WHY AN EFFECTIVE NATIONAL REGULATORY INFRASTRUCTURE IS ESSENTIAL FOR A COUNTRY'S RADIATION PROTECTION SYSTEM

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ABSTRACT

Regulatory control over all activities that may cause radiation hazards is essential to ensuring that people and the environment are protected from the harmful effects of ionizing radiation. Adequate regulatory control can only be achieved through the establishment of State, legal and regulatory frameworks for safety. The IAEA Safety Standards establish fundamental safety principles, requirements and guidance to assist States in building this framework. This paper elaborates the importance of establishing a national regulatory infrastructure for the control of sources and for radiation protection. A discussion is presented as to how the quality and robustness of a national regulatory framework affects the national radiation safety system. The impact of essential elements such as legislation, regulations, regulatory guidance documents, as well as the independence, adequate funding, staffing and training of a national regulatory body on radiation protection and safety is discussed. Regulatory activities such as authorization, inspections, enforcement and maintenance of safety-related records, contribute to ensuring the protection of people and the environment. An overview is presented of the IAEA role in strengthening radiation safety regulatory infrastructures worldwide.

KEY WORDS

Regulatory, infrastructure, radiation, safety, sources.

1. INTRODUCTION

Modern times are marked by widespread beneficial uses of ionizing radiation. This includes uses of radioactive sources and radiation generators. While many beneficial uses of radiation exist, radiation can be harmful if used without proper safety precautions. Modern and sophisticated radiation-based technologies, advanced and powerful radiation equipment, and complex procedures, may present significant challenges to keeping radiation doses at acceptable levels.

Devices such as industrial radiography cameras, radiation sources used in geophysical explorations or portable moisture/density gauges can present additional risks by the nature of their portability if not operated, transported and stored adequately.

Sources that are not controlled properly at the end of their useful lives may unintentionally become incorporated into other materials, such as recycled metal. Uncontrolled radioactive materials, mixed inadvertently with other processed substances, can make their way into commodities and finished products. Improperly stored, disposed or simply abandoned radioactive sources can pose radiation hazards to people unaware of their danger, or to the environment [1].

Radiological accidents that occurred in the past demonstrate that strong control over radiation sources and activities is indispensable in order to prevent such incidents. Multiple publications describe situations in which people were exposed to radiation or radioactive material was dispersed in the environment, due to inadequate regulatory infrastructures. Some of these publications are listed in References [2, 3, 4, 5, 6, 7 and 8]. Examples of radiological accidents include large-scale radioactive contamination of urban areas, exposure of persons caused by misplaced sources, exposure to operators of irradiators or radiography devices caused by insufficient training or negligence, and the misadministration of medical radiation doses. Some of the reported accidents resulted in fatalities and injuries to people. Apart from health effects and the loss of lives, inadequately controlled sources have also caused economic losses and social disruption.

For the purposes of this publication, safety means the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. Safety includes radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material. It does not include non-radiation-related aspects of safety [9].

For some countries, it is difficult to create national regulatory infrastructures with their own scarce resources. Establishment of such infrastructures can be assisted by international cooperation, coordinated by competent international organizations.

This text describes important elements of an effective national regulatory system and explains why the existence of such a system is a prerequisite for the development of techniques based on radiation sources and is essential for a national radiation protection system. The IAEA has an important role in assisting countries to establish regulatory infrastructures for radiation safety.

2. INTERNATIONAL STANDARDS FOR RADIATION SAFETY

The IAEA is an international organization within the United Nations system. It is a global focal point for the peaceful uses of atomic energy.

Moreover, the statutory functions of the IAEA include the development of Safety Standards and provisions for their application in Member States. The IAEA has a comprehensive programme for developing and updating Safety Standards and related publications (http://www-ns.iaea.org/standards/default.asp) and an extensive programme to support States in implementing these standards.

The IAEA Safety Standards promote a consistent approach to safety. Adherence to the safety standards provides assurance that nuclear and radiation related technologies are used safely worldwide. Built on international consensus, the Safety Standards provide a benchmark concerning adequate safety provisions.

The IAEA Safety Standards provide a robust framework of fundamental safety principles, requirements and guidance to ensure safety. They are developed through an open and transparent process for gathering, integrating and sharing the knowledge and experience gained from uses of technologies and from emerging trends. They incorporate lessons learned from on-going safety analyses and operational experience, including past incidents worldwide.

The IAEA Safety Standards address all aspects of nuclear and radiation safety national infrastructure. The Fundamental Safety Principles publication [10] establishes ten fundamental safety principles for radiation protection and safety.

Safety requirements documents establish the requirements that must be met in order to ensure the protection of people and the environment, now and in the future. They are governed by the principles of the Safety Fundamentals. General Safety Requirements Part 3 [11] (superseding, since 2011, the 1996 International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (BSS No. 115) is an essential document of the IAEA Safety Standards Series. It covers requirements for planned, emergency and existing exposures situations. It provides requirements related to limits for exemption and clearance, dose limits for planned exposure situations and criteria for use in emergency preparedness and response.

General Safety Requirements Part 1 [12] establishes the requirements for legal and governmental infrastructures for nuclear, radiation, radioactive waste and transport safety.

Numerous safety guides provide recommendations on how to meet the safety requirements. They reflect an international consensus on provisions that should be implemented to meet the requirements.

Other IAEA publications also play key roles in defining essential provisions for the adequate control of radiation sources, in particular the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources [13 and 14].

3. SOME ESSENTIAL ELEMENTS OF AN EFFECTIVE REGULATORY FRAMEWORK

Regulatory infrastructure is based on a properly established legal and governmental framework for radiation safety. Typically, States establish this framework by means of different instruments, statutes and laws. Since States may be governed through different legal and administrative arrangements, the legal and governmental framework for safety may vary in shape and structure from State to State. But it should meet certain criteria specified in relevant Safety Standards, in particular the General Safety Requirements, Part 1 [12]. This section briefly addresses some of the key components of a national regulatory infrastructure for radiation safety.

A properly established framework includes a regulatory body, confers on it the legal authority, determines the specific functions of the regulatory body and the allocation of responsibilities, and provides it with the technical and managerial competence and the human and financial resources necessary to fulfil its statutory obligation.

The State has to ensure that the regulatory body is effectively independent in its safety-related decision-making and that it has a functional separation from entities having responsibilities or interests that could unduly influence its decisions. In turn, the regulatory body has to perform its functions in a manner that does not compromise its effective independence.

An important aspect of the legal, governmental and regulatory framework is to ensure that the implementation of national policies, strategies and regulatory programmes are subjected to a graded approach, proportionate to the radiation risks associated with facilities and activities, in accordance with national circumstances. The extent of the regulatory control applied must be commensurate with the potential magnitude and nature of the hazard.

The regulatory body should maintain cooperative relationships with national and international partners and good relationships with its stakeholders, including the general public.

To effectively achieve sound regulatory oversight, the regulatory body staff must be competent and adequately trained. The regulatory body establishes human resources plans to cover its present and future staffing needs and to ensure knowledge continuity in order to discharge regulatory functions in a sustainable and effective manner.

The regulatory body should adopt a management system and related processes which enhance its capability to ensure effective control of radiation sources. To be effective, the management system incorporates a graded approach to ensure identification, prioritisation and allocation of resources to areas of highest need or risk, to ensure timely and effective action and efficient use of national resources.

The regulatory body may need to have access to professional advice or technical services, in support of its regulatory functions.

Authorization by the regulatory body, including specification of the conditions necessary for safety, is a prerequisite for all those facilities and activities that are either not explicitly exempted or approved through a notification process.

The regulatory body should carry out inspections of facilities and activities to verify that the authorized parties are in compliance with regulatory requirements including the conditions specified in the authorization.

In the event that issues requiring further attention are identified, corrective actions should be taken by authorized parties. Items of non-compliance that pose significant safety risks or uncorrected items of non-compliance from previous inspections, become violations that are subject to enforcement action. Enforcement constitutes actions and sanctions to compel a person, or organization responsible for facilities and activities, to comply with regulations and the conditions of the authorization. Enforcement incorporates a range of graded administrative actions that include orders to correct irregularities or suspend operations, civil penalties, legal investigations and ultimately, criminal prosecution.

Authorization, inspection and enforcement programmes are established and revised regularly by the regulatory body with due consideration of the level of risks associated with the facilities and activities.

The regulatory body must keep its regulations and guidance documents current with the evolving state of technology, scientific information and with the IAEA Safety Standards. Maintenance and management of national regulations and guidance documents is an on-going process, incorporating the risk-informed approach.

For its effectiveness, the regulatory body should make provisions for the maintenance and retrieval of records related to the safety of facilities and activities. This includes registers of sealed radioactive sources and radiation generators, records of occupational doses and staff training, safety analyses, records necessary for the decommissioning of facilities, records of unplanned events, equipment service logs and inventories of radioactive waste.

It is highly recommended that the regulatory body acquire adequate data management tools to facilitate data storage and treatment. A principal requirement for any data management system is conformity to the underlying regulatory system in the country. It has to reflect, for example, the applicable categorization of radiation sources, the system of national notification and authorizations, and the assignment of responsibilities and job classifications for occupationally exposed workers.

The regulatory body should establish an appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the process and decisions of the regulatory body [11].

4. IMPORTANCE OF AN EFFECTIVE REGULATORY FRAMEWORK TO THE NATIONAL RADIATION PROTECTION SYSTEM

As stated in the Safety Fundamentals [10], the prime responsibility for safety rests with the person or organization responsible for the source. This responsibility covers many different aspects, depending

on the source, the facility and the operations of the person or organization. To be discharged by all operators in an appropriate manner, this responsibility needs on one hand, to be clearly defined by a set of definitions and rules, and on the other hand, to be controlled by a dedicated organization.

An effective set of coherent laws, regulations and guidance documents, covering all aspects of radiation safety, ensures that the operational rules are defined. The rules should be clear and legally binding to all operators of radiation sources. They should be enforced in a manner proportional to the severity of the non-compliance. The regulatory framework should also provide a setting for establishing and implementing national standards for protection against radiation, ensuring harmonized and commonly accepted provisions for the safety and protection for all persons and organizations, without losing the benefits of using radiation. Its foundation on the IAEA Safety Standards ensures that the most recent knowledge and best practices are being considered.

The regulatory body, with the adequate authority and resources, is in charge of establishing, strengthening, and continuously improving the regulatory framework. It considers new technology developments, knowledge, and research results available internationally to revise the rules and adjust the level of safety and protection accordingly. Moreover, the regulatory body, by its legal empowerment, and through the conduct of its regulatory functions of authorization, inspection and enforcement, ensures for the State, that the rules are being implemented and that all operators fulfil their responsibility for safety in an adequate manner. The competence, independence, openness and transparency of the regulatory body, are central for ensuring that the control of the operators is consistent and fair. It also contributes to an atmosphere conducive to the establishment of a universal safety culture.

5. IAEA ASSISTANCE IN STRENGTHENING NATIONAL RADIATION SAFETY REGULATORY INFRASTRUCTURES

The IAEA has developed various support programmes and services that are made available to States, to assist with the establishment and strengthening of their national regulatory infrastructures for radiation safety.

Appraisal missions such as the Integrated Regulatory Review Service (IRRS) http://www-ns.iaea.org/reviews/rs-reviews.asp are conducted with the objective to strengthen and enhance the effectiveness of the regulatory infrastructure for safety, through a comprehensive assessment of the existing national regulatory system, vis-à-vis the requirements contained in the IAEA Safety Standards. Lessons learned from the IRRS missions are used to establish best international practices. The missions are also an effective mechanism for knowledge and operational experience-sharing among safety regulators internationally.

Some advisory missions are organized to advise and to provide technical assistance to States in specific safety areas, in order to support focussed efforts to improve particular elements of their national regulatory infrastructures. These missions are usually delivered to States at the early stages of establishing or initiating their regulatory infrastructures for safety. The advisory missions promote awareness of the need to establish a radiation safety infrastructure, as a prerequisite to the development or acquisition of any radiation technology by States.

Building competence in radiation safety is of a paramount importance to ensure the safe use of radiation sources. Standard IAEA training material, in areas such as authorization and inspection of radiation sources for newly recruited regulatory staff, advanced training material for senior regulators, and training material for the safe search for orphan sources have been developed and is available to Member States. Numerous training courses at national and regional levels, in various languages, have been designed and have been delivered for many years.

The IAEA Technical Cooperation programme is an important mechanism for providing international assistance. This programme enables scientific visits and practical training of regulatory staff of less

advanced regulatory bodies to Member States that have corresponding elements of their regulatory infrastructure developed at satisfactory levels.

The IAEA has developed tools to assist the effective implementation of regulatory activities in States. The Regulatory Authority Information System (RAIS) is the software developed to assist in managing regulatory activities. It enhances a consistent approach to regulatory control, in agreement with the IAEA Safety Standards. RAIS can be customized to address specific needs of States in accordance with their national circumstances.

The IAEA self-assessment methodology and tool (SAT) was developed with an objective to facilitate a regular self-assessment of national regulatory infrastructures for safety. Such a standardised self-assessment assists planned and progressive improvements of the effectiveness of States' infrastructures for safety.

A web-based collaborative platform, the Radiation Safety Information Management System (RASIMS), has been developed and implemented for establishing and maintaining the Radiation and Waste Safety Infrastructure Profiles of Member States participating in the IAEA Technical Cooperation support programme. Nominated persons in Member States can access their national profiles through this platform and maintain relevant national information regularly.

Technical support provided by the technical professional staff of the IAEA, or recruited international experts from relevant national organizations, is also available to States. Technical expertise includes training and assistance in installation and use of the different tools such as RAIS, SAT and RASIMS. Review, against IAEA Safety Standards, of radiation safety laws, regulations and regulatory guides may also be offered.

Software and equipment such as radiation detectors, RAIS servers, quality check instruments for inspectors are also being supplied to strengthen regulatory activities of national regulatory bodies of beneficiary States. Proper equipment and related knowledge are important for the regulatory body staff to discharge effectively their regulatory activities.

In accordance with an IAEA Board of Governors' resolution, the supply of radiation sources through the IAEA is conditional upon the existence of a functional national regulatory infrastructure for radiation safety consistent with requirements of the IAEA Safety Standards. This prerequisite is applied in order to ensure that there are adequate provisions in place, demonstrating that the acquired sources will be handled safely under proper regulatory control, leading to adequate radiation protection programmes covering relevant activities at source users' facilities.

6. CONCLUSIONS

- Peaceful uses of ionizing radiation in diverse applications provide many benefits but also present significant challenges to the management of radiation-related risks.
- An effective national regulatory infrastructure includes appropriate legislation and adequately empowered and resourced independent regulatory body that, through authorization and enforcement activities, ensures that required safety and radiation protection provisions are met when radiation sources are possessed, used, transported or stored.
- A graded and risk-informed approach to the regulation of radiation sources will concentrate the operational resources of regulatory bodies on high risk activities and potential problem areas.
- Alignment of national regulatory infrastructures with the IAEA Safety Standards helps States to develop effective regulatory infrastructures, contributing to a harmonized global safety system.

- The IAEA offers regulatory appraisals, advisory missions, training and tools for regulatory bodies and their technical services, to assist with the establishment of effective national regulatory infrastructures for radiation safety worldwide.

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