

A plan for formulating legal documents is being developed (See Action 19).

LEGAL FRAMEWORK: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1, Requirement 2, item 2.5(4) states that "The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated... The government has to promulgate laws and statutes... The rationale for the authorization of new facilities and activities and the applicable decision making process;"

BASIS:

Draft GSR Part 1, Requirement 4, item 2.12 states that "Where several authorities are involved in the authorization process, the regulatory requirements have to apply and they have to be applied consistently and without undue modification."

S40 **Suggestion:**

VARANS should make preparations to develop and formalize detailed requirements and guidance regarding the licensing process for the NPP taking into account the various regulatory authorities involved (VARANS, MOIT, MONRE, etc.).

10.5 REGULATORY FRAMEWORK

Phase 1

Action 23: In case the nuclear safety regulatory body is already established or identified in Phase 1 (which is not the scenario developed in this Safety Guide, where it is established at the beginning of Phase 2), it should be involved together with the government in the safety infrastructure development activities from the beginning.

The regulatory system in Vietnam consists of the Ministry of Science and Technology, the Ministry of Industry and Trade and the Ministry of Natural Resources and Environment.

These Ministries are taking part in implementing the Projects specified in the Master Plan for implementing the Strategy for peaceful uses of atomic energy, in order to establish an acceptable infrastructure for nuclear safety.

The Vietnam Agency for Radiation and Nuclear Safety (VARANS) is responsible for assisting the Ministry of Science and Technology in ensuring nuclear safety. The Agency's functions and responsibilities are specified in Article 8 of the Law on Atomic Energy. VARANS is actively involved in establishing and developing the safety infrastructure for all activities from the beginning of the nuclear power programme and is actively working with other ministries as necessary.

Action 24: The government should recognize the need for an effectively independent and competent regulatory body, and consider the appropriate position of the regulatory body in the State's structure.

The Government, in the Strategy for Peaceful Utilization of Atomic Energy up to 2020 recognized the importance of an effectively independent and competent regulatory body. The strategy has the stated goal "to perfect the system of state management agencies in charge of atomic energy, and radiation protection and nuclear safety on the principle of ensuring the independence between those bodies in the course of performance of their tasks."

Although the Law on Atomic Energy specifies functions and responsibilities of the regulatory body for radiation and nuclear safety in Article 8, the Law presents the following conflicts:

- While EVN as an NPP investor belongs to the Ministry of Industry and Trade, this Ministry will issue the Operating License for operating the nuclear power plants.
- The Ministry of Science and Technology is responsible for promoting atomic energy application and VARANS is a safety regulatory body under this same Ministry.

Project 23 of the Master Plan addresses strengthening the professional capability of the State regulatory body (VARANS). VARANS has drafted an action plan to implement Project 23 and submitted it to MOST for review and approval.

Action 25: The government should identify the prospective senior managers of the regulatory body.

The Government has not yet planned for long term succession of senior managers of the regulatory body.

- The resource for key persons in nuclear safety management in Vietnam is very limited

At present, VARANS has recognized the importance of human resource development for radiation and nuclear safety management. VARANS established a Division of Nuclear Safety in October 2008 and has initiated its plan for training young staff, especially key staff in relevant specializations, in order to ensure sufficient staff in future for the nuclear power programme. (3 VARANS staff have been sent to study Master and PhD Degrees in nuclear physics in France).

Action 26: The government should consider the various alternative regulatory approaches and recognize their importance with subsequent activities.

Related Ministries and agencies are responsible for addressing the appropriate regulatory approaches. In its activities in radiation and nuclear safety management, VARANS has consulted experiences and various alternative approaches from regulatory bodies in other countries such as USA, France, Japan, and Korea. However, applying those approaches depends on many factors (organizational structure, human resource, financial resource and capacity of the regulatory body). It is expected that this issue will be addressed and gradually improved in order to be able to respond to actual situations in future.

Phase 2

Action 27: The government in cooperation with legislative bodies should establish an effectively independent regulatory body, if not already established, and empower it with the adequate legal authority, technical and managerial competence, and human and financial resources to fulfil its responsibilities in the nuclear power programme.

See Action 24 with regard to independence. In the Law on Atomic Energy, the regulatory body licensing for activities in the field of atomic energy includes: the Ministry of Science and Technology; the Ministry of Natural Resources and Environment (licensing for mining radioactive ores), and the Ministry of Industry and Trade (licensing for operating nuclear power plants). In addition, Article 8 of the Law establishes and specifies functions and responsibilities of the Agency for Radiation and Nuclear Safety. VARANS currently has limited staff and technical capability with regard to nuclear safety. With less than 10 VARANS staff devoted to drafting legal documents, and the goal (and plan) for developing 45 legal technical documents before the end of 2011, it is very unlikely that VARANS has the capability (sufficient competent human resources) to accomplish the task.

Action 28: The government in cooperation with legislative bodies should, in particular, appoint senior managers and key experts to the regulatory body and form its organizational structure.

The Duties and responsibilities of VARANS are listed in Article 8 of the Law on Atomic Energy. The organizational structure of the regulatory body is defined in the MOST Decision on Promulgating the Charter of Organization and Operation of the VARANS, dated 10 October 2008. The functions, responsibilities and authorities of divisions under VARANS are identified in the VARANS DG decision dated June 03, 2009.

Although the structure of VARANS has been established, the number of staff is very limited. The number of staff with significant nuclear experience is very small, and in its current state, will likely pose a significant challenge to VARANS in meeting its regulatory obligations.

Action 29: The regulatory body should consider adopting the IAEA Safety Standards for developing a consistent regulatory approach, possibly supported with appropriate national requirements and guides.

Currently, VARANS (MOST) is developing a plan for the issuance of regulations, guides, and standards in accordance with the safety standards of IAEA and advanced nuclear industry countries such as the United States, France and Japan (see Action 19)

Action 30: The regulatory body should issue regulations or guides specifying the documentation and procedures needed in the various steps of licensing.

Requirements and guides related to nuclear power plant are being developed.

Recently, MOST issued Circular No 13/2009/TT-BKHCN, guidance on preliminary nuclear safety assessment for site selection of nuclear power plant in the investment decision stage.

Circular No. 05/2006/TT-BKHCN, Guidance on declaration and authorization issuance of radiation-related practice, is being revised in accordance with licensing regulations of the Law on Atomic Energy.

VARANS has developed a plan for developing legal regulatory documents. The proposed list of documents addresses a number of technical issues, although it is not a comprehensive list of all documents that will need to be developed for the nuclear programme development. The necessary procedures and details needed in the various steps of licensing are planned to be specified in these legal documents.

Action 31: The regulatory body should specify safety requirements needed for tendering process.

The safety requirements will be established in accordance with the requirements in the Law on Atomic Energy (Article 48) and the bidding law. Projects 20 and 21 of the Master Plan should address the development of the necessary safety requirements documents. The detailed process for developing the bid is planned to be described in the Feasibility Study report.

Action 32: The regulatory body should begin establishing suitable working relationship with the operating organization and international organizations.

The regulatory body has established good working relationships with various international organizations (e.g. IAEA, International Standard Organization (ISO, etc.). The regulatory body appears to have a good working relationship and cooperation with the proposed investor (EVN) for the NPP project.

REGULATORY FRAMEWORK: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1, Requirement 32, states that "the regulatory body shall promulgate regulations and guides to establish the principles and associated criteria for safety upon which its requirements, judgements and decisions are based."

R68 Recommendation:

The regulatory body should develop all necessary regulatory requirements and guidance documents (decrees, regulations, circulars, etc.) in an effective and timely manner, including the safety requirements necessary to support the NPP bidding process.

(1)**BASIS:**

Draft GSR Part 1 Requirement 4, states that "The government shall ensure that the regulatory body is effectively independent in its decision making and that it has functional separation from entities having

REGULATORY FRAMEWORK: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

responsibilities or interests that could unduly influence its decision making."

R69 Recommendation:

The Government should ensure that the decision making function of the regulatory body is effectively independent from the entity having responsibility for operating responsibility of the NPP.

10.6 TRANSPARENCY AND OPENNESS

Phase 1

Action 40: The government should establish a policy and guidance to inform general public and interested parties of the benefits and risks of nuclear power as needed to facilitate their involvement.

Information to the public is provided for in Article 57 of the Law on Atomic Energy. Additionally, Item k, Article 47 of the Law on Atomic Energy specifies that the application submitted to the Prime Minister for site approval shall include the Resolution of the Provincial People's Committee in the province that the proposed site is located, expressing public opinions on measures for safety and security assurance, and investment policy for developing infrastructure in the province. However, detailed guidance is not yet developed.

Action 41: The government should establish a process to ensure that the comments resulting from consultation with relevant interested parties are considered, and it should communicate about the results of these considerations to the interested parties.

While selecting a site for NPP, the Resolution of the Provincial People's Committee shall be taken into consideration (Article 47 of the Law on Atomic Energy). See Action 40 above.

In the process of developing legal documents, the procedure for a legal document to be developed and issued (Law on Public Information) includes consulting with relevant Ministries and agencies of the draft, posting of the draft document on the website for public comments; and then the organization responsible for drafting the document shall make justification based on those comments.

Phase 2

Action 42: The government should inform all interested parties regarding the safety implications of the decision on the implementation of a national nuclear power programme.

The public has been informed of the nuclear power programme through exhibition activities and news releases and articles. Public opinions regarding the nuclear power

project have been informally surveyed and collected by VAEI. More formal input has been received through meetings arranged by the Provincial People's Councils.

Action 43: All the relevant organizations should continue informing the general public and interested parties on safety issues, including health and environmental impacts.

Activities informing the general public and interested parties on safety issues, and health and environmental impacts have been conducted by the Ministry of Industry and Trade, the Vietnam Atomic Energy Institute, and VARANS. EVN has also organized information meetings. However, there does not appear to be a formal plan for communicating with the public regarding the NPP programme.

With regard to the regulatory body, VARANS maintains a website, both in Vietnamese and English, to provide information to the public. Inspection reports, enforcement actions and regulatory decisions are posted on the website. Regulatory and policy advice and recommendations proposed to higher level authorities or government agencies are not typically made public by VARANS. The decision what to make public regarding VARANS advice or recommendations rests with the higher government authority.

TRANSPARENCY AND OPENNESS: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1, Requirement 36, item 4.66 states that "The regulatory body has to establish, either directly or through authorized parties, provision for effective mechanisms of communication and has to hold meetings for informing interested parties and the public and to inform the decision making process."

S41 **Suggestion:**

VARANS and MOIT should continue to develop mechanisms to communicate with relevant parties on information regarding regulatory judgements and decisions and their bases; and to receive opinions from interested parties as may be considered appropriate and necessary to carry out its regulatory functions.

S42 **Suggestion:**

VARANS should begin to define mechanism(s) to communicate information regarding incidents, accidents, abnormal occurrences or other appropriate information to relevant interested parties (e.g. authorized parties, governmental bodies, national and international organizations, the public, etc.).

(1) BASIS:

Draft GSR Part 1, Requirement 36, item 4.68 states that "The authorized party has an obligation to inform the public about the possible radiation risks associated with a facility, and this obligation has to be specified in the regulations promulgated by the regulatory body, in

TRANSPARENCY AND OPENNESS: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

the authorization or by other legal means."

S43 **Suggestion:**

MOIT (EVN) should amplify the current processes to inform the public about the possible radiation risks associated with a facility.

R70 Recommendation:

VARANS should establish the appropriate legal document(s) to formalize the authorized party's obligation for communicating with the public regarding a facility's radiation risk.

10.7 FUNDING AND FINANCING

Phase 1

Action 49: The government in cooperation with legislative bodies should plan funding for education and training, research centres, support activities, etc.

Relevant Ministries and agencies are preparing plans for education and training, safety research centres, support activities, etc. Currently, the Ministry of Science and Technology is developing a General Programme to implement the Strategy for peaceful uses of atomic energy up to 2020. This programme shall include plans for human resource development, nuclear power development and infrastructure development. Project 16 in the Master Plan addresses Training and development of human resources on nuclear science and technology. The Master Plan does not address the time line for implementation. The implementation plans are being drafted for submittal to the appropriate Ministry offices.

Action 50: The government should consider funding mechanisms for the regulatory body, and plan it.

The Government has no special funding mechanism for the regulatory body. At present, the regulatory body for radiation and nuclear safety is annually funded by the State budget plan, although Finance Minister Decision: Fees and Charges from Radiation Safety and Control Management Activities states that "The State Regulatory Authority in radiation safety and control as stipulated in Decree No. 50/1998/ND-CP (hereinafter called as the fee and charge collecting agency) shall have 85% (eighty-five percents) of the fund from the collected charges to cover the cost in radiation verification activities." No other special funding mechanism for the development of the regulatory body for the nuclear power programme has yet been specified. Currently, VARANS is preparing a plan on developing infrastructure for the regulatory body (Project 21 of the Master Plan) to submit to the Ministry of Science and Technology which includes aspects for increased funding for nuclear safety regulatory capabilities.

Action 51: The government should plan funding for radioactive waste and spent fuel management, decommissioning and final disposal.

The Government is currently directing the construction of the national radioactive waste storage; and funding for long term management of spent fuels, decommissioning and final disposal is being considered.

Item 1e, Article 14 of the Law on Atomic Energy prescribes that the Ministry of Construction shall plan sites for radioactive waste disposal and storage.

At present, the Ministry of Construction is developing an implementation plan for Project 10 (selection of sites for the NPP and waste repository) of the Master Plan to implement the Strategy for peaceful uses of atomic energy.

Article 25, item 7, of the Law on Atomic Energy specifies that the Government shall provide funding to construct national radioactive waste storage.

Action 52: The government should consider financing mechanisms of a nuclear power plant to ensure long term safety.

At present, the Government is considering specific provisions in the Decree on the nuclear power plant regarding financing mechanisms in the following areas:

- Safety management of radioactive waste, spent fuels and decommissioning;
- Insurance, funds for emergency response;

In addition, the financing mechanisms are addressed in the following documents:

- The Section of Implementation of the "Strategy for peaceful uses of atomic energy up to 2002" specifies the role and responsibility of the Ministry of Planning and Investment, and the Ministry of Finance in ensuring financial resources for the nuclear power programme.
- Article 5, Item 2, of the Law on Atomic Energy specifies the State's policies, in which the State focuses its investment on nuclear power development and on technological infrastructure, human resources, scientific research and technological development to facilitate the development of nuclear power.
- The investor EVN is currently preparing to submit to the Government for approval a plan to mobilize capital for the first nuclear power plant to ensure long term safety (Investment Report).

Phase 2

Action 53: The government in cooperation with legislative bodies should establish the necessary arrangements to provide assured long-term financing for education and training, research centres, support activities, etc.

See Action 49. In the strategy on peaceful uses of atomic energy up to 2020, the Government has specified measures to implement the strategy, in which the responsibilities of ministries and branches have been assigned. The Ministry of Finance, in cooperation with the Ministry of Investment and Planning, is assigned to ensure funding for implementing the nuclear power plant project. Plans for

implementation are being drafted by the applicable agencies to submit to the appropriate ministries for review.

Action 54: The government in cooperation with legislative bodies should be adequately implementing funding mechanism for the regulatory body.

See Action 50. The regulatory bodies involved in the State management in the field of atomic energy have received certain interests and budgets. However, the budgets are not necessarily adequate for the given obligations (as noted in the VARANS 2008 Annual Report) and the anticipated level of activity necessary to support nuclear programme development.

Action 55: The operating organization should plan and ensure appropriate financing so as not to compromise safety during all the stages of the nuclear power programme.

See Action 52. The funding mechanisms are still being established (part of the PFS). The nuclear power plant investor (EVN) is providing the cost estimate for the nuclear power plant project. However, capital mobilization or financial arrangements are still not clear at this point. The cost estimates should ensure that appropriate safety concerns are taken into account for all stages of the NPP lifetime.

Action 56: The government in cooperation with legislative bodies should enact legislation that requires collection of funds and securing these funds for long term management of waste and decommissioning.

Articles 36 and 40 in the Law on Atomic Energy stipulate that radiation and nuclear facilities shall bear all the cost associated with dismantlement, and storage and handling of radioactive waste resulted from decommissioning process. However, at present the specific regulation and guidance on how to establish and maintain appropriate financial resources has not been issued.

FUNDING AND FINANCING: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

Draft GSR Part 1 Requirement 1, Section 2.3, states, in part, "...account has to be taken of the following... The need for and provision for human and financial resources;"

R71 Recommendation:

The government should define the mechanisms by which all relevant organizations and activities related to nuclear and radiation safety for the NPP project (regulatory body, operating organization, NPP project, education and training centres and programmes, development of industrial capability, research centres, etc.) are provided with adequate financial resources, establishing appropriate priorities.

FUNDING AND FINANCING: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

Draft GSR Part 1 Requirement 2, Section 2.5(16), states, in part, "The framework for safety has to set out the 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;"

R72 **Recommendation:**

The government should define the mechanisms by which decommissioning and radioactive waste management activities will be provided with adequate financial resources.

10.8 EXTERNAL SUPPORT ORGANIZATIONS AND CONTRACTORS

Phase 1

Action 60: The government should consider the availability of expertise, industrial capability, technical infrastructure and services that could support the long term national safety infrastructure.

This has been addressed in the Master Plan to implement the Strategy for peaceful uses of atomic energy. Projects 6 and 9 in the long term plan for developing nuclear power plants and implementing the project on constructing the first nuclear power plant address the need for localization of the programme for manufacturing fuel, developing the overall plan for enhancing the capability of domestic industries, and strengthening the technological infrastructure to ensure nuclear safety during construction, operation and maintenance of the NPP. The actual implementation plans are still being developed.

Action 61: The government should assess the need to create or to enhance national organizations providing support to the nuclear power programme, and to improve the national technical infrastructure.

See Action 60. The Vietnam Atomic Energy Institute (VAEI) is well established. Projects 8 and 18 in the Master plan address further develop of the Vietnam Atomic Energy Institute capabilities to support a nuclear power programme. Currently, VAEI has a group of 10 experts that it is planning on developing into a technical support organization for the nuclear programme. VAEI is also responsible for coordinating the development of the action plan to address the Master Plan project regarding human resources development. The action plan addresses staffing plan and human resources development for VAEI, VARANS, and EVN (see Action 64).

Phase 2

Action 62: The operating organization and the government as appropriate should encourage national industrial organizations to develop their capabilities

with the objective of participating in the construction of nuclear power plant and supporting safe long term operation.

Multiple Projects (7, 8, 9, and 11) in Section II in the Master Plan provide for building of infrastructure necessary for the national long-term programme for nuclear power development. Part of this infrastructure building addresses concerns with development of industrial capability, and the project action/implementation plans are currently under development.

Action 63: The government should establish organizations providing expertise, engineering or other technical support to the national nuclear power programme, as identified in Phase 1.

VAEI is well established and is planned to be the institute for training essential human resources for the nuclear power programme. Section III in the Master plan provides for developing human resources for the nuclear power programme. However, the current arrangements for providing technical support to the Operating Organization (EVN) and the Regulatory Body (VARANS) for the national nuclear power programme are not finalized. Conflicts of interest can arise when organizations that provide the regulatory body with advice or services also provide advice or services to the NPP operating organization (e.g. if they were to advise an authorized party on the same subject).

Action 64: Expertise, engineering and other technical support organizations should begin building competence and quality assurance programmes.

VAEI is coordinating the Master Plan action plan for increasing human resources in VAEI, VARANS and EVN. VAEI is currently functioning as the TSO for nuclear safety in Vietnam. However, VAEI is also very involved in the development of activities within EVN regarding nuclear programme development. The draft plans include increasing staffing in VAEI from the current approximately 100 staff devoted to the NPP and fuel cycle activities to approximately 250 staff by 2020. The goal is to increase staffing by 15-20 staff per year until 250 total is reached. The issue of where the TSO function will ultimately reside (within VARANS, in VAEI, or a separate organization) has not been determined.

Action 65: The regulatory body and the operating organization should plan arrangements for overseeing the activities performed by external support organizations and contractors.

Regulations will be established to address this issue. The regulatory body and operating organization do not currently have plans for oversight of activities performed by technical support organizations and contractors. EVN has used the technical support services of a Japanese partner to assist in preparation of the prefeasibility and feasibility reports for the nuclear power plant in Ninh Thuan.

Action 66: The operating organization and the government should start to implement plans for improving national technical infrastructure, as needed to fill in previously identified gaps.

See actions above.

EXTERNAL SUPPORT ORGANIZATIONS AND CONTRACTORS: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GSR Part 1 Requirement 20 states that "The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."

R73 Recommendation:

The responsible government entity should determine the organizational location of the technical support resources (inside or outside VARANS) that provide support to the regulatory body, and make arrangements to ensure that there is no conflict of interest with those organizations which provide the regulatory body with technical advice or services.

10.9 LEADERSHIP AND MANAGEMENT FOR SAFETY

Phase 1

Action 73: The government should recognize the essential role of safety management and leadership in order to achieve a high level of safety and to foster safety culture within organizations.

The Government has not properly taken into consideration the essential role of safety management and leadership in order to achieve a high level of safety (see Action 25). Some actions are underway to implement a more structured management system within VARANS. A project has been proposed by VARANS regarding "Improve Nuclear Safety Culture" although it has not yet been approved.

Action 74: The government should ensure that all the activities conducted in Phase 1 are included in the framework of an effective management system.

Some actions are planned to implement a more structured management system, taking safety into account.

Action 75: The government should give emphasis to persons with a strong safety culture and strong leadership capabilities when identifying senior managers for the prospective organizations to be established.

See Action 25. The Government has not made any specific plans to address this issue. Currently, persons who have demonstrated strong leadership capabilities are nearing retirement age. Most of the remaining staff have been recently recruited and have little experience. This is expected to be a significant challenge to find and recruit sufficient staff with strong leadership capabilities, adequate professional knowledge and experience, and safety minded attitude.

Phase 2

Action 76: The regulatory body and the operating organization should start developing and implementing effective management systems in their respective organizations and promote a strong safety culture.

Action 77: The regulatory body and the operating organization should develop competences in managing growth and change of the organization.

Action 78: The regulatory body and the operating organization should start making appropriate arrangements for measurement, assessment (both self assessment and independent assessment) as well as continuous improvement of their management systems.

The operating organization and the regulatory body are aware of the importance of effective management systems and safety culture. VARANS is currently working toward implementing a management system, but the programme is not very far along. VARANS has proposed a project to "Improve Nuclear Safety Culture" although it has not yet been approved. The operating organization EVN, in the early stages of development, has not taken any steps toward implementing a formal Management System.

LEADERSHIP AND MANAGEMENT FOR SAFETY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

GSR Part 1 Requirement 19 states that "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."

R74 Recommendation:

VARANS should continue actions to develop and implement a formal management system, including promoting and developing its internal safety culture.

(1)**<u>BASIS</u>**:

NS-R-2, Requirement 2.19 states that "The operating organization shall prepare and put in place a comprehensive quality assurance programme covering all activities which may affect the safe operation of the plant."

R75 Recommendation:

As it is developed, the operating organization (EVN) should take action to ensure that a comprehensive management system is implemented, including development and promotion of safety culture, throughout all phases of the NPP project (construction, commissioning, operation, etc.).

10.10 HUMAN RESOURCES DEVELOPMENT

Phase 1

Action 86: The government should consider a strategy for securing high-quality personnel.

Currently, there are 5 universities in Vietnam that can contribute to training personnel for the nuclear power programme.

In Project 16 of the Master Plan, the Government has assigned the Ministry of Education and Training responsibility to develop a programme for developing human resources.

Project 18 in the Master Plan addresses building and developing the Vietnam Atomic Energy Institute to be a high quality Research and Development centre in the field of atomic energy in order to keep pace with advanced countries in the region.

All of the Projects in the Master Plan are no further developed than in the drafting stage, so very little concrete action has been taken to implement the strategy for addressing this issue.

In addition, incentives for securing high-quality personnel is specified in Law on Atomic Energy, including Article 16, Item 2, which specifies that the State shall establish a priority policy to attract Vietnamese and foreign experts who work in the field of atomic energy.

Action 87: The government should identify competencies required in nuclear safety areas and approximate number of experts needed.

Both the regulatory body and operating organization have estimated the number as well as the qualifications of personnel needed for the nuclear power plant project. VARANS has developed an Action Plan, with consultation from the US NRC experts, on human resource development for the nuclear power plant programme. However, this Action Plan may or may not be implemented depending on many factors.

Article 16, Item 1, of the Law on Atomic Energy specifies that the State shall establish a programme for human resource development, especially high level experts so as to meet the need of research, development and applications, and assurance of safety and security in the fields of atomic energy.

VAEI has been assigned the coordination responsibility to provide input to MOST regarding human resources development for VAEI, VARANS and EVN. The current estimate is that there are approximately 800 persons involved in the nuclear sector throughout Vietnam. Only 20 of those are what would be considered national experts. The proposed human resources plan, which is only in draft form, includes the following details:

- VAEI currently has approximately 100 staff involved in Nuclear Safety and fuel cycle activities. The proposed action plan would increase VAEI staffing, at the rate of 15-20 staff per year, until a total of approximately 250 staff involved in those activities by the year 2020.
- VARANS currently has about 10 staff involved in Nuclear Safety activities. The proposed plan would increase the Nuclear Safety staff by an additional 50 persons immediately to support development of technical regulatory documents to support

continued nuclear programme development. An additional 10 staff would be added later. The additional 60 staff will be necessary to support regulatory activities for a single nuclear unit. VARANS estimates that an additional 20 Nuclear Safety staff would be needed for each additional unit.

- EVN currently has approximately 50 persons devoted to NPP development. The proposed plan would increase that number to approximately 600 by 2015 and to 1000 by 2020.

The Ministry of Education and Training's goal is to have approximately 2400 persons competent to support the nuclear energy programme. This total includes University staff as well as the applicable technical agencies and organizations.

Action 88: The government should explore national and foreign institutions that could provide education and training.

Vietnam has conducted surveys and received active support from the IAEA, France, Korea and other countries in providing training for its personnel.

In Vietnam, there are currently 5 universities that can contribute to training personnel for the nuclear power programme.

Project 18 in the Master Plan addresses building and developing the Vietnam Atomic Energy Institute, which can be utilized to conduct training for nuclear safety.

Action 89: The government should identify gaps in existing training institutions and plan to start training and establish new institutions as needed.

The Government has identified potential training gaps in staff and is preparing relevant plans based on the following requirements:

- Article 16, Item 1, of the Law on Atomic Energy specifies that the State shall establish a programme for human resource development, especially high level experts so as to meet the need for research, development and applications, and assurance of safety and security in the fields of atomic energy.
- In the Master Plan, Project 7 on building and implementing a human resources development plan, developing human resource for the nuclear power programme and Project 11 on planning and investing on large construction corporations regarding construction capability and training of personnel and competent technical workers.

However, all of these projects are in the implementation planning stage. No activities have actually been conducted to identify the weakness of the universities or institutions in order to establish specific training programmes for the nuclear power programme.

Action 90: The government should consider sending nuclear trainees to study and work in foreign institutions.

Vietnam has received positive support from the IAEA, France, Korea and other countries in training its personnel. However, these are short term training activities, and do not meet the need for human resources for the nuclear power programme.

The Government has been implementing a project (Project 322) to send students abroad to be trained. In implementing the Master Plan, the Ministry of Education and Training is also developing a project on training and education for developing and providing personnel for the nuclear power programme.

VARANS has developed an Action Plan to develop and strengthen the capability for nuclear safety assessment. This includes general knowledge training in Vietnam and 6 months of specialized training in foreign countries (through on the job training) for approximately 20 staff. This action plan is dependent on VARANS obtaining the increase in staff necessary to implement the nuclear programme development needs.

Phase 2

Action 91: All the relevant organizations should implement a strategy to attract and retain trained high-quality personnel.

Article 16 of the Law on Atomic Energy requires that a policy of priority be established to attract high-quality personnel. This strategy is being considered to be included in the Master Plan for developing human resources and conditions to attract high-quality personnel.

Currently, Vietnam has 5 universities to provide training on nuclear physics and nuclear engineering, namely: Hanoi University of Natural Science, Hanoi University of Technology, University of Electricity, Dalat University, and Ho Chi Minh University of Natural Science.

The Ministry of Education and Training has established a project for human resources training for the nuclear power plant from now to the time when the first nuclear power plant of Vietnam come into operation.

The strategy for attracting and preventing the potential loss of experience and highlevel skills in the field of atomic energy has not yet been fully developed and implemented.

Action 92: All the relevant organizations should support the training of prospective nuclear staff in foreign nuclear organizations.

VARANS and VAEI have sent staff to study abroad under cooperation with foreign counterparts. Recently, VARANS has sent 2 staff to France for studying CATHARE. In the near future, 2 other staff will attend the Master programme and 1 PhD programme in France. In addition, some staff of VARANS are also provided with short-term training on nuclear safety and nuclear technology. However, a long term plan has not yet been developed.

Some relevant organizations have sent a limited number of staff abroad under their own multilateral and bilateral cooperation arrangements; however it has not yet proven to be sufficient. Continued support for sending staff abroad to receive additional training and experience is strongly encouraged.

Action 93: The regulatory body and the operating organization should actively recruit staff so as to ensure capability in the relevant areas in a timely manner.

Recruitment is being conducted, but with difficulties.

Both the regulatory body and the operating organization are very actively recruiting more staff; however the available human resources in the country are still limited in competency and quantity. The regulatory body also faces other difficulties in that the authorization to recruit and hire the large number of staff necessary to meet the work requirements has not yet been given by the government.

Action 94: The government in cooperation with legislative bodies and other applicable organizations should establish new institutes or new curricula, as identified in Phase 1.

At present, there have not yet been any new institutes or new curricula established, although a curriculum in nuclear technology is being developed by the Institute of Industry.

Action 95: All the relevant organizations should start education and training of necessary number of persons in academic and vocational institutions.

This activity is in the preparation stages of development. At present, national educational institutes, such as the Institute of Industry, are staffing and preparing the faculty for implementation of a new curriculum in nuclear technology. Relevant agencies, organizations have created favourable conditions for sending staff to training. However, a well-developed plan and programme has not yet been implemented.

HUMAN RESOURCES DEVELOPMENT: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

BASIS:

Draft GSR Part 1, Requirement 11 states that "The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."

BASIS:

GS-R-3, Requirement 4.3 states that "Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence."

R76 Recommendation:

The applicable Ministries should authorize and implement actions to identify gaps in competences, and to increase and maintain the competence of the staff of VARANS, EVN and other organizations involved in safety of the nuclear power programme. Training programmes should be established as necessary to address the identified gaps. Resources should be made available to develop the necessary competence of the regulatory body staff.

HUMAN RESOURCES DEVELOPMENT: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

Draft GSR Part 1, Requirement 18 states that "the regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."

R77 Recommendation:

The regulatory bodies (VARANS and MOIT) should be given the authority to recruit the appropriate number of staff to be able to competently conduct its functions and responsibilities at the appropriate time: legal regulatory document development, inspections, review and assessment, <u>fulfilment and implementation of the applicable international obligations (conventions, treaties, etc.)</u>.

(1) BASIS:

NS-R-2, Requirement 2.8. states that "The operating organization shall be staffed with competent managers and sufficient qualified personnel having a proper awareness of the technical and administrative requirements for safety and motivated to be safety conscious."

R78 Recommendation:

The operating organization (EVN) should be given the authority and resources to recruit the appropriate number of staff to be able to competently conduct its safety responsibilities.

10.11 RESEARCH FOR SAFETY AND REGULATORY PURPOSES

Phase 1

Action 100: The government should consider areas where in-depth knowledge is necessary to assess and analyze safety aspects of a nuclear power plant and identify research centres that can start research programmes in necessary knowledge areas.

Areas have not yet been specifically identified, although the process is underway by VAEI. It is expected that difficulties will arise when it comes time to implement due to lack of staff and other resources.

At present, there are 5 universities that could contribute to training personnel for the nuclear power programme. Vietnam Atomic Energy Institute also has training programmes in relevant fields and is the principal institute for research and development in Vietnam.

Action 101: The government should identify gaps in domestic research centres' capabilities to meet the needs in core areas, and plan to establish new research centres for core areas as deemed needed.

As noted in Action 100, the process of identifying gaps is underway by VAEI. The identification of gaps in domestic research centres' capabilities to meet the needs in core areas for the nuclear power programme has been done only at a certain level. This is presented in EVN's Pre-Feasibility Study report, indicating the current status and the need for human resources in the nuclear field. The report has proposed a human resource development programme in the current domestic research centres and universities. However, it does not specify plans for improving these centres, especially for nuclear safety management. Moreover, these centres and universities also lack manpower and expertise.

Phase 2

Action 102: The operating organization and the regulatory body should be involved in the definition of safety research areas.

This activity is being carried out with limited progress. VARANS and EVN have the opportunity to provide input to VAEI regarding the identification of research topics, although they have not actively defined safety research areas applicable to the nuclear power programme. Identifying research areas is somewhat limited by the lack of experience of the regulatory staff and anticipated operating organizations. VAEI is of the opinion that they know the areas in which additional research is needed and thus input from other organizations is not critical.

Action 103: The government in cooperation with legislative bodies should implement plans to establish new research institutes, as identified in Phase 1.

At present, there is a nuclear research reactor in Vietnam, the Dalat nuclear research reactor, a TRIGA MAX II. This reactor has been operated and utilized since1983. Thanks to the utilization of this reactor, Vietnam has performed valuable research as well as carried out training for operators and reactor safety calculation staff, which provides the current basic foundation for the operation and management of the future nuclear power plant.

There have not yet been any studies or specific proposals for new research institutes. However, in the Master Plan, Project 18 addresses improving the capability of the Vietnam Atomic Energy Institute. However, this Project has not yet been executed.

Action 104: Research centres should begin conducting safety research in core areas in which in-depth knowledge is essential to support safe long term operation.

This activity is being conducted with limited results. Up to now, in-depth research activities in the areas related to the nuclear power plant programme have not been performed due to lack of coordination between the various key organizations and the limited number of researchers.

RESEARCH FOR SAFETY AND REGULATORY PURPOSES: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1 Requirement 11, item 2.38, states that "Development of the necessary competence for the operation and regulatory control of facilities and activities has to be facilitated by the establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety."

R79 **Suggestion**:

The applicable authorities should develop a mechanism to identify key safety areas where research information will be needed to support development of a nuclear power programme.

R80 **Suggestion:**

The research organizations, such as VAEI and universities, should self-assess to identify specific safety areas where their capabilities need to be strengthened to conduct research to support development of a nuclear power programme.

10.12 RADIATION PROTECTION

Phase 1

Action 106: The government should consider the additional radiation hazards and special needs presented by nuclear power plant operation.

The Government has started to take this issue into consideration and is in the process of reviewing the investment report (as part of the Pre-Feasibility Study) for the Ninh Thuan nuclear power plant project. The Government has taken into consideration radiation impacts of the project to the environment and population in the vicinity of the site.

Additionally, the Law on Atomic Energy (Item 1d, d of Article 38; Item 1a, and d of Article 47; Item 2c, and d of Article 52) provides for radiation hazards assessment.

Action 107: The government should ensure that a radiological environmental impact analysis 3 is conducted.

The Law on Atomic Energy specifies that radiological impacts shall be assessed (Items 1d and d of Article 38; Items 1a, d, 2d, d, and h of Article 47; Items 2 c and d of Article 48; and Article 52). The radiological impact assessment has been conducted for the proposed NPP sites as provided in the Investment Report.

³ The radiological environmental impact analysis is part of both the Environmental Impact Assessment (EIA) mentioned in the chapter "National policy and strategy" of this Safety Guide and the Site Evaluation Report (SER) addressed in the chapter "Site survey, site selection and evaluation" of this Safety Guide.

Action 108: The government in cooperation with legislative bodies should recognize the need for integrating radiation protection and new nuclear power plant safety regulations.

The Law on Atomic Energy integrates radiation protection into regulations for safety of the nuclear power plant. Legal documents currently being developed to implement the law take this into account.

Phase 2

Action 109: The regulatory body and/or the government in cooperation with legislative bodies should amend the national legislation and/or regulations as appropriate for radiation protection.

This activity is under implementation. After the promulgation of the Ordinance on Radiation Safety and Control in 1996, VARANS submitted to MOST and the Government 18 regulatory documents related to radiation safety. The National Assembly approved and issued the Law on Atomic Energy in 2008 to replace the Ordinance on Radiation Safety and Control.

At present, the regulatory body is actively developing documents guiding the implementation of the Law on Atomic Energy as well as a system of technical standards and regulations on radiation and nuclear safety.

Action 110: The regulatory body should establish the radiological criteria regarding workers, the public and the environment, both for normal operation and for accidental conditions of a nuclear power plant.

This activity is in the planning process. Item 1 of Article 33 of the Law on Atomic Energy prescribes that MOST is responsible for establishing dose limit and controlling radiation exposure. At present, Vietnam has a regulation on radiation dose limits for radiation workers and the public and for the requirements on the level of radiation waste released to the environment. However, the regulatory body has not yet developed the regulations on criteria and guides relating to radiation dose levels and radiation waste levels in the case of incidents and accidents for the nuclear power plant.

Action 111: The operating organization should update the radiological environmental impact analysis for the selected site, as appropriate.

VARANS is in the process of developing relevant detailed provisions in the Decree on nuclear power plants. At present, the site has not yet been selected.

Action 112: The regulatory body should review and assess the radiological environmental impact analysis for the selected site, as appropriate.

VARANS, in conjunction with the Ministry of Natural Resources and Environment, is in the process of developing relevant detailed regulations. Article 38 of the Law on Atomic Energy prescribes that the operating organizations shall submit the environmental impact assessment report to the regulatory body in order to review safety aspects. The operating organization (EVN) has submitted a draft or preliminary

EIA to the Ministry of Natural Resources and Environment, although the review on the document has not been started.

Action 113: The operating organization should use all the appropriate safety and regulatory information regarding radiation protection to prepare the bid specifications for the nuclear power plant.

Details of the bidding process will be included in the Feasibility Study which will be conducted following approval of the Pre-Feasibility Study. The stated intention is to include the appropriate safety requirement into the bidding process documents.

RADIATION PROTECTION: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

Draft GSR Part 1, Requirement 32 states that "The regulatory body shall promulgate regulations and guides to establish the principles and associated criteria for safety upon which its requirements, judgements and decisions are based."

R81 Recommendation:

VARANS in conjunction with applicable ministries should ensure that the principles and criteria for radiation safety regarding workers, the public and the environment for a nuclear power plant are established.

(1)**<u>BASIS</u>**:

NS-R-3, Requirement 2.12, states that "For each proposed site the potential radiological impacts in operational states and in accident conditions on people in the region, including impacts that could lead to emergency measures, shall be evaluated..."

R82 Recommendation:

EVN should prepare the radiological environmental impact analysis report, as part of the overall site Environmental Impact Assessment, and submit this Assessment to the Ministry of Natural Resources and Environment for review and approval.

10.13 SAFETY ASSESSMENT

Phase 1

Action 118: The government should consider the safety goals and principles that are to be applied to the development of the national nuclear power programme.

The Master Plan for implementing the Strategy for peaceful uses of atomic energy up to 2020 covers many proposed activities for developing the national nuclear power. Projects 9, 17, and 20 of the Master Plan include items related to strengthening the national capacity for ensuring nuclear safety.

Fundamental principles of safety such as defence in depth are specified in Article 23 and the principles for activities and the assurance of safety and security in the field of

atomic energy are specified in Article 6 of the Law on Atomic Energy. However, the defence-in-depth concept addressed in Article 23 needs to be further developed in guidance documents. See Actions 1 and 5.

Phase 2

Action 119: The operating organisation, the regulatory body and external expert support organizations as appropriate should develop the expertise to prepare for the conduct or the review of safety assessments.

The capability to conduct adequate safety assessments is under development.

- Article 8 of the Law on Atomic Energy assigns to VARANS responsibility to conduct and organize verification on radiation and nuclear safety. Article 16 addresses the development of overall human resources for the assurance of safety and security in the fields of atomic energy. Article 56 prescribes the responsibilities of the owners of the nuclear power plants for ensuring adequate human resources for safe operation of the NPP.

The regulatory bodies are in the process of developing capacity and skills and accumulating experience for the review of the safety assessment report, through verifying the investment report of Ninh Thuan nuclear power plant project and verifying the application dossier for renewal of operating license for the nuclear research reactor of the Nuclear Research Institute in 2009. Training programmes to further develop skills related to safety assessment are being developed in accordance with the applicable Master Plan Project plans.

SAFETY ASSESSMENT: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GSR Part 1 Requirement 11, item 2.35, states that "The building of competence has to be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety."

R83 **Suggestion:**

The applicable authorities (VARANS, EVN and VAEI) should continue to develop skills associated with conducting and reviewing safety assessments.

10.14 SAFETY OF RADIOACTIVE WASTE, SPENT FUEL MANAGEMENT AND DECOMMISSIONING

Phase 1

Action 123: The government should consider a range of options for radioactive waste management (including disposal), spent fuel management and decommissioning, based on a comprehensive long term strategy.

Article 14.e) assigns responsibility for planning sites for radioactive waste storage and disposal to the Ministry of Construction. Article 25 of the Law on Atomic Energy establishes responsibility for treatment and storage of radioactive wastes and spent nuclear fuel. Article 25 also assigns responsibility to the Government for funding of the radioactive waste repository. Article 26 assigns responsibility for monitoring and controlling radioactive waste to the manager of the licenses organization. Project 17 of the Master Plan addresses studying, acquiring and mastering the technologies for radioactive waste treatment and management. Project 19 of the Master plan includes strengthening the national capability to manage radioactive waste in accordance with international standards. The implementation plan for Project 10 in the Master Plan on the construction site for the national radioactive waste storage is being developed.

Action 124: The government should recognize long term safety requirements and cost implications of radioactive waste management (including disposal), spent fuel management and decommissioning.

Article 25 of the Law on Atomic Energy provides for treatment and storage of radioactive wastes, disused radioactive sources and spent nuclear fuel. Article 48, item G, requires that operators provide, in the dossier for investment project to build a NPP, to the Prime Minister, a plan for decommissioning of the nuclear power plant, and financial ensurance for decommissioning, and for managing spent nuclear fuel and radioactive waste. Article 56 of the Law on Atomic Energy provides for responsibilities of nuclear power plant owner for ensuring an adequate human resource in the management of nuclear fuel, storage and handling radioactive waste and decommissioning of the nuclear power plant.

Action 125: The government should plan to establish, or expand as appropriate, a national organization responsible for radioactive waste management.

Article 14, item e, assigns responsibility to the Ministry of Construction for planning sites for radioactive waste storage and disposal. Article 26 assigns responsibility for monitoring and controlling radioactive waste to the manager of the licenses organization. No specific national organization is specified other than the Ministry of Construction.

Phase 2

Action 126: The government in cooperation with legislative bodies should establish the radioactive waste management organization, as necessary.

Article 25 of the Law on Atomic Energy prescribes that the State shall invest in constructing the national radioactive waste storage; the operating organizations shall be responsible for handling and storing radioactive waste; and Article 33 prescribes that MOST shall issue provisions on the national radioactive waste storage. However, there has not yet been specified a single national organization for radioactive waste management.

Action 127: The government in cooperation with legislative bodies, the radioactive waste management organization and the regulatory body should establish the national strategy for radioactive waste and spent fuel management and decommissioning, and set the goals for its implementation in appropriate schedule, including site investigations for radioactive waste disposal.

Article 25 of the Law on Atomic Energy prescribes the basic principles for handling and storage of radioactive waste, disused radioactive sources and spent nuclear fuels. The Master Plan addresses the development and implementation of the project on siting of the national radioactive waste storage (Project 10). The implementation plan for Project 10, as noted earlier, is still in draft form.

Action 128: The regulatory body should issue the necessary regulatory requirements on waste and spent fuel management and decommissioning, as appropriate.

Article 33 of the Law on Atomic Energy assigns responsibility for developing detailed regulations regarding handling and storage of radioactive waste and spent nuclear fuel, requirements for the national radioactive waste storage, and disposal sites of radioactive waste. These regulations have yet to be developed.

Action 129: The operating organization shall consider the necessary arrangements for ensuring safe management of radioactive waste, spent fuel and decommissioning, and for minimizing the generation of radioactive waste.

Project 17 of the Master Plan includes elements related to studying, acquiring and mastering the technologies for radioactive waste treatment. Project 19 contains elements to strengthen the capability to manage radioactive waste in accordance with international standards and for ensuring the control of nuclear fuel, technology and equipment related to the nuclear fuel cycle. Although the responsibility is recognized by the operating organization, there has been little formal movement on developing definitive arrangements.

SAFETY OF RADIOACTIVE WASTE, ,SPENT FUEL MANAGEMENT AND DECOMMISSIONING:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

BASIS:

R84

GSR Part 5 Requirement 1 states that "The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected."

Recommendation: VARANS and MOST should cooperate with other relevant governmental bodies to issue a national strategy plan for a sustainable management of radioactive wastes, including those for the proposed nuclear power programme.

10.15 EMERGENCY PREPAREDNESS AND RESPONSE

Phase 1

Action 135: The government should recognize the need for early establishment of emergency plans.

The government recognizes the need for early establishment of emergency plans. Various aspects are addressed in the Law on Atomic Energy. Article 82 of the Law on Atomic Energy provides descriptions of radiation and nuclear incidents. Article 83 provides for plans for radiation and nuclear incident response. Article 84 addresses the responsibilities of organizations and individuals in case of incidents. Article 86 addresses radiation and nuclear incident response in emergency.

In the Master plan for implementation of the Strategy on peaceful uses of atomic energy up to 2020, the Ministry of Defence has been assigned to develop and implement Project 12 on emergency preparedness for radiation and nuclear incidents and accidents

Action 136: The government should identify national institutions and new arrangements to support Emergency Preparedness and Response (EPR).

Article 84 in the Law on Atomic Energy provides for responsibilities of related organizations and individuals in case of incidents. Many aspects of emergency preparedness and response are to be addressed during the formulation of the action plan to address Project 12 of the Master Plan. However, detailed regulations on an emergency response system have yet to be established.

Phase 2

Action 137: The government should define the national institutions with responsibilities for EPR.

Article 83 of the Law on Atomic Energy defines organizations and individuals that are responsible for developing and approving emergency response plans. Article 84 prescribes the responsibilities of relevant organizations and individuals in the case of incidents. There are 3 levels of EPR (national, provincial, and local). The NPP is responsible for developing an emergency response plan for its facility. VARANS is responsible for establishing regulations related to EPR for the NPP. These regulations have not yet been developed.

Action 138: The government should define the general approach based on the severity of the emergency situations.

Article 82 of the Law on Atomic Energy defines 5 groups of radiation and nuclear incidents in order to develop the plan for emergency response. Article 83 of the Law on Atomic Energy prescribes that the emergency response plans at the facility level shall be applicable to incidents in groups 1, 2 and 3; at the provincial level for incidents in group 4; and at the national level for incidents in group 5 or incidents in group 4 that go beyond the provincial response capability.

Action 139: The government should start implementing new arrangements as identified in Phase 1 for strengthening the emergency infrastructure.

Project 12 in the Master Plan addresses the development of national capability and emergency response and preparedness for radiation and nuclear incidents and accidents. At present, the project is still under development and definitive actions have not been identified or implemented.

Action 140: The regulatory body should develop basic regulations on emergency planning.

VARANS has responsibility for developing regulations related to EPR. The requirements have not yet been drafted. Article 83 of the Law on Atomic Energy prescribes for the emergency response plans at facility, provincial and national level. This item will also be further addressed in other documents under the law.

Action 141: The operating organization should start developing a general nuclear power plant emergency preparedness programme.

The initial requirement for the operating organization has been established in Article 26 of the Law on Atomic Energy which prescribes that the operating organizations are responsible for establishing and implementing emergency response plans at the facility level. The operating organization has not begun to develop the emergency preparedness plan for the proposed NPP.

EMERGENCY PREPAREDNESS AND RESPONSE: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) BASIS:

GS-R-2 Requirement 3.9 states that "In fulfilling its statutory obligations, the regulatory body... shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;... shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify... the requirements for incident reporting;...and emergency preparedness arrangements."

S44 **Suggestion**:

MOST and VARANS should begin to develop the EPR requirements that will be imposed on the NPP operating organization.

(1) BASIS:

GS-R-2 Requirement 5.3 states that "All the operating organizations and local and national organizations involved in the performance of the functions specified in Section 4, or in support of their performance, shall document their own roles, functions, authorities and responsibilities in an emergency response and assent to the authorities, roles and responsibilities of other response organizations.

S45 Suggestion:

The operating organization and relevant authorities should begin

EMERGENCY PREPAREDNESS AND RESPONSE: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

developing the basic framework for the NPP emergency preparedness programme and plans.

10.16 OPERATING ORGANIZATION

Phase 1

Action 148: In case the operating organization is already established or identified in Phase 1 (which is not the scenario developed in this Safety Guide, where it is established at the beginning of Phase 2), it should be involved together with the government in the safety infrastructure development activities from the beginning.

The Electricity of Vietnam (EVN) is proposed to be the operating organization of the first nuclear power plant in Vietnam and it is now actively participating in the development of safety infrastructure, including providing comments on legal documents that are being developed.

Action 149: The government should consider the financial strength and the necessary competencies and staffing that are expected from an organization operating a nuclear power plant so as to ensure long term safety.

The investment report of EVN, part of the Pre-Feasibility Study, contains assessments of many facets of the proposed operating organization. The Government is reviewing the assessments of the EVN investment report to determine whether it is sufficiently developed to justify the proposed expenditure.

Action 150: The government should prepare a plan to define or establish, as necessary, the operating organization.

The Electricity of Vietnam (EVN) has been established as the operating organization, although the operational structure has yet to be determined. EVN plays the main role as the utility/operator in the preparation for the introduction of the first nuclear power plant in Vietnam.

Phase 2

Action 151: The operating organization should be established, if not already established, and recognize that it has prime responsibility for safety.

Article 26 of the Law on Atomic Energy prescribes responsibilities of the head of organizations and individuals granted with the licence for performing radiation practices. With regard to the first nuclear power plant (in Ninh Thuan), EVN shall have the prime responsibility for safety. See Action 150.

Action 152: The operating organization should appoint managers and key experts, and define its organizational structure.

The Management and initial staff of the Nuclear Power and Renewable Energy Projects Pre-Investment Board have been assigned and are functioning as the operating organization at this time, although a true operating structure and staff have not been assigned.

Legal requirements include:

- Article 26 of the Law on Atomic Energy prescribes that the operating organization shall appoint and stipulate the authority and responsibility of the safety officer in writing.
- Article 56 of the Law on Atomic Energy prescribes that operating organization shall assign well-qualified staff to chief engineer, head of the operation shifts, nuclear fuel handling officer, and safety officer.

Action 153: The operating organization should establish a suitable working relationship with the regulatory body and with relevant national and international organizations.

The relationship has been gradually developed. Both organizations stated that the working relationship was good.

Action 154: The operating organization should establish the bid evaluation process, giving due consideration to safety aspects.

The detailed bid process will be described in the Feasibility Study which will be developed following approval of the Pre-Feasibility Study.

OPERATING ORGANIZATION: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

NS-R-2 Requirement 2.4(6) states that "The organizational structure shall be established and documented so as to ensure that the following responsibilities are discharged with respect to achieving safe operation of nuclear power plants:... Adequate resources, services and facilities shall be provided."

R85 Recommendation:

The Government, in evaluating the acceptability of the Pre-Feasibility Study, including the Investment Report, should fully recognize the level of financial resources that will be needed to safely develop the nuclear power programme.

S46 **Suggestion:**

The Government should start to prepare the construction and operating organizational structures with clear responsibilities for safety.

10.17 SITE SURVEY, SITE SELECTION AND EVALUATION

Phase 1

Action 161: The government should ensure that potential sites are identified and candidate sites are selected on the basis of a set of defined criteria, at a regional scale and using available data4.

- Article 47 in the Law on Atomic Energy provides for site selection.
- Project 10 in the Master Plan for the selection of sites for nuclear power plants and the national radioactive waste repository.
- Circular No. 13/2009/TT-BKHCN providing criteria for preliminary nuclear safety assessment of site selection for nuclear power plant.

In the investment report for nuclear power plant at Ninh Thuan, EVN has been requested by the Government to identify and take into consideration the criteria for site selection for the nuclear power plant. Based on the report and the newly promulgated Circular No. 13/2009/TT-BKHCN, "Guiding On Preliminary Nuclear Safety Assessment For Site Selection for Nuclear Power Plants in the Investment Decision Stage," issued 20 May 2009, the Government will assess the investment report and submit the investment policy to the National Assembly for approval. The preliminary site selection criteria are being used for identifying preliminary sites. Two preliminary sites have been identified. However, final detailed criteria for final site selection and evaluation have not yet been established.

Phase 2

Action 162: The regulatory body should establish specific safety requirements for site evaluation, including the process for authorizing the selected site, in compliance with applicable IAEA Safety Standards.

This has been addressed in the Pre-Feasibility Study and shall be further specified in the Feasibility Study (FS) stage.

Article 38 of the Law on Atomic Energy prescribes for site approval of nuclear power plants. Article 47 prescribes for the sites of nuclear power plants including basic requirements for the construction site and application dossier for approval of construction site.

Circular No.13/2009/TT-BKHCN provides guiding on preliminary nuclear safety assessment for site selection for nuclear power plants in the investment decision stage. This Circular was developed based on IAEA's recommendations, standards and guides, and after consultation with experts from the U.S.

There is a plan to develop regulations on site approval for nuclear power plants, and regulations on safety requirements for the design of nuclear power plants. Preliminary

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⁴ In case the operating organization is already established or identified in Phase 1 (which is not the scenario developed in this Safety Guide, where it is established at the beginning of Phase 2), it should be involved in the site survey.

selection criteria have been established as noted. Also as noted in Action 161, final site selection and evaluation criteria have not been established.

Action 163: The operating organization should complete the investigations related to the suitability of the candidate sites and select the preferred candidate site for the first nuclear power plant, using specific site data, information, studies and assessments conducted with the full temporal and spatial scales of investigations.

This activity is in progress. Article 47 of the Law on Atomic Energy provides for basic requirements of the candidate sites for constructing nuclear power plants. The operating organization shall submit the overview report on the site selection, the report on assessment of environmental impact and the preliminary safety analysis report to the Prime Minister.

EVN has surveyed the candidate sites for the nuclear power plant and submitted to the Prime Minister the investment report which specifies site selection and assessment of candidate sites utilizing the preliminary selection criteria. The report is currently being adjusted in accordance to the preliminary requirements of the regulatory body. Final requirements have not yet been established.

Action 164: The operating organization should prepare the Site Evaluation Report (SER) and submit it to the regulatory body, based on a full assessment of the selected site and including the confirmation of site acceptability and the characterization of the site for the definition of the site related design basis parameters.

This activity is in progress albeit at an early stage. It is currently in the Pre-FS stage, and the final site approval shall be made in FS stage.

Action 165: The regulatory body should review and assess the SER, and make a regulatory decision regarding the acceptability of the selected site and the site related design bases.

At present, it is in the Pre-FS stage, and the site approval shall be made in FS stage.

Action 166: The operating organization should use all the appropriate safety and regulatory information related and derived from the site assessment to prepare the bid specifications for the nuclear power plant.

At present, it is in the Pre-FS stage, and the site approval shall be made in FS stage.

Action 167: The operating organization should start the site and environmental monitoring programme as described in the SER.

The operating organisation has not yet submitted the site assessment report and environmental control programmes.

SITE SURVEY, SITE SELECTION AND EVALUATION: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

BASIS:

Draft GSR Part 1, Requirement 32 states that "The regulatory body shall promulgate regulations and guides to establish the principles and associated criteria for safety upon which its requirements, judgments and decisions are based."

R86 Recommendation:

VARANS should establish the necessary regulatory requirements necessary for Radiological Environmental Impact Assessment, final site acceptance as well as the process for conducting the regulatory reviews associated with these submittals.

10.18 DESIGN SAFETY

Phase 1

Action 171: The government should understand the objectives of nuclear safety, and why and how nuclear safety impacts the design of a nuclear power plant.

A Circular on requirements for NPP design is being developed. The Government and related agencies and organizations have reached a certain level of understanding of safety objectives and how and why safety issues affect the design of the NPP, but due to the lack of experience and training, the understanding is not very thorough or widespread. This results in difficulty in developing in-depth safety requirements and supporting legal requirements and regulations.

Action 172: The government should consider the various designs available from vendors and understand the most important safety features.

The various designs are addressed in the Pre-FS and will be addressed in more detail in the FS. In the EVN Investment report, one chapter was devoted to analysing the selection of technologies for the nuclear power plant as well as safety features of each technology. However, the analysis was not sufficiently detailed.

Phase 2

Action 173: All the relevant organizations should obtain an in-depth understanding of safety principles and requirements applicable to the design of nuclear power plants.

The safety principles and requirements for designs are under development. Although the safety principles are under development, there is still a limited understanding of design safety principles and design applicability due to limited staff experience. This is expected to continue until more experienced staff are obtained or trained. Outside assistance is expected to be utilized to assist in the development of safety principles and design requirements.

Action 174: The operating organization should conduct a thorough market survey on the available nuclear power technologies and investigate their safety features.

This review is in progress by EVN. EVN has studied the market of nuclear power technologies and proposed the methodology for technology selection in the investment report submitted to the Prime Minister. However, VARANS determined that the study lacks comprehensiveness and depth. EVN is making further revisions to the document.

Action 175: The regulatory body should prepare and enact national safety regulations on design necessary for bid specification.

There is a plan to develop the regulation on safety requirements for the design of nuclear power plants (projected completion date of 2012).

Action 176: The operating organization and/or the regulatory body, in referencing the IAEA Safety Standards, should specify the codes and standards which provide acceptable reference for design and construction of the plant.

Currently, the codes and standards necessary to apply to safety system design have not been addressed by the nuclear programme projects. The proposed list of regulatory documents to be developed contains a number of documents referencing various codes and standards although it is not clear how these will be incorporated into requirements.

Action 177: The operating organization should include in the bid specification all the safety and regulatory aspects, as necessary for design considerations.

The bid development process has not yet been developed, but will be included in the Feasibility Study. The intention is to include the applicable safety requirements in the bid specification.

DESIGN SAFETY:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

Draft GSR Part 1 Requirement 32, states that "The regulatory body shall promulgate regulations and guides to establish the principles and associated criteria for safety upon which its requirements, judgements and decisions are based."

R87 Recommendation:

The Regulatory Body, in conjunction with other applicable organizations as determined by the government, should establish basic design requirements to support NPP technology selection review and to support bid preparation.

DESIGN SAFETY:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS**:

NS-R-1 Requirement 3.1 states, in part, that "The design organization shall ensure that the installation is designed to meet the requirements of the operating organization, including any standardized utility requirements; that it takes account of the current state of the art for safety; that it is in accordance with the design specifications and safety analysis; that it satisfies national regulatory requirements; that it fulfils the requirements of an effective quality assurance programme".

S47 **Suggestion:**

The Operating Organization should prepare to provide the appropriate safety design requirement information in the bid such that the vendors have accurate and sufficient information.

10.19 PREPARATION FOR COMMISSIONING

Not Applicable

10.20 TRANSPORT SAFETY

Phase 1

Action 189: The government should consider the impact on the legal and regulatory framework by the transport of nuclear fuel and nuclear waste, beyond the existing transport of radioactive material.

The Ministerial Circular No. 14/2003/TT-BKHCN dated on July 11, 2003 provides guidance on safety transport of radioactive materials, but specifically excludes fissile material and spent fuel. In the Law on Atomic Energy, Chapter VII provide for safety transportation of nuclear devices, radioactive materials. However, the requirements on safety transportation of spent fuel and nuclear wastes have not been clearly specified. The Circular on safe transportation is planned to be revised to include safety of transportation of nuclear materials and nuclear wastes.

Phase 2

Action 190: All relevant organizations should implement a plan to meet the intent of the international safety requirements and start to fill in the gaps identified in Phase 1.

Article 62 of the Law on Atomic Energy prescribes that the organizations, individuals shall make plans for ensuring safety, security and incident preparedness during transportation.

However, it is necessary to develop more specific requirements. The current plan it to revise the Circular on transportation in accordance with the newly adopted Law.

Action 191: The regulatory body and organizations in charge of transport should join international associations to enhance mutual support.

Article 63 of the Law on Atomic Energy prescribes responsibilities of organizations, individuals in transportation. With regard to international associations specifically, this item has not been addressed. Therefore, the regulatory body will need to study and propose a plan for participation in international organizations and associations related to transportation.

TRANSPORT SAFETY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**BASIS:**

TS-R-1, states several requirements associated with transport of irradiated fuel.

R88 Recommendation:

The Government should begin to develop regulations and guidance regarding transport of radioactive material to ensure that activities associated with the developing nuclear programme, including spent nuclear fuel, are included.

10.21 INTERFACES WITH NUCLEAR SECURITY

Phase 1

Action 193: The government should consider the need to promote both safety and security cultures, taking into account their similarities and differences.

This is not yet under consideration. Many agencies and organizations have concerns related to development of safety and security cultures, although no obligation or requirements to establish these cultures have been specified. A VARANS project has been proposed (although not yet approved) to improve nuclear safety culture, and it is expected that this will be included in the development of the various organizations Management Systems.

Phase 2

Action 194: All the relevant organizations should coordinate safety and security aspects from the early stages of development, establishing maximum synergy and, where necessary, integration.

During the site selection, site assessment and verification, operating organizations and regulatory bodies both share certain concerns for the overall safety and security. There does not appear to be an emphasis of the need to be cognizant of the interaction and potential effects between nuclear safety and nuclear security needs.

Action 195: The government in cooperation with legislative bodies should define the responsibilities of the operating organization and other competent authorities in relation to security.

Article 22 of the Law on Atomic Energy prescribes for responsibilities and duties of operating organizations and regulatory bodies for security of radioactive sources, nuclear materials and nuclear equipments. More detailed guidance regarding the requirements of security plans and physical protection plans is needed. Article 33 includes "security" in its title for assigning responsibility for providing detailed regulation, but security is not listed as one of the subjects in the detailed list that follows.

Action 196: The government should develop mechanisms to communicate appropriate information to the public regarding safety and security.

The Government provides the public with information related to radiation safety, legal requirements, radiation incidents via newspapers, radio, television; responding to mails inquiring information on radiation safety, especially the cases related to radiation incidents; and public meetings to answer questions from the public.

Communication with the public is specified in Articles 57, 84, 85 of the Law on Atomic Energy. Guidance for the mechanisms to communicate appropriate information to the public is under further development.

INTERFACES WITH NUCLEAR SECURITY: RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)**<u>BASIS</u>**:

GSR Part 1 Requirement 12, item 2.40, states that "Safety measures and nuclear security measures have to be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."

R89 **Recommendation:**

The organization(s) responsible for security, physical protection, nuclear safety design review, and review and assessment should develop processes to integrate their design and implementation activities such that neither safety nor security is compromised.

APPENDIX I. LIST OF PARTICIPANTS

| | INTERNATIONAL EXPERTS | |
|----------------------------|---|--|
| Peter FUNDAREK | Canadian Nuclear Safety Commission Canada | peter.fundarek@cnsc- ccsn.gc.ca |
| Igor GRLICAREV | Slovenian Nuclear Safety Administration Slovenia | igor.grlicarev@gov.si |
| Mohammad Hassan KHARITA | Atomic Energy Commission of Syria (AECS) Syria | mhkharita@aec.org.sy; atomic@aec.org.sy |
| John KINNEMAN | United States Nuclear Regulatory Commission USA | john.kinneman@nrc.gov |
| Monalija KOSTOR | Atomic Energy Licensing Bard (AELB) Malaysia | monalija@aelb.gov.my |
| Laurent KUENY | Autorité de sûreté nucléaire (ASN) France | laurent.kueny@asn.fr |
| Ana LARCHER | Autoridad Regulatória Nuclear (ARN) Argentina | alarcher@sede.arn.gov.ar |
| Shahid MALLICK | Pakistan Nuclear Regulatory Authority Pakistan | shahid.mallick@pnra.org |
| | IAEA STAFF MEMBERS | |
| John WHEATLEY | Division of Radiation, Transport and Waste Safety Team Coordinator | J.Wheatley@iaea.org |
| Lingquan GUO | Division of Nuclear Installation Safety Deputy Team Coordinator | L.Guo@iaea.org |
| Trevor BOAL | Division of Radiation, Transport and Waste Safety Review Area Facilitator | T.Boal@iaea.org |
| David GRAVES | Division of Nuclear Installation Safety Review Area Facilitator | D.Graves@iaea.org |

| | IAEA STAFF MEMBERS | | |
|---------------|--|--------------------|--|
| Jacky NEUFING | Division of Radiation, Transport and Waste Safety Logistic support | J.Neufing@iaea.org | |
| | OFFICIAL VARANS LIAISON OFFICER | | |
| NGUYEN Hong | Vietnam Agency for Radiation and | nhloan@most.gov.vn | |

APPENDIX II. MISSION PROGRAMME

| Time | Contents | Notes |
|---------------------|--------------------|---|
| | | |
| Sunday 27 S | ер. 2009 | |
| 10:00-17:00 | IRRS Team Briefing | Location:Movenpick HotelParticipation:IRRS TeamVARANS |
| Monday 28 Sep. 2009 | | |

| Monday 28 Sep. 2009 | | |
|---------------------|--|--|
| 09:00-10:30 | Entrance Meeting: Opening speech by Vice Minister of MOST Opening remarks from IAEA Opening remarks from IRRS Team Leader Introductions (IRRS review team & IAEA staff; VARANS management, liaison officer & counterparts, observers) | Location: Movenpick Hotel Participation: Dr Tran Quoc Thang John Wheatley on behalf of Eliana Amaral John Kinneman VARANS team & senior management IRRS Experts IAEA staff |
| 10:30-11:00 | Break | |
| 11:00-12:00 | VARANS Presentations | VARANS counterparts |
| 12:00-13:00 | Lunch | |
| 13:00-14:00 | VARANS Presentations (continued) | Location: VARANS head office (70 Tran Hung Dao Str.) |
| | Interviews with counterparts on Module III (Room No. 1) | DDG DTLuong, I Grlicarev, D Graves |
| 14:00-17:00 | Interviews with counterparts on Module IV (Room No. 3) | Mr DNQuang, H Kharita, L Kueny |
| | Interviews with counterparts on Module VIII (Room No. 2) | DDG LCDung, S Mallick, T Boal |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Tuesday 29 Sep. 2009 | | |
|----------------------|--------------------------|--------------------|
| | | By VARANS staff |
| 8:45 | Pick-up at hotel's lobby | Location: |
| | | VARANS head office |

| | Interviews with counterparts on Module V (Room No. 4) | Mr NHQuang, H Kharita, S Mallick |
|-------------|--|--|
| 09:00-12:00 | Interviews with counterparts on Module VII (Room No. 3) | Mr ĐNQuang, P Fundarek, L Kueny |
| | Interviews with counterparts on Medical Safety (Room No. 2) | DDG DTLuong, Pham Xuan Linh & A Larcher, T Boal |
| 9:30-12:00 | Interviews with counterparts on Module I (Room No. 1) | DDG LCDung, J Kinneman, D Graves, J Wheatley, L Guo |
| 12:00-13:00 | Lunch | |
| | Interviews with counterparts on Medical Safety (Room No. 2) | DDG DTLuong, Phạm Xuân Linh & A Larcher, T Boal |
| 12.00 17.00 | Interviews with counterparts on Module II (Room No. 3) | DDG LQHiep, I Grlicarev, L Kueny, L Guo |
| 13:00-17:00 | Interviews with counterparts on DS 424 (Room No. 1) | DDG LCDung, J Kinneman , S Mallick, David Graves, L Guo |
| | Interviews with counterparts on Code of Conduct (Room No. 4) | Dr Vi, P Fundarek |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Wednesd | Wednesday 30 Sep. 2009 | | |
|---------|---|---|--|
| 8:45 | Pick-up at hotel's lobby | By VARANS staff Location: VARANS head office | |
| 9:00 | Visit to Hospitals to observe inspection and meet senior management of hospital | A Larcher T Boal VARANS inspection team Location: Friendship Hospital | |
| 10:30 | Visit to VAEI | DDG LCDung, Loan J Kinneman, L Kueny, D Graves, J Wheatley, L Guo | |

| | Interviews with counterparts on Module VI (Room No. 3) | Mr DQHung, P Fundarek, S Mallick |
|-------------|---|---|
| 9:00-12:00 | Interviews with counterparts on Education and training (and briefing on field trip to training facilities in INST and HUT) (Room No. 2) | DDG LQHiep, Ms Ngọc, & H Kharita |
| | Interviews with counterparts on Emergency Response (Room No. 1) | DDG DTLuong, Manh, Khanh & I Grlicarev |
| 12:00 | Lunch | |
| 13:30 | Visit to the Management Board for Nuclear Power Project, EVN | DDG LCDung, Loan J Kinneman, L Kueny, D Graves, J Wheatley, L Guo |
| 15:30 | Visit to MOIT and Department of Energy | DDG LCDung, Loan J Kinneman, L Kueny, D Graves, J Wheatley, L Guo |
| | VARANS briefing for P Fundarek on field trip to HCM | Mr DQHùng, Ms Thư P Fundarek |
| 13:00-17:00 | Interviews with counterparts on Education and Training (continued) (Room No. 2) | DDG LQHiep, Ms Ngọc Nguyễn Thị Như Trang & H Kharita |
| | Interviews with counterparts on Emergency Response (continued) (Room No. 1) | DDG DTLuong Manh, Khanh, NHQuang, & I Grlicarev |
| | Interviews with counterparts on Safety of Research Reactors (including preparation for field trip) | Mr LNHai & S Mallick |
| 17:00-20:00 | (Room No. 3) IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Thursday 1 Oct. 2009 | | |
|----------------------|--|--|
| 5:30 | Travel to HCM to observe inspection and meet senior management of the facility | P Fundareck VARANS inspection team <i>Location</i> : Vinnagamma |
| 8:45 | Pick-up at hotel's lobby | Location: VARANS head office |
| 10:30 | Visit to Hanoi Department of Science and Technology | DDG DTLuong, Loan J Kinneman, A Larcher J Wheatley, T Boal |

| 9:00 | Visit to training Centre at INST | DDG LQHiep, Ms Ngọc, Nhu Trang, H Kharita |
|-------------|---|--|
| 10:30 | Visit to training Centre at HUT | |
| 10:00 | Visit Dalat NRI observe inspection and meet senior management of the facility | IRRS: S Mallik VARANS inspection team <i>Location:</i> Dalat NRI |
| 12:00 | Lunch | |
| 14:00 | Visit to Ministry of Natural Resources & Environment | DG, DDG DTLuong, Loan, J Kinneman, J Wheatley, L Guo, A Larcher, T Boal |
| 14:00 | Visit to Technical Support Centre | I Grlicarev, H Kharita, Dan Huyen |
| 15:30 | Visit to MOH | DG, DDG LCDung, Loan J Kinneman, J Wheatley, A Larcher, T Boal, L Guo |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Friday 2 Oct. 2009 | | |
|--------------------|--|--|
| 8:45 | Pick-up at hotel's lobby as needed | Location: VARANS head office |
| 09:00-17:00 | Follow-up interviews with counterparts as needed/report writing. | Participation: Experts & counterparts |
| 9:30-12:00 | Policy discussion | VARANS DG, TL & IAEA |
| 10:00 | Visit Bach Mai hospital for review of management of radiotherapy practices | A Larcher, Mr NHQuang, Thuy Anh |
| 12:00 | Lunch | |
| 16:00 | Return of expert from HCM | P Fundareck and VARANS inspection team |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Saturday 3 Oct. 2009 | | |
|----------------------|---|------------------------------------|
| 09:00-17:00 | Report writing | Location: Movenpick Hotel Experts |
| 15:40 | Return of expert from Dalat | Mallick and VARANS inspection team |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report preparation | IRRS Team & VARANS L.O |

| Sunday 4 Oct. 2009 | | |
|--------------------|----------------|--------------------------|
| | Technical tour | IRRS Team & VARANS staff |

| Monday 5 Oc | Monday 5 Oct. 2009 | | |
|-------------|---|---|--|
| 8:45 | Pick-up at hotel's lobby as needed | Location: VARANS head office | |
| 09:00-12:00 | Follow-up interviews on Code of Conduct (Room No. 1) | Participation: Ms Vi, P Fundarek | |
| 12:00 | Lunch | | |
| 14:00-17:00 | Follow-up interviews on Module VI (Room No. 1) | Participation: Mr DQHung, P Fundarek, S Mallick | |
| 17:00-20:00 | IRRS Team Coordination Meeting (Hotel) & report writing | IRRS Team & VARANS L.O | |

| Tuesday 6 O | Tuesday 6 Oct. 2009 | | |
|-------------|---|------------------------------|--|
| 8:45 | Pick-up at hotel's lobby as needed | Location: VARANS head office | |
| 9:00-12:00 | Follow-up interviews as needed Report writing | IRRS Team & VARANS L.O | |
| 12:00 | Lunch | | |
| 14:00-20:00 | Review and revision of report (Hotel) | IRRS Team | |

| Wednesday 7 Oct. 2009 | | | |
|--|--|---|--|
| 8:45 | Pick-up at hotel's lobby as needed | Location: VARANS head office | |
| 9:00 | Follow-up interviews on Emergency Response (Room No. 1) | Participation: I Grlicarev, DDG. DTLuong, Loan, representative from National Committee on Search and Rescue | |
| | Review and revision of draft report - handover to VARANS | by email | |
| | VARANS review of report | VARANS | |
| Thursday 8 Oct. 2009 | | | |
| 9:00 Discussion of VARANS comments on report | | VARANS & IRRS team <i>Location:</i> At Movenpick Hotel | |

| | Finalize report | IRRS team |
|-------------|--|--|
| Friday 9 Oc | t. 2009 | |
| 10:00 | Exit Meeting Official handover of draft report Closing ceremony Closing remarks: VARANS, IRRS team leader, IAEA Director of Nuclear Installations Division | At MOST meeting room VARANS DG Mr J Kinneman Mr P Jamet |
| 11:30 | Courtesy meeting with Minister of MOST | All |

APPENDIX III. SITE VISITS AND MEETINGS

III.1 LIST OF SITE VISITS AND MEETINGS

| 1. | Vietnam Atomic Energy Institute (VAEI) |
|-----|---|
| 2. | Nuclear Power and Renewable Energy Projects Pre-Investment Board, Vietnam Electricity (EVN) |
| 3. | Ministry of Industry and Trade (MOIT) and Department of Energy |
| 4. | Hanoi Department of Science and Technology |
| 5. | Training centre at INST |
| 6. | Training centre at HUT |
| 7. | Ho Chi Minh City to observe inspection and meet senior management of the irradiator facility |
| 8. | Dalat to observe inspection of research reactor and isotope production facility, and meet senior management of the facilities |
| 9. | Ministry of Natural Resources and Environment (MONRE) |
| 10. | Technical Support Centre |
| 11. | Ministry of Health (MOH) |
| 12. | Friendship Hospital to observe inspection and meet senior management of hospital |
| 13. | Bach Mai Hospital for review of management of radiotherapy practices |

III.2 OBSERVATIONS OF INSPECTION OF DALAT RESEARCH REACTOR

The inspection team:

| 1. | Mr. Luu Nam Hai | Director of Nuclear Safety Division, | Team leader |
|----|----------------------|--------------------------------------|-------------|
| | | VARANS | |
| 2. | Mr. Tao Xuan Khanh | Staff of VARANS | Member |
| 3. | Mr. Nguyen Tien Manh | Staff of VARANS | Member |
| 4. | Mr. Phan Thanh Son | Staff of VARANS | Member |
| 5. | Mr. Tran Minh Chau | Chief inspector, DOST of Lam | Member |
| | | Dong province | |
| 6. | Mr. Phan Van Dat | Director of Technology | Member |
| | | Management and Intelligence | |
| | | Possessing Division, DOST of Lam | |
| | | Dong province | |

Representatives of the inspected facility:

| 1. | Mr. Nguyen Nhi Dien | Director General |
|----|---------------------|-------------------------|
| 2. | Mr. Pham Van Lam | Deputy Director General |

| 3. | Mr. Nguyen Thanh Binh | Deputy Director General |
|-----|-----------------------|---------------------------------------|
| 4. | Mr. Hoang Van Nguyen | Director of Radiation Safety Division |
| 5. | Mr. Pham Van Dung | Deputy Director of Radiation Safety |
| | | Division |
| 6. | Mr. Luong Ba Vien | Director of Reactor Center |
| 7. | Mr. Le Vinh Vinh | Deputy Director of Reactor Center |
| 8. | Mr. Van Ngoc | Staff of Reactor Center |
| 9. | Mr. Duong Van Dong | Temporary Director of Center for |
| | | Research and Production of |
| | | Radioactive Isotope |
| 10. | Ms. Nguyen Thi Thu | Deputy Director of Center for |
| | | Research and Production of |
| | | Radioactive Isotope |

III.3 LIST OF PARTICIPANTS FROM MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT FOR MEETINGS WITH IRRS TEAM

| 1. | Mr Nguyen Thai Lai | Vice Minister |
|----|----------------------|------------------------------------|
| 2. | Mr Nguyen Tien Cuong | Department of International |
| | | Cooperation |
| 3. | Mr Trinh Xuan Ben | DDG, Vietnam Agency for Geology |
| | | and Minerals |
| 4. | Mr Nguyen Dac Dong | Director of Science and Technology |
| | | Department |
| 5. | Mr Tran Tan Van | Vice President of Institute for |
| | | Geological and Minerals Science |
| 6. | Mr Tran Binh Trong | Senior official, Science and |
| | | Technology Department |
| 7. | Ms Nguyen Phuong Lan | Journalist, Magazine on Natural |
| | | Resources and Environment |

III.4 LIST OF PARTICIPANTS FROM MINISTRY OF HEALTH FOR MEETINGS WITH IRRS TEAM

| 1. | Mr Nguyen Quoc Trieu | Minister of Health |
|----|----------------------|------------------------------------|
| 2. | Mr Nguyen Thi Minh | Vice Director of International |
| | Chau | Cooperation Department |
| 3. | Mr Vu Minh Tuan | Director of Department for |
| | | Equipment and medical devices |
| 4. | Mr Le Ngoc Kinh | Director of Department for health- |
| | | check and treatment |
| 5. | Ms PhamThi Loan | Deputy Director of Administration |
| | | for Preventive Medicine and |
| | | Environment |
| 6. | Mr Tran Quang Hung | Staff of International Cooperation |
| | | Department |

III. 5 LIST OF PARTICIPANTS FROM MINISTRY OF INDUSTRY AND TRADE FOR MEETINGS WITH IRRS TEAM

| 1. | Mr Do Huu Hao | Vice Minister |
|----|------------------|---|
| 2. | Mr Ta Van Huong | Director of Department of Energy |
| 3. | Mr Cao Quoc Hung | Director of Department of International |
| | | Cooperation |
| 4. | Mr Le Tuan Phong | Deputy Director of Department of Energy |

APPENDIX IV. SUMMARY OF RECOMMENDATIONS / SUGGESTIONS / GOOD PRACTICES

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES |
|---|---|---|---|
| A | Legislative and governmental responsibilities | R1 | The Government should make legal provisions to clarify and strengthen regulatory independence within and across MOST, MOIT, and MONRE, to ensure a clear separation between the functions of regulation and promotion or operation of radiation and nuclear activities. |
| | | R2 | The Government should ensure that VARANS has adequate staffing and financial resources to discharge their assigned responsibilities, both now and in the future. |
| | | R3 | The Ministry of Science and Technology should provide the detailed regulations and guidelines on exemption levels for notification and licensing, clearance level, procedures for verification, appraisal, approval and measures for clearance of radioactive sources, radioactively contaminated objects, as required by Article 33 (k) of the Law on Atomic Energy. |
| | | R4 | A graded approach to authorization, inspection and enforcement should be incorporated into the legal structure. |
| | | R5 | MOST should issue the Circular proposed by VARANS which specifies the procedures and formalities described in Articles 36(5) and 40(5)). |
| | | S1 | VARANS should be involved in the development of the national strategy for research and development to improve safety and such research and development should be further expanded. |
| | | S2 | Even though the legal basis for liabilities is in place, the proposed draft legal instrument to implement the requirements of the Law on Atomic Energy by Articles (90(2) & 91(3)) should be issued. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY |
|---|---|---|---|
| В | Responsibilities and functions of the regulatory body | S3 | The "prime responsibility for safety of the operator" principle, addressed in article 6 of the Law on Atomic Energy, should be more developed and explained in further regulation. |
| | | S4 | VARANS should expand its communication and information policies and report to other governmental bodies and to the public on the safety aspects (including health and environmental aspects) of facilities and activities and on its regulatory processes. |
| | | S5 | MOST should keep the Government informed about the safety aspects of DALAT research reactor, due to the role played by the reactor in the supply of radioisotopes for Vietnam. |
| | | R6 | VARANS should identify all areas where it has to cooperate with other relevant authorities. |
| | | S6 | The Government should develop a regulation or an administrative instruction for these areas to clarify the roles and responsibilities, and facilitate more direct communication. |
| | | S7 | A regulation should be issued to: - put a process in place for notification of abnormal events, incidents or accidents according to criteria defining the severity of the event; - establish a time limit for notification considering these criteria; - establish a requirement for the operator to report on the events occurring, to the regulatory body within a specified period of time, depending on their severity; - facilitate dissemination. |
| | | R7 | VARANS and MOST should cooperate with other relevant governmental bodies to issue a national strategy plan for a sustainable management of radioactive wastes, which defines aims and needs. This plan should appraise the existing management modes of radioactive wastes, identify the foreseeable needs for storage or disposal installations, provide for the implementation of research and studies on the management of radioactive wastes and define roles and responsibilities between State Agencies and Ministries. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY |
|-------|---|--|
| | R8 | VARANS should take steps to satisfy themselves that the work of their Technical Support Centre does not lead to conficts of interest, especially when advice is provided to licenees. |
| | R9 | The Government should conduct a review to determine other places in the regulatory body where there may be conflicts of interest as a result of technical support services, and take action to avoid the conflict. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ORGANIZATION OF THE REGULATORY BODY |
|---|-------------------------------------|---|---|
| С | Organization of the regulatory body | R10 | MOST should ensure that the reporting lines of its bodies charged with regulatory functions preserve the independence of regulatory decision making from those bodies charged with promotional activities. The same principle should be applied to other relevant Ministries involved in regulatory activities. |
| | | R11 | The Government should ensure that the National Council for Nuclear Safety, when advising the Prime Minister and when reviewing and assessing reports made by VARANS, does not relieve VARANS of its responsibility for making decisions and recommendations. |
| | | R12 | The Government should ensure that the various regulatory authorities appropriately coordinate their regulatory activities at the national level, including the relevant Councils of the Prime Minister, and also at the provincial level. |
| | | S8 | In those areas in which VARANS is not entirely self sufficient, mechanisms and resources should be provided for VARANS to use external services. Accordingly, they should develop criteria for authorization of external consultants and ensure their independence from the operator. |
| | | G1 | VARANS use of international peer review teams and services is a good practice. |
| | | S9 | Thorough analysis of staffing and qualification needs should be done and this should be reflected in a |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ORGANIZATION OF THE REGULATORY BODY |
|-------|---|---|
| | | VARANS management document. |
| | | The staffing and competence issues should be systematically addressed regularly at least once a year and corrective actions should be adopted. |
| | S10 | VARANS should establish a training programme for its staff on an annual basis paying attention that new staff receives adequate training and address the areas where there is a lack of expertise, e.g. establish on the job training in medical area for inspectors. |
| | R13 | The regulatory body should be provided with the necessary staff with the necessary skills to meet its statutory responsibilities, including staff who are capable of performing safety assessments for the scope of radiation/nuclear infrastructure which exists in the country. |
| | G2 | VARANS is very much engaged in the framework of international cooperation to gain as much experience as possible. It cooperates with, and has concluded bilateral agreements with, some countries that have developed nuclear power programmes worldwide and in the region. These activities support and complement the statutory requirement to incorporate international best practices and experience into regulatory decisions. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
|---|-----------------------------------|---|---|
| D | Activities of the regulatory body | R14 | Activities of possession, ownership and transfer should be included in the detailed technical regulations. |
| | | R15 | VARANS should improve their procedures for the handling and assessment of applications for registration certificate, license for radiation related practice. This should include technical criteria for detailed demonstration of safety. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
|-------|---|---|
| | S11 | VARANS should evaluate the use of RAIS 3.1 Web rather than developing its own version of RAIS to support web-based authorization. |
| | R16 | The requirement for authorization of radiation-related practices should be commensurate with the potential magnitude and nature of the hazard presented by the radiation facility and practice. Several discrete stages of authorization should be considered for other practices, not only nuclear facilities. |
| | R17 | VARANS should develop clearly defined procedures for any subsequent amendment, renewal, suspension or revocation of an authorization. This should include technical criteria for detailed demonstration of safety. |
| | R18 | A graded approach should be implemented for the authorization of radiological medical practices |
| | S12 | To facilitate the graded approach to licensing, medical practices could be considered to be four distinct areas: Radiotherapy, Nuclear medicine, Interventional radiology and Diagnostic radiology. These four areas could then be further subdivided according to the relative risk. |
| | R19 | MOST and VARANS should establish a formal procedure determining which medical practices will be licensed by MOST and which will be licensed by VARANS. |
| | R20 | VARANS should develop a set of detailed regulations, clearly defined procedures and guidance documents to establish a comprehensive process to issue, amend and revoke authorizations for nuclear facilities. The regulation process should ensure that all aspects of safety, including limitation of releases of radioactive material in the environment and environmental monitoring, are covered. |
| | R21 | The regulation should provide criteria to define the modifications of nuclear facilities subjected to a review and assessment and to authorization by the regulatory body, with the potential magnitude and nature of the associated hazard being taken into account. |
| | R22 | Well defined procedures for industrial and research facilities and activities should be developed by VARANS to ensure that review and assessment is performed in accordance with potential magnitude and |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
|-------|---|--|
| | | nature of the hazard of the practice. These procedures should state and make available to the operator the principles and associated criteria on which decisions are based. |
| | R23 | VARANS should develop procedures for industrial and research facilities and activities to ensure that safety related modifications are subject to review and assessment commensurate with the potential magnitude and nature of the hazard presented. |
| | R24 | The review and assessment process should be based on a graded approach i.e.: one that takes into consideration the potential magnitude and nature of the hazard, and for medical practices the processes should include specific considerations for the protection of patients. |
| | R25 | VARANS should define a review and assessment process taking into account the different stages e.g. the design, construction, commissioning, operation and decommissioning of research reactor. |
| | R26 | VARANS should develop detailed documents specifying the principles and associated criteria on which judgment and regulatory decisions are made for research reactor and make them available to the operators. |
| | R27 | VARANS should develop capacity for review and assessment of technical submission to determine whether the research reactor complies with the relevant safety objectives, principles and criteria. |
| | R28 | VARANS should develop a detailed programme for review and assessment of research reactor facility so as to follow the development of research reactor from initial selection of site through design, construction, commissioning and operation, to decommissioning and closure. |
| | R29 | VARANS should define the modification process in the review and assessment so that any modification to safety related aspects of research reactor shall be subjected to thorough review and assessment, taking into account the potential magnitude and nature of associated hazard. |
| | S13 | VARANS should be provided with a legal document that specifies clear guidelines that allow for non-reactive, unannounced inspections, at the discretion of VARANS. |
| | R30 | VARANS and DOST should have a more formal, defined process to conduct inspections following the reporting of abnormal occurrences and other incidents, based on the risk posed by the event. Conducting |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
|-------|---|---|
| | | unplanned inspections should not be limited to situations where violations are known to have occurred. |
| | R31 | The regulatory body should be provided with the authority to withdraw an authorization for a period of greater than six months, as may be necessitated by the severity of the noncompliance. |
| | S14 | The regulatory body should ensure that development continues to proceed on the Decree on administrative penalty in accordance with Law on Atomic Energy, as identified in task 1.1.2 of the Proposal of Action Planned for Regulatory Body Vietnam, 2009. |
| | S15 | VARANS should provide specific timelines in which all remedial actions must be taken following the reporting of deviations or violations of minor safety significance on inspection reports. Where the facility cannot carry out the necessary actions in the time period allowed, the facility should report to VARANS on the reasons for failing to respond so that VARANS can decide on the appropriate regulatory follow-up action. |
| | R32 | MOST, VARANS and the DOSTs should determine the extent of the authority of the regulatory inspectors to take on the spot enforcement actions. |
| | S16 | MOST, VARANS and DOST inspectors should be provided with a legal document which describes the sanctions and timeliness of the application of those sanctions, which can be imposed by the inspector without further consultation. Where such approval is not possible to be given to the inspector in the field situation, the same information should be framed so that immediate action can be taken once the appropriate level of approval has been secured. |
| | S17 | The regulatory enforcement policy in the field of medical facilities should be discussed and coordinated among MOST, VARANS, DOSTs and the Ministry of Health and its implementation should be clearly established in the forthcoming regulations that the Ministry of Health will issue in compliance with the requirement 33 (2) (b) of the Law on Atomic Energy. |
| | R33 | VARANS should develop specialized on the job training for its inspectors and DOST inspectors of medical facilities. |
| | S18 | For the implementation of the on-the-job training, VARANS should make arrangements with a teaching hospital in order to allow the inspectors to be trained by specialists in the medical uses of radiation, e.g. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
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| | | medical physicists, medical specialists, medical technologists. |
| | R34 | VARANS should develop a planned and systematic inspection programme and procedures for research reactor which should take account of the potential magnitude and nature of hazard associated with different stages of research reactor. |
| | S19 | VARANS should be provided with a legal document that specifies clear guidelines that allow for non-reactive, unannounced inspections, at the discretion of the VARANS in research reactor. |
| | R35 | VARANS should make the database system for the tracking and trending of inspection findings readily available to all inspectors for use as a trending tool for research reactor and for assisting in inspection planning. |
| | R36 | MOST and VARANS should ensure effective coordination so that enforcement actions can be taken in a timely manner commensurate with the potential nature and hazard pose to workers, public or the environment. |
| | | The draft plans on the development of regulation should be completed to become a National Strategy for the production of regulations and guides and for the revision of existing ones, covering all fields of nuclear safety and radiation safety controlled by VARANS. This strategy should include the following elements: |
| | S20 | determination of the need for the new regulations or the revision of the existing documents, including all relevant information; |
| | setting the priority for development of the regulations; | |
| | | determination of the scope of the proposed regulations or revisions; and |
| | | • determination of the resources to be employed, depending on the resources available and on the time-scale for the preparation and establishment of regulations and guides. |
| | | • the necessary time for implementing the new regulations. |
| | S21 | VARANS should review this national strategy, taking account of good international practices and with broad consultation, to ensure that it covers all important areas and to help defining priorities. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ACTIVITIES OF THE REGULATORY BODY |
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| | G3 | The processes to issue legal documents in the field of nuclear energy include comprehensive provisions to take comments from all interested parties into consideration. |
| | R37 | Regulations and guides for each specific medical practice should be developed by MOST, VARANS and the Ministry of Health, as appropriate. |
| | S22 | The relevant professional societies should be involved at an early stage during the development of those regulations and guides. |
| | S23 | VARANS should benchmark the different existing regulatory system regarding nuclear facilities to develop its own regulatory approach, with an appropriate balance between performance based and prescriptive regulations, before developing detailed regulations and standards. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES CONTROL OF MEDICAL EXPOSURES |
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| E | Control of medical exposures | R38 | The Government should ensure the provision of the regulations which are necessary for implementing the Standards according to the requirement in Art.33 2 b) Law on Atomic Energy and their timely issuance. |
| | | S24 | VARANS should assume a proactive role in fostering the cooperation among the Vietnamese regulatory authorities and the Ministry of Health providing sound information on the risks derived from the lack of regulatory control of medical exposures and offering assistance in drafting the regulations that allow to implement the requirements of the Standards. |
| | | R39 | The Government through the appropriate authorities should develop a comprehensive programme for |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES CONTROL OF MEDICAL EXPOSURES |
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| | | providing adequate and specific training at least to the following persons: Physicians who are responsible for individual justification and conducting the exposures Radiation technologists or equivalent staff and other relevant health professionals. |
| | R40 | The Government, through the appropriate authorities, should develop a national strategy for building competence in the Medical Physics area and establish formal means for accrediting qualifications. |
| | R41 | The Government, through the appropriate bodies, should expand the programmes under development for performing comprehensive surveys of patient doses with special focus on CT and interventional radiology, and to engage professional societies in developing and implementation of Diagnostic Reference Levels (DRLs). |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES EMERGENCY PREPAREDNESS AND RESPONSE |
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| F | Emergency preparedness and response | R42 | VARANS should write a National Radiological Emergency Plan and the task should be finished in a reasonable timeframe. |
| | | R43 | Threat assessment shall be performed by VARANS for all radioactive sources and installations in Vietnam for the full range of postulated events taking into account their probability of occurrence. |
| | | R44 | The threat categorization as required in GS-R-2, para. 3.6, should be addressed and applied whenever needed. |
| | | G4 | VARANS recognized that good knowledge of counterparts is essential for the effective and efficient work in the group. Therefore, VARANS plans to provide basic training on radiation protection and emergency preparedness for the provincial officials, who will take part in the working group, which is |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES EMERGENCY PREPAREDNESS AND RESPONSE |
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| | | going to draft provincial radiological emergency plan. |
| | R45 | An emergency classification system should be in place which would enable prompt initiation of coordinated and pre-planned emergency response on and off the site. |
| | R46 | For the sake of consistency with international standards, the operational intervention levels (OILs) should be adopted by VARANS and arrangements for their implementation made. |
| | S25 | Responsibilities for decision-making regarding agricultural countermeasures and food consumption in the event of an emergency should be clearly addressed in the national emergency plan. Also sampling procedures for food, crops, and agricultural soil in the event of an emergency should be included in the appropriate procedure and the measuring capabilities designated. |
| | R47 | All relevant organizations should take part in the development of emergency response management and operations organization, and implement a command and control system for adequate response to a nuclear or radiological emergency. |
| | R48 | VARANS should initiate the establishment of a network of notification points across the country that includes radiological emergencies. |
| | S26 | This network can be used to receive notification and to initiate the off-site response to an emergency of any type (conventional, nuclear or radiological). |
| | R49 | Vietnam should establish its Early Notification Contact Point in line with the IAEA requirements, including the operation of communication system (ENAC) and taking part in the exercises/tests aimed at testing the system. |
| | R50 | Emergency workers should be designated and informed about risks of radiation exposure in advance and dose limits for emergency workers should be adopted. |
| | R51 | Public information should be addressed in the future documents, i.e. national and provincial emergency plan and relevant procedures. The staff responsible for preparation of press releases should be designated in advance. In addition, the information pathways should be described, outlining which media information should be sent, by which means (facsimile, e-mail, telephone), and identifying the |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES EMERGENCY PREPAREDNESS AND RESPONSE |
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| | | responsible person to authorize and send out this information. |
| | R52 | All emergency response organizations should begin developing procedures for radiological emergency response. |
| | R53 | The NREP preparation by VARANS and other organizations should include a thorough analysis to determine whether the available resources meet the needs of emergency response, including scenarios anticipated by the threat assessment. |
| | R54 | VARANS should develop a procedure to activate the Technical Support Centre staff in case of an emergency, send its staff to the scene and carry out a response (could be for different scenarios/events). This procedure needs to be exercised before it comes into effect. |
| | R55 | After the provincial and national emergency plans and procedures are developed, VARANS should assist other organizations to prepare and conduct an emergency preparedness training programme. For first responders, this requirement can be met earlier. |
| | R56 | All relevant organizations should take part in testing their emergency response capabilities in an exercise. The exercise should be thoroughly analyzed, and lessons learned should be integrated to improve the emergency response capability. |
| | R57 | The response organizations should include provisions for establishing and maintaining the required quality assurance programme for radiation monitoring instrumentation and other equipment. |

| | AREAS | IAEA Comment No R: Recommendations | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES |
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| | | S: Suggestions G: Good practices | CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES |
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| G | Code of conduct on safety and security of radioactive sources | R58 | The regulatory body, in conjunction with other Ministries, should begin the promotion of safety culture within the country |
| | | R58 | VARANS should make arrangements to provide training to its staff for the implementation of the Code of Conduct. Such training should be sufficient to allow the required staff to evaluate proposals made by facility operators to achieve compliance with the Code. |
| | | R60 | VARANS should undertake a programme of outreach for police and other emergency responders to ensure that they clearly understand their actions upon the discovery of, or reporting of, an orphan source. This information should include contact information for persons who are available to respond to such events. |
| | | R61 | Decision No. 17/2007/QD-BKHCN should be updated to reflect the Law on Atomic Energy and revised to include categorization of the sources as provided in the Code of Conduct. This should be done in accordance with the IAEA Safety Guide RS-G-1.9. |
| | | R62 | The State should establish a process whereby notification may be made in the event of a situation with potential transboundary implications. The process should include prompt, complete notification of the potentially affected neighbouring States and also provide notification to the IAEA. |
| | | S27 | VARANS should conduct more outreach with scrap metal dealers to ensure they understand the implications of the discovery of an orphan source. In addition, the Government should consider ways of mitigating the costs for scrap metal dealers to obtain the necessary monitoring equipment. |
| | | R63 | VARANS should expedite the development of the new Circular regarding radioactive waste management, including the management of disused sources. VARANS should also ensure that guidance |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES is provided to all facility operators regarding the reuse and recycling of radioactive sources. |
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| | R64 | VARANS should establish a process for providing prior notification of any exporting activity to the corresponding regulatory body of the importing State. VARANS should also establish a process for receiving such notifications from any exporting State. |
| | R65 | VARANS should set up a system, including prior notification, to ensure that the intended recipient in an importing State is authorized to receive the material. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES EDUCATION AND TRAINING |
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| Н | Education and training | S28 | VARANS should develop national strategy for education to ensure that national infrastructures are adequate to provide for education and training of specialists in radiation protection and safety. This national strategy consists of several phases: analysis of training needs; design of a national training programme in a realistic time frame; development and implementation of this programme; evaluation of the effectiveness of the national strategy and its individual components. |
| | | S29 | The relevant authority should approve the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam" which address education and training in nuclear safety. |
| | | S30 | MOST should develop a well defined procedure for certification of E&T centers, which may include syllabus. |
| | | S31 | VARANS should consider the development of a structured training programme to bridge existing gaps (especially in inspection and review and assessment) in education and training of regulatory staff. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES EDUCATION AND TRAINING |
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| | S32 | VARANS should develop a standard training programme for RPO. |
| | G5 | In nuclear safety, under the draft action plan on "Strengthening capacity in nuclear safety oversight for nuclear power programme in Vietnam" as specified in Part IV "Enhancing human resource for nuclear safety oversight" provides a detailed programme and action plan for training the staff of the regulatory authority for NPP project review. This draft plan is very comprehensive and sufficient for training regulators is the assessing and reviewing the NPP project. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES THE MANAGEMENT SYSTEM FOR THE REGULATORY BODY |
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| I | The management system for the regulatory body | R66 | VARANS should establish and implement a documented management system that is understandable to all of those who will use it, and make it available to all staff to use. |
| | | S33 | VARANS while developing the management system should take account of the graded application of management system and the promotion of safety culture. |
| | | S34 | VARANS should include a process to identify its stakeholders and their expectations in the management system. |
| | | S35 | VARANS, while developing the processes, should take account of the control of documents, products and records. |
| | | S36 | VARANS in developing its management system ensure that it provides for management at all levels to evaluate the performance of work and the improvement of safety culture, and that it is monitored and measured to confirm that its processes achieve their intended results, and to identify opportunities for improvement. |

| | AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES SAFETY INFRASTRUCTURE FOR EMBARKING ON NUCLEAR POWER |
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| J | Safety infrastructure for embarking on nuclear power | R67 | The government should ensure that there is appropriate coordination between the government (Ministries), regulatory authorities (VARANS and others as applicable) and the operating organization (EVN) to assure all fundamental safety principles are addressed in the nuclear safety infrastructure. |
| | | S37 | As part of the coordination, the government should conduct assessments of all areas that are required to support the national nuclear safety infrastructure that are sufficient in detail to develop national action plans. |
| | | S38 | The Government should continue efforts to approve and ratify the appropriate and applicable international instruments associated with the development of a nuclear power programme. |
| | | S39 | The regulatory body should ensure that communications are established with all neighbouring countries regarding the development of the nuclear power programme and the sharing of information related to nuclear operating and regulatory experiences. |
| | | S40 | VARANS should make preparations to develop and formalize detailed requirements and guidance regarding the licensing process for the NPP taking into account the various regulatory authorities involved (VARANS, MOIT, MONRE, etc.). |
| | | R68 | The regulatory body should develop all necessary regulatory requirements and guidance documents (decrees, regulations, circulars, etc.) in an effective and timely manner, including the safety requirements necessary to support the NPP bidding process. |
| | | R69 | The Government should ensure that the decision making function of the regulatory body is effectively independent from the entity having responsibility for operating responsibility of the NPP. |
| | | S41 | VARANS and MOIT should continue to develop mechanisms to communicate with relevant parties on information regarding regulatory judgements and decisions and their bases; and to receive opinions from interested parties as may be considered appropriate and necessary to carry out its regulatory functions. |
| | | S42 | VARANS should begin to define mechanism(s) to communicate information regarding incidents, accidents, abnormal occurrences or other appropriate information to relevant interested parties (e.g. authorized parties, governmental bodies, national and international organizations, the public, etc.). |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES SAFETY INFRASTRUCTURE FOR EMBARKING ON NUCLEAR POWER |
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| | S43 | MOIT (EVN) should amplify the current processes to inform the public about the possible radiation risks associated with a facility. |
| | R70 | VARANS should establish the appropriate legal document(s) to formalize the authorized party's obligation for communicating with the public regarding a facility's radiation risk. |
| | R71 | The government should define the mechanisms by which all relevant organizations and activities related to nuclear and radiation safety for the NPP project (regulatory body, operating organization, NPP project, education and training centres and programmes, development of industrial capability, research centres, etc.) are provided with adequate financial resources, establishing appropriate priorities. |
| | R72 | The government should define the mechanisms by which decommissioning and radioactive waste management activities will be provided with adequate financial resources. |
| | R73 | The responsible government entity should determine the organizational location of the technical support resources (inside or outside VARANS) that provide support to the regulatory body, and make arrangements to ensure that there is no conflict of interest with those organizations which provide the regulatory body with technical advice or services. |
| | R74 | VARANS should continue actions to develop and implement a formal management system, including promoting and developing its internal safety culture. |
| | R75 | As it is developed, the operating organization (EVN) should take action to ensure that a comprehensive management system is implemented, including development and promotion of safety culture, throughout all phases of the NPP project (construction, commissioning, operation, etc.). |
| | R76 | The applicable Ministries should authorize and implement actions to identify gaps in competences, and to increase and maintain the competence of the staff of VARANS, EVN and other organizations involved in safety of the nuclear power programme. Training programmes should be established as necessary to address the identified gaps. Resources should be made available to develop the necessary competence of the regulatory body staff. |
| | R77 | The regulatory bodies (VARANS and MOIT) should be given the authority to recruit the appropriate |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES SAFETY INFRASTRUCTURE FOR EMBARKING ON NUCLEAR POWER |
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| | | number of staff to be able to competently conduct its functions and responsibilities at the appropriate time: legal regulatory document development, inspections, review and assessment, <u>fulfilment and implementation</u> of the applicable international obligations (conventions, treaties, etc.). |
| | R78 | The operating organization (EVN) should be given the authority and resources to recruit the appropriate number of staff to be able to competently conduct its safety responsibilities. |
| | R79 | The applicable authorities should develop a mechanism to identify key safety areas where research information will be needed to support development of a nuclear power programme. |
| | R80 | The research organizations, such as VAEI and universities, should self-assess to identify specific safety areas where their capabilities need to be strengthened to conduct research to support development of a nuclear power programme. |
| | R81 | VARANS in conjunction with applicable ministries should ensure that the principles and criteria for radiation safety regarding workers, the public and the environment for a nuclear power plant are established. |
| | R82 | EVN should prepare the radiological environmental impact analysis report, as part of the overall site Environmental Impact Assessment, and submit this Assessment to the Ministry of Natural Resources and Environment for review and approval. |
| | R83 | The applicable authorities (VARANS, EVN and VAEI) should continue to develop skills associated with conducting and reviewing safety assessments. |
| | R84 | VARANS and MOST should cooperate with other relevant governmental bodies to issue a national strategy plan for a sustainable management of radioactive wastes, including those for the proposed nuclear power programme. |
| | S44 | MOST and VARANS should begin to develop the EPR requirements that will be imposed on the NPP operating organization. |
| | S45 | The operating organization and relevant authorities should begin developing the basic framework for the NPP emergency preparedness programme and plans. |

| AREAS | IAEA Comment No R: Recommendations S: Suggestions G: Good practices | RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES SAFETY INFRASTRUCTURE FOR EMBARKING ON NUCLEAR POWER |
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| | R85 | The Government, in evaluating the acceptability of the Pre-Feasibility Study, including the Investment Report, should fully recognize the level of financial resources that will be needed to safely develop the nuclear power programme. |
| | S46 | The Government should start to prepare the construction and operating organizational structures with clear responsibilities for safety. |
| | R86 | VARANS should establish the necessary regulatory requirements necessary for Radiological Environmental Impact Assessment, final site acceptance as well as the process for conducting the regulatory reviews associated with these submittals. |
| | R87 | The Regulatory Body, in conjunction with other applicable organizations as determined by the government, should establish basic design requirements to support NPP technology selection review and to support bid preparation. |
| | S47 | The Operating Organization should prepare to provide the appropriate safety design requirement information in the bid such that the vendors have accurate and sufficient information. |
| | R88 | The Government should begin to develop regulations and guidance regarding transport of radioactive material to ensure that activities associated with the developing nuclear programme, including spent nuclear fuel, are included. |
| | R89 | The organization(s) responsible for security, physical protection, nuclear safety design review, and review and assessment should develop processes to integrate their design and implementation activities such that neither safety nor security is compromised. |

APPENDIX V. LIST OF REFERENCE MATERIAL PROVIDED BY VARANS

IRRS Reference Materials

| No. | Titles |
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| 1 | Law on Atomic Energy No.18/2008/QH12 |
| 2 | Ordinance on Radiation Safety and Control |
| 3 | Governmental Decree No. 50/1998/ND-CP detailing the Implementation of the Ordinance on Radiation Safety and Control |
| 4 | Governmental Decree No. 51/2006/ND-CP on Sanctions against Administrative Violations in the field of Radiation Safety and Control |
| 5 | Governmental Decree No. 87/2006/ND-CP on the Organization and Operation of the Science and Technology Inspectorate |
| 6 | Governmental Decree providing Details and Guidance for the Implementation of some articles in the Atomic Energy Law (draft) |
| 7 | Governmental Decree on Nuclear Power Plants (draft) a) Decree on nuclear power plants |
| 8 | Decision No. 115/2007/QD-Ttg on issuing Regulations on Ensuring the Security of Radioactive Sources |
| 9 | Regulations for the Recovery and Handling of Orphan Radioactive Sources |
| 10 | a) Regulation on Management of Hazardous Waste b) Annex 2A |
| 11 | Circular No. 14/2003/TT-BKHCN on Safe Transport of Radioactive Material |
| 12 | Circular No. 05/2006/TT-BKHCN guides on Declaration and Authorization Issuance of Radiation -related Practice |
| 13 | Circular No. 10/2006/TT-BKHCN guides on Inspection specializing in Radiation Safety and Control |
| 14 | Circular No. 12/2007/TT-BKHCN on guiding some articles of Decree No. 51/2006/ND-CP on Penalties against Administrative Violations in the field of Radiation Safety and Control |
| 15 | Joint ministerial Circular No.2237/1999/TTLT/BKHCNMT-BYT guidance on Radioactive Safety Implementation in Medical Practices |
| 16 | Circular No. 31/2007/TT-BKHCN guidance on Working and Rest Duration for the Workers working in Radiation and Nuclear Practices |
| 17 | Circular No. 13/2009/TT-BKHCN guiding on Preliminary Nuclear Safety Assessment for Site Selection for Nuclear Power Plants in the Investment Decision stage |

| 18 | Decision No. 17/2007/QD-BKHCN on the Issuance of Radioactive |
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| 18 | Sources Categorization complying with Security Requirements |
| 19 | Regulation on Nuclear Control (draft) |
| 20 | Decision No. 38/2006/QD-BTC on Fees and Charges from Radiation Safety and Control Management activities and their usage |
| | a) Decision No. 2314/QD-BKHCN on the Decentralization of |
| 21 | Authority in Issuing Radiation Safety Registrations and Licenses b) Licensing Procedure |
| | Decision No. 483/QD-BKHCN on Establishing and Issuing |
| 22 | Organization and Operation Regulations of the Inspectorate Vietnam Agency for Radiation and Nuclear Safety |
| | Decision No. 1112/QD-BKHCN on Adjustment of the |
| 23 | Organizational Structure of the Vietnam Agency for Radiation and Nuclear Safety |
| | Decision No. 3616/2004/QD-BYT on the Issuance of the |
| 24 | Regulations on Safety and Sanitation of Foods preserved by Irradiation |
| 25 | Decision No. 32/2007/QD-BKHCN on Issuance of Regulation on |
| | Testing X -ray Equipment for Medical Diagnosis |
| 26 | Decision No. 33/2006/QD-BYT on the Issuance of List of Radioactive Drugs and Tracers for Diagnosis and Treatment |
| 27 | Directive No. 13/2006/CT-BKHCN on Strengthening the State |
| | management on Radiation Safety and Radioactive Source Security |
| 28 | Document No.1092 /BKHCNMT-ATBX of MOSTE to provincial /city departments of science, technology and environment |
| • | Decree No.28/2008/ND_CP defining the functions, Tasks, Powers |
| 29 | and Organizational Structure of the Ministry of Science and Technology |
| 2.0 | Decision No. 114/2007/QĐ-TTg approval of the Master Plan for |
| 30 | Implementation of the Strategy for Peaceful Uses of Atomic Energy up to 2020 |
| | Decision No. 1201/QD-TTg on Establishment of the State Review |
| 31 | Council for Assessing the Investment Report for the Nuclear Power Plant Project in Ninh Thuan |
| | Decision No. 2248/QD-BKHCN on Promulgating the Charter of |
| 32 | Organisation and Operation of the Vietnam Agency for Radiation and Nuclear Safety |
| 33 | Decision No.136/QD-ATBXHN on promulgation of functions, responsibilities and authorities of divisions under VARANS |
| | Decision No. 117/QD-ATBXHN promulgating Procedures for |
| 34 | Handling Registration and License Applications for Radiation Activities |
| 35 | Content of a Radiation Safety Assessment |
| 36 | Licence samples for conducting radiation practices: a) use and transport of radioactive sources; |
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| | b) import and transport of radioactive sources |
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| 37 | Inspection Report on Radiation Safety |
| 38 | Procedures for Emergency Response to Radiological Incidents at Vietsovpetro |
| 39 | Annual Reports of VARANS: |
| 39 | a) Year 2006 |
| | b) Year 2007 |
| | c) Year 2008 |
| 40 | a) Viet Nam Code 1999 (Abstract) |
| | b) Vietnam Penal Code (full text) |
| 41 | Order No. 11/2004/L-CTN on the Promulgation of the Law on Inspection |
| 42 | Ordinance on Handling of Administrative Violations |
| 43 | Decree No. 134/2003/ND-CP detailing the Implementation of a number of Articles of the 2002 Ordinance on Handling of Administrative Violations |
| 44 | Decree No. 13/2008/ND-CP regulating organization of specialized bodies under provincial People Committees |
| 45 | Decree No. 175/CP on providing Guidance for the Implementation of the Law on Environmental Protection |
| 46 | Decree No. 59/2006/ND-CP detailing the Commercial Law regarding Goods and Services banned from Business, subject to Business Restriction or to Conditional Business |
| 47 | Decree No.11/2004/L-CTN of providing for State management over Product and Goods Quality |
| 48 | List of Equipment at the Centre for technical Support and Emergency Response |
| 49 | List of Viet Nam national technical standards (TCVN) |
| 50 | Decision on the establishment, organization and operation of The National Council for Nuclear Safety |
| 51 | TCVN 6561 : 1999:Radiation protection for Medical Installations using X-Ray machine |
| 52 | TCVN 6869: 2001: Radiation protection – Medical exposure – General provisions |
| 53 | Decision on Promulgating the Regulation on Organization and Operation of the Scientific Council of Vietnam Agency for |

| | Radiation and Nuclear Safety and Control |
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| 54 | Decision on Establishment of Scientific Council of Viet Nam Agency for Radiation and Nuclear Safety & Control |
| 55 | Decision on the organizational structure and functions of Technical Support Centre for Radiation Safety and Emergency Response |
| 56 | Decision No.01/2006/QD-TTg of January 3,2006 Approving the strategy for peaceful utilization of Atomic energy up to 2020 |

APPENDIX VI. BIBLIOGRAPHY: IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1.] IAEA SAFETY STANDARDS SERIES GS-R-1 Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety
- [2.] IAEA SAFETY STANDARDS SERIES GS-G-1.1 Organization and Staffing of the Regulatory Body for Nuclear Facilities
- [3.] IAEA SAFETY STANDARDS SERIES GS-G-1.2 Review and Assessment of Nuclear Facilities by the Regulatory Body
- [4.] IAEA SAFETY STANDARDS SERIES GS-G-1.3 Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
- [5.] IAEA SAFETY STANDARDS SERIES GS-G-1.4 Documentation for use in Regulation of Nuclear Facilities
- [6.] IAEA SAFETY STANDARDS SERIES GS-G-1.5 Regulatory Control of Radiation Sources
- [7.] IAEA SAFETY STANDARDS SERIES GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements
- [8.] IAEA SAFETY STANDARDS SERIES GS-R-3 Management System for Facilities and Activities
- [9.] IAEA SAFETY STANDARDS SERIES NS-R-1 Safety of Nuclear Power Plants: Design Safety Requirements
- [10.] IAEA SAFETY STANDARDS SERIES NS-R-2 Safety of Nuclear Power Plants: Operation Safety Requirements
- [11.] IAEA SAFETY STANDARDS SERIES NS-R-4 Safety of Research Reactors
- [12.] IAEA SAFETY STANDARDS SERIES NS-G-4.1 Commissioning of Research Reactors
- [13.] IAEA SAFETY STANDARDS SERIES SS115 International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of
- [14.] IAEA SAFETY STANDARDS SERIES TS-R-1 Regulations for the Safe Transport of Radioactive Material
- [15.] IAEA SAFETY STANDARDS SERIES WS-G-2.1 Decommissioning of Nuclear Power Plants and Research Reactors
- [16.] IAEA SAFETY STANDARDS SERIES WS-G-2.2 Decommissioning of Medical, Industrial and Research Reactors
- [17.] IAEA SAFETY STANDARDS SERIES WS-R-1 Near Surface Disposal of Radioactive Waste

- [18.] IAEA SAFETY STANDARDS SERIES WS-R-2 Predisposal Management of Radioactive Waste including Decommissioning
- [19.] IAEA SAFETY STANDARDS SERIES WS-G-2.3 Regulatory Control of Radioactive Discharges to the Environment
- [20.] IAEA SAFETY STANDARDS SERIES WS-G-2.4 Decommission of Nuclear Fuel Cycle Facilities
- [21.] IAEA SAFETY STANDARDS SERIES WS-G-2.5 Predisposal Management of Low and Intermediate Level Radioactive Waste
- [22.] IAEA SAFETY STANDARDS SERIES WS-G-2.6 Predisposal Management of High Level Radioactive Waste
- [23.] IAEA SAFETY STANDARDS SERIES WS-G-2.7 Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture,
- [24.] IAEA SAFETY STANDARDS SERIES WS-R-3 Remediation of areas contaminated by past activities and accidents
- [25.] IAEA SAFETY STANDARDS SERIES WS-R-5 Decommissioning of facilities using Radioactive Material
- [26.] IAEA SAFETY STANDARDS SERIES WS-G-6.1 Storage of Radioactive Waste
- [27.] IAEA SAFETY STANDARDS SERIES RS-G-1.7 Application of the Concepts of Exclusion, Exemption and Clearance
- [28.] IAEA SAFETY STANDARDS SERIES RS-G-1.8 Environmental and Source monitoring for Purpose of Radiation Protection
- [29.] IAEA SAFETY STANDARDS SERIES RS-G-1.9 Categorization of Radioactive Sources
- [30.] IAEA CODE OF CONDUCT on the Safety and Security of Radioactive Sources
- [31.] IAEA CODE OF CONDUCT on the Safety of Research Reactors
- [32.] IAEA GUIDANCE on the Import and Export of Radioactive Sources
- [33.] IAEA SAFETY SERIES NO. 111-G-1.1 Classification of Radioactive Waste
- [34.] SAFETY SERIES NO. 35 G2 Safety in the Utilization and Modification of Research Reactors
- [35.] IAEA TECDOC 1388 Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies
- [36.] INSAG SERIES NO. 17 Independence in Regulatory Decision Making

- [37.] INSAG SERIES NO. 20 Stakeholder Involvement in Nuclear Issues
- [38.] INSAG SERIES NO. 21 Strengthening the Global Nuclear Safety Regime
- [39.] IAEA LEGAL SERIES NO.14 Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency Adopted on 26 September 1986 at the 18th 1986 plenary meeting
- [40.] IAEA SAFETY STANDARDS SERIES NS-R-3 Site Evaluation for Nuclear Installations Safety Requirements
- [41.] IAEA SAFETY STANDARDS SERIES GSR Part 5 Predisposal Management of Radioactive Waste
- [42.] IAEA SAFETY STANDARDS SERIES DS-415 Draft GSR Part 1 Governmental, Legal and Regulatory Framework for Safety
- [43.] IAEA SAFETY STANDARDS SERIES Draft DS-424 Establishing a Safety Infrastructure for a National Nuclear power programme

APPENDIX VII. RADIATION SOURCES IN VIETNAM

Industrial

| | | Sealed S | | | Unsealed Source | Accelerator |
|-----|--------------------------------|----------|------------|-------|--------------------|-------------|
| No. | Application | In Use | In Storage | X_K9V | | |
| 1 | Sterilization Irradiator | 6 | 2 | 0 | 0 | 2 |
| 2 | NDT | 67 | 148 | 33 | 0 | 0 |
| 3 | Gauge | 402 | 71 | 27 | 0 | 0 |
| 4 | Well logging | 88 | 30 | 0 | х | 0 |
| 5 | Tracer | 0 | 0 | 0 | X | 0 |
| 6 | X-ray fluorescent spectrometry | 59 | 0 | 18 | 0 | 0 |
| 7 | Main-board Scanner | 0 | 0 | 7 | 0 | 0 |

Health Care

| | | Sealed S | ource | X-Ray | Unsealed Source | Accelerator |
|-----|---|----------|------------|-------|--------------------|---------------|
| No. | Application | In Use | In Storage | | | |
| 1 | Tele-therapy | 19 | 5 | 0 | 0 | 7 |
| 2 | Brachy-therapy (HDR) | 3 | 15 | 2 | 0 | 0 |
| 3 | Brachy-therapy (Low & Medium dose rate) | 0 | 508 | 0 | 0 | 0 |
| 4 | X-Ray Diagnose | 0 | 0 | 2900 | 0 | 0 |
| 5 | Nuclear Medicine | 0 | 0 | 0 | 0 | X |
| 6 | Blood Irradiation | 1 | 1 | 0 | 0 | 0 |
| 7 | Radioisotope Production | 0 | 0 | 0 | X | 3 (Cyclotron) |

Education, research and others

| . . | | Sealed Source | | X- | Unsealed | |
|------------|--|------------------|-------------------|----|----------|-------------|
| No. | Application | | In In Use Storage | | Source | Accelerator |
| | Education & Research | | | | | |
| 1 | Education & Research | 316 | 105 | 11 | X | 1 |
| | Others | | | | | |
| 1 | Agricultural irradiators | 0 | 2 | | | |
| 2 | Geology | 4 | 120 | 0 | X | 0 |
| I 🗅 | X-Ray scanner (security & customs) | 0 | 0 | 37 | 0 | 0 |
| | Radiothermal generators (RTG's) | 0 | 0 | 0 | 0 | 0 |
| | X-ray fluorescent spectrometry (in gold trading) | 31 | | | | |

APPENDIX VIII. LEGAL SYSTEM OF VIETNAM

I. LEGAL SYSTEM OF VIETNAM

In Vietnam, legal documents and promulgation competence are defined by the *Law on the Promulgation of legal documents* (Law No. 17/2008/QH12). This Law was passed by the National Assembly (12th legislature, 3rd session) on 3rd June 2008 and came into force since 1st January 2009. The Government promulgated the Decree No. 24/2009/ND-CP dated 5th March 2009 *detailing and providing measures for the implementation of the Law on Promulgation of legal documents*. This Decree came into force since 20th April 2009.

By virtue of the Law No. 17/2008/QH12 (Article 2), system of legal documents consists following documents:

- 1. **Constitution, laws** and **resolutions** of the National Assembly.
- 2. **Ordinances** and **resolutions** of the Standing Committee of the National Assembly.
- 3. **Orders** and **decisions** of the State President.
- 4. **Decrees** of the Government.
- 5. **Decisions** of the Prime Minister.
- 6. **Resolutions** of the Justices' Council of the Supreme People's Court and **circulars** of the Chief Justice of the Supreme People's Court.
- 7. **Circulars** of the President of the Supreme People's Procuracy.
- 8. **Circulars** of Ministers or Heads of Ministry-equivalent Agencies.
- 9. **Decisions** of the State Auditor General.
- 10. **Joint resolutions** of the Standing Committee of the National Assembly or the Government and the central offices of socio-political organizations.
- 11. **Joint circulars** of the Chief Justice of the Supreme People's Court and the President of the Supreme People's Procuracy; those of Ministers or Heads of Ministry-equivalent Agencies and the Chief Justice of the Supreme People's Court, the President of the Supreme People's Procuracy; those of Ministers or Heads of Ministry-equivalent Agencies.
- 12. **Legal documents** of People's Councils and People's Committees.

II. CONTENT OF LEGAL DOCUMENTS

1. Constitution

The National Assembly shall develop and revise the country's Constitution. The Constitution is basic law.

The drafting, approval, launching and revision of the Constitution as well as procedures and sequential order of steps in interpreting the Constitution shall be prescribed by the National Assembly

2. Law

Laws of the National Assembly shall address fundamental issues in the following fields: economics, society, national defense and security, finance, money, budget, tax, ethnicity, religion, culture, education, health, science and technology, environment,

external relations, organization and functioning of the state apparatus, civil service, public officials and civil servants, rights and obligations of citizens.

3. Resolutions (of the National Assembly)

Resolutions of the National Assembly shall reflect its decisions on the following issues: socio-economic development tasks; state budget plans and central budget allocations; state budget adjustments; approval of state budget balance sheets; working regimes of the National Assembly as well as of its Standing Committee, Ethnic Council, other Committees and Deputies; ratification of international treaties; and decisions on other issues within the authority of the National Assembly.

4. Ordinance (of the NA Standing Committee)

Ordinances of the Standing Committee of the National Assembly shall contain regulations on issues upon instruction by the National Assembly. After a certain period of implementation, these issues shall be proposed to be developed into laws for the National Assembly's consideration and decision.

5. Resolutions (of the NA Standing Committee)

Resolutions of the Standing Committee of the National Assembly shall aim to interpret the Constitution, laws and ordinances; guide the operations of People's Councils; decide to announce war and issue national or local appeals for resource mobilization; declare national or local emergencies; and decide on other issues within the authority of the Standing Committee.

6. Orders and decisions (of the State President)

Orders and decisions of the State President shall aim to exercise the tasks and authority of the State President defined in the Constitution, laws and resolutions of the National Assembly, ordinances and resolutions of the Standing Committee of the National Assembly.

7. Decrees (of the Government)

Decrees issued by the Government shall:

- 1. Provide detailed guidelines on the implementation of laws and resolutions of the National Assembly, ordinances and resolutions of the Standing Committee of the National Assembly, orders and decisions of the State President;
- 2. Provide specific actions to implement policies in the following fields: economics, society, national defence and security, finance, money, budget, tax, ethnicity, religion, culture, education, health, science and technology, environment, external relations, organization and functioning of the state apparatus, civil service, public officials and civil servants, rights and obligations of citizens and other issues within the Government's management and administration authority;
- 3. Specify tasks, authority and organizational structures of Ministries and Ministry-equivalent Agencies, Government-affiliated Agencies and other agencies within the authority of the Government;

4. Identify other important issues which are not mature enough to be developed into laws or ordinances to meet governance and socio-economic management requirements. The issuance of decrees shall be subject to agreement by the Standing Committee of the National Assembly.

8. Decisions (of the Prime Minister)

Decisions of the Prime Minister shall focus on:

- 1. Ways to lead, manage and administer the Government's operations and public administration system from the central to grassroots levels, working regimes of the cabinet members, Chairmen of People's Committees of provinces and cities under central management and other issues within the Prime Minister's authority;
- 2. Ways to guide and coordinate the cabinet members' activities; and examine operations of Ministries and Ministry-equivalent Agencies, Government-affiliated Agencies and People's Committees at all levels in compliance with the State's directions, policies and laws.

9. Circulars (of Ministers and Heads of Ministry-equivalent Agencies)

Circulars of Ministers and Heads of Ministry-equivalent Agencies shall provide:

- 1. Detailed guidelines on the implementation of laws and resolutions of the National Assembly, ordinances and resolutions of the Standing Committee of the National Assembly, orders and decisions of the State President, decrees of the Government and decisions of the Prime Minister;
- 2. Regulations on technical processes and standards as well as techno-economic norms of the sector/area covered by each Ministry or Ministry-equivalent Agency;
- 3. Ways to exercise management of the sector/area covered by each Ministry or Ministry-equivalent Agency and other issues upon instruction by the Government.

10. Resolutions (of the Justices' Council of the Supreme People's Court)

Resolutions of the Justices' Council of the Supreme People's Court shall guide courts in applying/interpreting laws in a consistent manner.

11. Circulars (of the Chief Justice of the Supreme People's Court)

Circulars of the Chief Justice of the Supreme People's Court shall aim to exercise management of local people's courts and military courts in terms of organizational matters; and provide regulations on other issues within the authority of the Chief Justice of the Supreme People's Court.

12. Circulars (of the President of the Supreme People's Procuracy)

Circulars of the President of the Supreme People's Procuracy shall provide ways to ensure the fulfillment of the tasks and authority of local people's procuracies and military procuracies and regulations on other issues within the authority the President of the Supreme People's Procuracy.

13. Decisions (of the State Auditor General)

Decisions of the State Auditor General shall prescribe the State's auditing standards and guide their implementation; and provide detailed auditing process/procedures and supporting documentation.

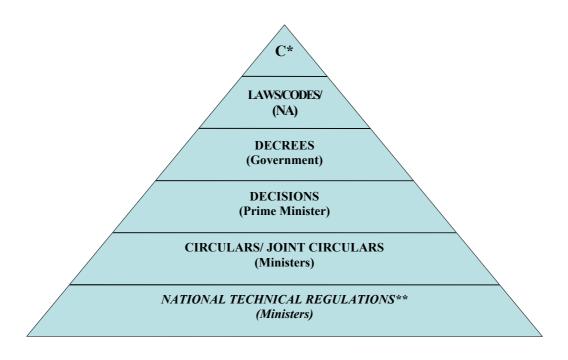
14. Joint legal documents

- 1. Joint resolutions of the Standing Committee of the National Assembly or the Government and the central offices of socio-political organizations shall provide guidelines on how to address the issues related to the participation of those organizations in state management as stipulated by law.
- 2. Joint circulars of the Chief Justice of the Supreme People's Court and the President of the Supreme People's Procuracy as well as those of Ministers/Heads of Ministry-equivalent Agencies and the Chief Justice of the Supreme People's Court/the President of the Supreme People's Procuracy shall guide the consistent application/interpretation of laws in litigation activities and provide regulations on other issues related to the tasks and authority of those agencies.
- 3. Joint circulars of Ministers and Heads of Ministry-equivalent Agencies shall provide guidelines on the implementation of laws and resolutions of the National Assembly, ordinances and resolutions of the Standing Committee of the National Assembly, orders and decisions of the State President, decrees of the Government and decisions of the Prime Minister related to the functions, tasks and authority of each Ministry and Ministry-equivalent Agency.

15. Legal documents of People's Councils and People's Committees

Legal documents of People's Councils and People's Committees shall comply with the Law on the Promulgation of Legal Documents of People's Councils and People's Committees (Law No. 31/2004/QH11 passed on 14th December 2004 and came into force since 1st April 2005) in terms of contents, authority, formats, sequential order of steps and procedures.

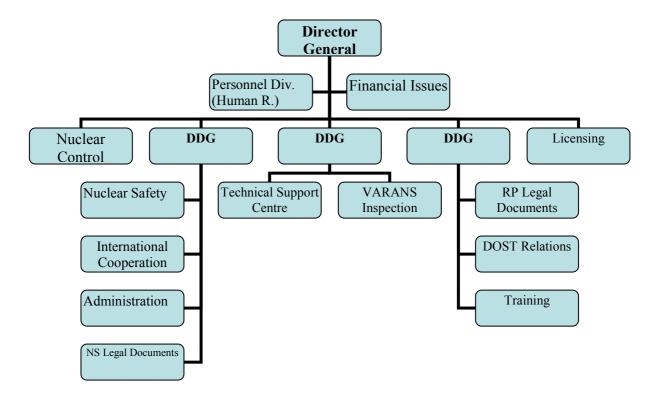
DIAGRAM OF LEGAL DOCUMENTS PROMULGATED BY THE NATIONAL ASSEMBLY, THE GOVERNMENT, THE PRIME MINISTER AND MINISTERS



^{*} Constitution 1992 (Amended 2001)

^{**} National technical regulations is not legal document. However, according to the Clause 3, Article 3 of the *Law on Standard and Technical Regulation (Law No. 68/2006/QH11 passed on 29th June 2006)*, the mentioned regulations issued by minister are legally binding.

APPENDIX IX. ORGANIZATIONAL CHART OF VARANS



APPENDIX X. EXAMPLE PROCESS FOR RENEWAL OF LICENCE

PHASE 1: Submission of application dossier for renewal of the Research Reactor licence

Simple application letter from DALAT Research Institute (DRI), requesting requirements for application dossier

November 2008

Official letter from VARANS List of requested documents January 2009

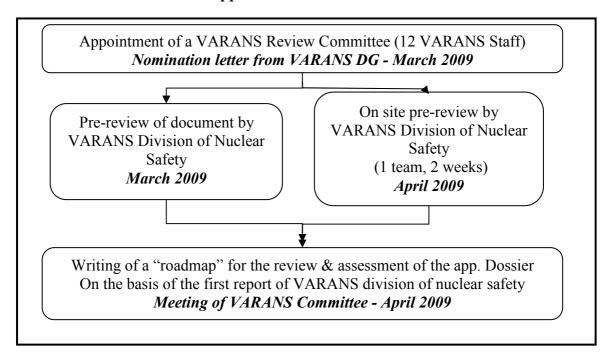
- Report on technical specification of the reactor
- Update version of safety analysis report
- Ageing management report
- Safety report on the production of radioisotopes
- Report on human resources and changing plan
- Quality insurance program
- Report on emergency response plan for incidents
- Report on documentation quality insurance

Additional operators documents were already available by VARANS and were used for review and assessment

Operation manual, operation/maintenance procedures for cooling system, rules for nuclear, radiation and labour safety applicable to reactor workers, procedure for collecting radioactive waste, procedure for replacing exchange filters, guidance for transport and storage of spent fuel, emergency response plan etc.

Application Dossier
Transmitted by Dalat Research Institute
February 2009

PHASE 2: Pre-review of the application



PHASE 3: Review and assessment of application for renewal of licence

On review and assessment by Review and assessment of VARANS Division of Nuclear document by VARANS Division Safety of Nuclear Safety (5 team of 3 staff, 1 week) **April 2009** May 2009 Review of the VARANS division report by VARANS Committee Meetings of VARANS Committee - May 2009 Transmission of final report by VARANS Committee to MOST special Committee MOST Committee is appointed by the Minister (around 10 people, among them 3 from VARANS, 1 from VAEI) Review of VARANS Report by MOST Committee – Summer 2009 Proposal for a licence including: - conditions of renewal licence - term of licence (5 years for DALAT renewal) Transmitted by MOST Committee to the Minister – August 2009 Signature of the renewal licence by the Minister 4 September 2009

APPENDIX XI. EDUCATION AND TRAINING

XI.1 RADIATION PROTECTION TRAINING ACTIVITIES FOR YEAR 2008

| No. | Training Centre | No. of Courses | No. of Participants |
|-----|---|----------------|------------------------|
| 1. | Technology Application and Development Company (NEAD), Vietnam Atomic Energy Institute (VAEI) | 17 | 361 |
| 2. | Institute for Nuclear Science and Technology (INST) | 22 | 852 |
| 3. | Ho Chi Minh Center for Nuclear Techniques | 13 | 548 |
| 4. | Vietnam Agency for Radiation and Nuclear Safety (VARANS) | 7 | 352 |
| 5. | Department of Science and Technology (DOST) | 2 | 83 |
| 6. | Ministry of Science and Technology (MOST) | 3 | 175 |
| | TOTAL | 64 | 2371 |

APPENDIX XII. LIST OF ABBREVIATIONS AND ACRONYMS

CPPNM Convention on Physical Protection of

Nuclear Materials

DOST Department of Science and Technology

Joint Convention Joint Convention on the Safety of Spent

Fuel Management and on the Safety of.

Radioactive Waste Management

ICS Incident Command System

Master Plan for Implementation of the

Strategy for Peaceful Uses of Atomic

Energy up to 2020

MOIT Ministry of Industry and Trade

MONRE Ministry of Natural Resources and

Environment

MOST Ministry of Science and Technology
NREP National Radiological Emergency Plan

PIC Public Information Center

TSC Technical Support Center (of VARANS)

TSO Technical Support Organization
VARANS Vietnam Agency for Radiation and

Nuclear Safety

ERROR: undefined OFFENDING COMMAND:

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