Report of the
Comptroller and Auditor General of India
on
Activities of
Atomic Energy Regulatory Board
for the year ended March 2012

Union Government

Department of Atomic Energy

Report No. 9 of 2012-13
(Performance Audit)

Contents

PREFACE

*This Report of the Comptroller and Auditor General of India for the year ended March 2012, containing the results of the performance audit of the '**Activities of Atomic Energy Regulatory Board'** has been prepared for submission to the President of India under Article 151 of the Constitution.*

Executive Summary

Why did we decide to examine this issue?

Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. At the same time, the risks of radiation that may arise from these applications to the people working in these fields, the general public and the environment are enormous and therefore, need to be assessed and controlled effectively. Since radiation risks can transcend national borders, international co-operation is essential to promote and enhance global safety by exchanging experiences as well as by improving capabilities for controlling hazards, preventing accidents, responding to emergencies and mitigating any harmful consequences.

In India, the Atomic Energy Regulatory Board (AERB) was set up in 1983 under the Atomic Energy Act 1962 to carry out certain regulatory and safety functions envisaged under the Atomic Energy Act.

The national and international regulatory scenario and criticality of the issue of radiation risks and safety prompted us to undertake a study of the structure and status of AERB and the effectiveness of its role as the nuclear regulator of India.

What were our audit objectives?

The objectives of this performance audit were to examine whether:

i. AERB has the necessary legal status, authority, independence and adequate mandate to fulfil the responsibilities expected of a nuclear regulator.

ii. AERB, keeping in view the international recommendations and local requirements, has been able to develop safety policies in nuclear, radiological and industrial safety areas as well as safety codes, guides and standards for siting, designing, constructing, commissioning, operating and decommissioning different types of nuclear and radiation facilities.

iii. AERB has been able to regulate nuclear and other radiation utilities through a system of consents effectively.

iv. AERB has ensured compliance of the prescribed regulatory requirements by nuclear power plants, other nuclear facilities and radiation facilities through a system of efficient regulatory inspection and enforcement.

v. AERB is monitoring and discharging its responsibilities relating to radiation exposure to occupational workers and members of the public and release of radioactive substances in the environment in an efficient and effective manner.

vi. emergency preparedness plans are in place for nuclear and radiation facilities and during transport of large radioactive sources, irradiated fuel and fissile material.

vii. adequate and effective regulatory systems exist in the country for decommissioning of nuclear and radiation facilities and creation of decommissioning reserves.

viii. the regulator has taken adequate measures for maintaining liaison with international bodies dealing with nuclear regulatory issues.

What did our performance audit reveal?

It revealed that:	
Regulatory framework for nuclear and radiation facilities	*Although international commitments, good practices and internal expert committees' recommendations were available, the legal status of AERB continued to be that of an authority subordinate to the Central Government, with powers delegated to it by the latter.* *AERB did not have the authority for framing or revising the rules relating to nuclear and radiation safety.* *The maximum amounts of fines were too low to serve as deterrents against offences/contraventions related to nuclear and radiation facilities which involve substantial risks. Further, AERB had no role in deciding the quantum of penalties and no powers with regard to imposition of the same.* *(Paragraph 2.3, 2.5, 2.8)*
Development of safety policy, standards, codes and guides	*AERB failed to prepare a nuclear and radiation safety policy for the country in spite of a specific mandate in its Constitution Order of 1983. The absence of such a policy at a macro-level can hamper micro-level planning of radiation safety in the country.* *AERB had not developed 27 safety documents despite recommendations of the Meckoni Committee in 1987 and the Raja Ramanna Committee in 1997 to expedite development of safety documents. There were significant delays in development of the safety documents test-checked in audit.* *(Paragraph 3.1, 3.2)*
Consents	*The consenting process and system for monitoring and renewal were found to be weak in respect of radiation facilities. This led to a substantial number of units of radiation facilities operating without valid licences. Non-availability of basic licence documents in files also indicated deficiencies in the maintenance of important consent files.* *Around 91 per cent of the medical X-ray facilities in the country had not been registered with AERB and, as such, were out of its regulatory control.* *The Supreme Court had directed (2001) the setting up of a Directorate of Radiation Safety (DRS) in each State for regulating the use of medical diagnostic X-rays. However, as on date (July 2012), out of 28 States and*

	seven Union territories, DRS had been set up only in Kerala and Mizoram. *AERB had not framed any rules to prescribe and fix the fees for recovery of the cost of services rendered for the regulatory and consenting process, as a result of which, it had to bear the cost of the consenting process.* *(Paragraph 4.2 & 4.3)*
Compliance and enforcement of regulatory requirements	*Frequencies of regulatory inspections had not been prescribed for radiation facilities. In the absence of any benchmarks laid down by AERB, we compared the performance of AERB in carrying out such inspections of radiation facilities with the periodicity (lowest frequency from range) suggested by IAEA-TECDOC[1] and observed that :* • *AERB had not conducted 85 per cent regulatory inspections for both industrial radiography and radiotherapy units, even though these were identified as having a high radiation hazard potential.* • *There was a shortfall of over 97 per cent in the inspection in the case of diagnostic radiology facilities every year which showed that AERB was not exercising effective regulatory oversight over units related to the health of the public.* *AERB had failed to enforce safety provisions and compliance with its own stipulations even when its attention was specifically drawn to deficiencies in the case of units in Kerala.* *(Paragraph 5.2, 5.6)*
Radiation protection	*The functions of monitoring of radiological exposure as well as the responsibility of radiological surveillance of Nuclear Power Plants (NPPs) lay with the operators of NPPs. Consequently, AERB had no direct role in conducting independent assessments and monitoring to ensure radiological protection of workers despite being the nuclear regulator of India.* *AERB did not have a detailed inventory of all radiation sources to ensure effective compliance of regulations for safe disposal of disused sources.* *There were no proper mechanisms in place to ensure/verify that :* • *radioactive waste had actually been disposed off safely after utilisation.* • *the sources for which consents for transport of radioactive material for safe disposal had been given, had really been disposed off or not.*

[1] IAEA Technical Documents

	• *the radioactive sources did not get out of regulatory control. The regulatory response mechanism to trace and discover lost and/or orphan radioactive sources in the country was not effective.* *(Paragraph 6.3, 6.4)*
Emergency preparedness for nuclear and radiation facilities	*On-site emergency preparedness plans were being put in place by the Plant Managements of NPPs and nuclear fuel cycle facilities were being tested by them. Though actual periodic exercises prescribed, based on various types of emergencies were conducted by them, AERB only reviewed the reports of these exercises and did not directly associate itself in these exercises, even as observers.* *Off-site emergency exercises carried out highlighted inadequate emergency preparedness. Further, AERB was not empowered to secure compliance of corrective measures suggested by it.* *No specific codes on emergency preparedness plans for radiation facilities such as industrial radiography, radiotherapy and gamma chambers etc had been brought out although the hazard potential of these were rated as high.* *(Paragraph 7.3, 7.4)*
Decommission-ing of nuclear and radiation facilities	*There was no legislative framework in India for decommissioning of nuclear power plants and AERB did not have any mandate except prescribing of codes, guides and safety manuals on decommissioning.* *Even after the lapse of 13 years from the issue of the Safety Manual relating to decommissioning by AERB, none of the NPPs in the country, including those operating for 30 years and those which had been shut down, had a decommissioning plan.* *Neither the Atomic Energy Act, 1962 nor the Rules framed thereunder had any provision for creation of decommissioning reserves by the utilities. Besides, AERB had no role to play in ensuring availability of adequate funds.* *(Paragraph 8.2, 8.3, 8.4)*
Maintaining liaisons with international bodies dealing with nuclear regulatory issues	*Although AERB maintained liaisons with international nuclear organisations, it was slow in adopting international benchmarks and good practices in the areas of nuclear and radiation operation.* *AERB had not yet availed of the opportunity of the peer review and appraisal services of IAEA to get its regulatory framework and its effectiveness reviewed by them.* *(Paragraph 9.2, 9.3)*

What do we recommend?

- *The Government may ensure that the nuclear regulator is empowered and independent. For this purpose, it should be created in law and should be able to exercise necessary authority in the setting of regulations, verification of compliance with the regulations and enforcement of the same in the cases of non-compliance.*
- *The maximum amount of fines leviable as per the Atomic Energy Act may be reviewed and AERB as the regulator, may be empowered to take recourse to a range of remedies, including penalties proportionate to the severity of the violations.*
- *A nuclear and radiation safety policy may be framed in a time-bound manner.*
- *The 27 codes and guides required for nuclear and radiation safety, out of which 11 were identified in 2001, may be developed expeditiously.*
- *The licensing process for radiation facilities may be strengthened to bring all the radiation facilities in the country under the regulatory control of AERB.*
- *The process of setting up Directorates of Radiation Safety in all the States as per the Supreme Court directive may be speeded up.*
- *AERB may frame rules for levying suitable fees for recovering the cost of the consenting process from licensees and the amounts of levies so made should be reviewed and revised from time to time.*
- *AERB may strengthen the processes of regulatory inspections of nuclear and radiation facilities by:*
    - *prescribing periodicities of regulatory inspections by conducting risk analyses and keeping international benchmarks for such inspections in view;*
    - *undertaking regulatory inspections in terms of the norms prescribed by IAEA for radiation facilities;*
    - *stipulating the timely issuance of regulatory inspection reports and securing compliance thereof.*
- *The regulatory role of AERB may be strengthened by bringing the monitoring agencies viz. Health Physics Units, Environmental Survey Laboratories etc. under the direct control of AERB.*
- *AERB may strengthen its system to ensure continuous updating of its inventory of all radiation sources till date to prevent radioactive sources from going out of regulatory control and ensure safe disposal of disused sources.*
- *AERB may be more closely associated with on-site emergency preparedness exercises.*

- *The Government may set up clear timelines within which NPPs, which are in operation and those which are in the course of being set up, should prepare and obtain approval for their decommissioning plans.*

- *The financial arrangements for decommissioning may be laid down more clearly and the decommissioning charges reviewed on a periodic basis with a view to ensuring their adequacy.*

- *AERB may avail of the peer review and appraisal services of IAEA to help make the nuclear regulatory infrastructure effective and sustainable.*

What was the response of the Department of Atomic Energy to our recommendations ?

The Department of Atomic Energy acknowledged the concerns highlighted by us. While there were no specific assurances giving time-lines within which our recommendations would be acted upon, we were assured that these were being looked into.

Chapter 1: Introduction

1.1 Background

Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. At the same time, the risks of radiation that may arise from these applications to the people working in these fields, the general public and the environment are enormous and therefore, need to be assessed and controlled effectively. Regulating safety is a national responsibility. Since radiation risks can transcend national borders, international co-operation is essential to promote and enhance global safety by exchanging experiences as well as by improving capabilities for controlling hazards, preventing accidents, responding to emergencies and mitigating any harmful consequences.

Every country has an obligation to fulfill its national and international undertakings and obligations. International safety standards evolved over a period of nearly five decades provide support to countries in meeting their obligations under the general principles of international law.

1.2 Formation of the Atomic Energy Regulatory Board

The Atomic Energy Act, 1962 (AE Act) provides for the development, control and use of atomic energy for the welfare of the people of India and for other peaceful purposes as well as for matters connected therewith.

For safety reviews of the commissioning and operating activities of the Tarapur Atomic Power Station (TAPS) and Unit-1 of the Rajasthan Atomic Power Station, the Department of Atomic Energy (DAE) set up a Department of Atomic Energy Safety Review Committee (DAE-SRC) in 1972. The Committee's scope was enlarged (1975) to deal with major safety issues related to all DAE installations. In 1979, the Secretary, DAE constituted another Committee to study the existing terms of reference of the SRC, its functions, the modalities of reporting by the units as well as the impediments faced by it. The report of this Committee, submitted in 1981, was titled 'Reorganisation of Regulatory and Safety Functions'. It recommended the creation of an Atomic Energy Regulatory Board (AERB), with powers to lay down safety standards and assist DAE in framing rules and regulations for enforcing the regulatory and safety requirements envisaged under the AE Act.

Accordingly, AERB was set up in 1983, under Section 27 of the AE Act, which allowed the Central Government to delegate any power conferred or any duty imposed on it by this Act

to any officer or authority subordinate to the Central or State Government. The mandate of AERB was to carry out certain regulatory and safety functions envisaged under Sections 16, 17 and 23 of the AE Act. The relevant provisions are in *Annex 1*.

1.3 Functions of the Atomic Energy Regulatory Board

The functions and responsibilities of AERB are outlined below:

- to develop safety policies in nuclear, radiological and industrial safety areas.
- to develop safety codes, guides and standards for siting, designing, constructing, commissioning, operating and decommissioning different types of nuclear and radiation facilities.
- to grant consents for siting, constructing, commissioning, operating and decommissioning, after appropriate safety reviews and assessment, for establishment of nuclear and radiation facilities.
- to ensure compliance of the regulatory requirements prescribed by it during all stages of consenting through a system of review and assessment, regulatory inspections and enforcement.
- to prescribe the acceptance limits of radiation exposure for occupational workers and members of the public and approve acceptable limits of environmental releases of radioactive substances.
- to review the emergency preparedness plans for nuclear and radiation facilities and for transport of large radioactive sources, irradiated fuel and fissile material.
- to review the training programmes, qualifications and licensing policies for personnel of nuclear and radiation facilities and prescribe the syllabi for training of personnel in safety aspects at all levels.
- to take such steps as necessary to keep the public informed on major issues of radiological safety significance.
- to promote research and development efforts in the areas of safety.
- to maintain liaison with statutory bodies in the country as well as abroad regarding safety matters.

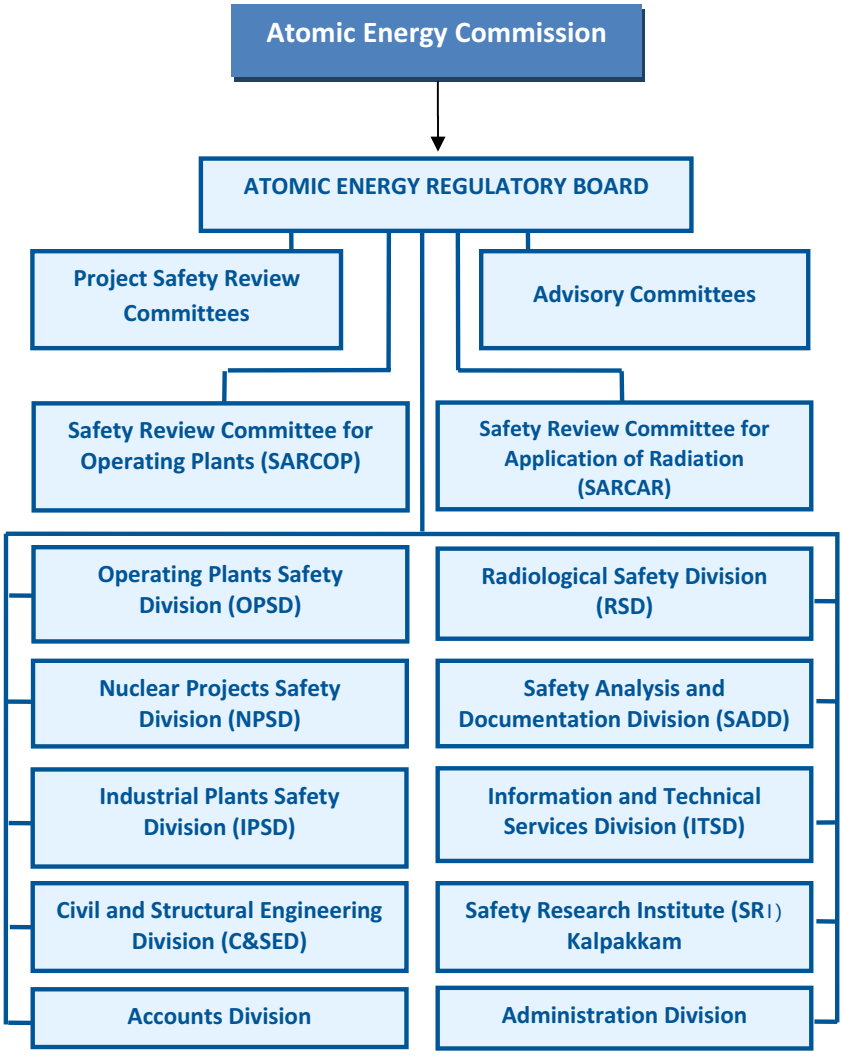
1.4 Constitution of the Board and its organisational structure

The Governing Board of AERB consists of a Chairman, four Members and a Secretary. The Chairman, Safety Review Committee for Operating Plants (SARCOP) of AERB, is also an ex-officio member of the Board. The Secretary of the Board is an employee of AERB. The Members of the Board are eminent serving or retired persons from the Government, academic institutions or national laboratories. The Chairman, AERB functions as the

executive head of the AERB Secretariat. The Board is responsible to the Atomic Energy Commission (AEC).

The Board is supported by two apex level committees viz. the Safety Review Committee for Operating Plants (SARCOP) and the Safety Review Committee for Application of Radiation (SARCAR) as well as by advisory committees, which are set up from time to time. SARCOP monitors and enforces safety regulations in nuclear power plants (NPPs) and other radiation facilities identified by the Central Government. SARCAR is the safety monitoring and advisory committee of AERB, which reviews safety aspects related to the application of radiation sources and equipment in industry, medicine, agriculture and research for non-DAE units as well as for transportation of radioactive materials in the public domain.

The organisational structure of AERB is as follows:



The staff of AERB mainly consists of technical and scientific experts in different areas of nuclear and radiation technology. Besides its own staff, AERB draws the required expertise from technical support organisations, academic institutions and retired experts.

1.5 Why we took up this performance audit

The national and international regulatory scenario and the criticality of the issue of radiation risks and safety prompted us to undertake a study of the structure and status of AERB as well as the effectiveness of its role as the nuclear regulator of India.

1.6 Audit objectives

The objectives of this performance audit were to examine:

i. whether AERB has the necessary legal status, authority, independence and adequate mandate to fulfil the responsibilities expected of a nuclear regulator.

ii. whether AERB, keeping in view the international recommendations and local requirements, has been able to develop safety policies in nuclear, radiological and industrial safety areas as well as safety codes, guides and standards for siting, designing, constructing, commissioning, operating and decommissioning different types of nuclear and radiation facilities.

iii. whether AERB has been able to regulate nuclear and other radiation utilities through a system of consents effectively.

iv. whether AERB has ensured compliance of the prescribed regulatory requirements by nuclear power plants, other nuclear facilities, and radiation facilities through a system of efficient regulatory inspection and enforcement.

v. whether AERB is monitoring and discharging its responsibilities relating to radiation exposure to occupational workers and members of the public and release of radioactive substances in the environment in an efficient and effective manner.

vi. whether emergency preparedness plans are in place for nuclear and radiation facilities and during transport of large radioactive sources, irradiated fuel and fissile material.

vii. whether adequate and effective regulatory systems exist in the country for decommissioning of nuclear and radiation facilities and creation of decommissioning reserves.

viii. whether the regulator has taken adequate measures for maintaining liaison with international bodies dealing with nuclear regulatory issues

1.7 Scope of audit

We reviewed the legal and regulatory framework of AERB and examined the prevailing management controls and administrative procedures connected with licensing, inspection and enforcement activities for the period 2005-06 to 2011-12. We reviewed the functioning of the emergency preparedness in selected NPPs[1] and districts[2].

Technical appropriateness of the analysis performed by AERB, technical capabilities of AERB staff and the appropriateness and effectiveness of the various procedures used were kept out of the scope of this performance audit**.** Nuclear and radiation-related activities of Bhabha Atomic Research Centre (BARC) installations, which were outside the purview of AERB, were also not covered in the performance audit.

1.8 Audit criteria

The criteria for this performance audit were derived from the following:

- The Atomic Energy Act, 1962
- Rules framed under the Atomic Energy Act, 1962
- AERB Constitution Order dated 15 November 1983
- IAEA Handbook, Safety Guide, Standards, Conventions, Manuals etc.
- AERB Safety Codes, Standards, Guides, Manuals, etc.

1.9 Audit methodology

We held an entry conference on 6 September 2010 with representatives of AERB, DAE, and other stakeholders to explain the audit objectives and approach. In principle, AERB agreed with the objectives and methodology adopted in this performance audit. The report was finalized, based on the responses received from AERB in February 2012 and the discussions held during the exit conference on 22 March 2012.

We scrutinised records relating to issue of consents, authorisations, licences, and regulatory inspections; minutes of various committee meetings; utility correspondence files; project reports, etc. during the period September to November 2010 and September to October 2011 at the offices of AERB, DAE, the Safety Research Institute, Kalpakkam and the Directorate of Radiation Safety, Thrissur.

[1] Tarapur Atomic Power Station (TAPS) – 1 & 2, Kaiga Generating Station – 1 & 2 and Madras Atomic Power Station

[2] Boisar, Karwar and Kancheepuram

We attempted a comparative study of the systems prevailing in AERB with the best practices available in other countries. For this purpose, we used literature available in the public domain, especially from the IAEA website and the websites of similar regulatory bodies in other countries.

We acknowledge the co-operation of AERB, DAE, Nuclear Power Corporation of India Ltd (NPCIL) and the Directorate of Radiation Safety (DRS), Thrissur.

Chapter 10: Conclusion

The spurt of economic growth in the developing world, particularly in Asia, requires substantial augmentation of energy facilities. A large part of the enhanced energy demand in Asia can be provided by nuclear energy. The expansion of nuclear power in the context of nuclear safety and security requires an appropriate regulatory oversight framework. Stakeholders, including the Government, need to be assured that nuclear energy and associated technologies can be used safely and that society can repose its trust in the regulator. The Chernobyl accident of 1986 provided the trigger of international consensus on the need to effectively separate nuclear power development from nuclear safety oversight functions.

The performance audit of AERB was undertaken in the context of the criticality of issues relating to radiation risks and the effectiveness of the nuclear regulator in the exercise of its role. A determining characteristic of an independent regulator is that it should be created by law and have clarity of jurisdiction, powers and responsibilities. The regulator must also have the authority to take decisions including decisions on enforcement action. In the present framework, the legal status of AERB is one of a subordinate office, exercising delegated functions of the Central Government and not that of a regulator. It is notable that in countries with significant nuclear establishment like Australia, Canada, France, United States, etc. the regulators have been provided complete independence through legislation. In India, inadequate priority has been accorded by the Government towards bringing about necessary legislative changes to create an independent nuclear regulator. Consequently, AERB has no rule-making powers and neither does it have powers of enforcement and levy of penalties in the context of nuclear safety oversight. The contravention of rules under the Act, on safety and regulatory matter is subject to levies of as little as ₹ 500 and even its enforcement is not with AERB but with DAE. Failure to have an autonomous and empowered regulator is fraught with grave risks as the recent report of the Fukushima Nuclear Accident Independent Investigation Commission has confirmed.

At the policy level, AERB has not yet prepared a radiation safety policy even after three decades of its existence. Standard setting is an essential part of the functions of a regulatory authority. While AERB has identified the development of 168 Standards, Codes & Guides, 141 have been developed till date. Delays in development of these safety documents have also been observed in audit.

Regulation of nuclear and radiation utilities, which have varying degrees of hazard potential, involves an elaborate set of permissions. These are in the form of licences, authorisations, registrations and approvals. While in the case of nuclear power plants, the issuing of licences

and their renewals adhere to the laid down procedures, there are various types of radiation facilities which are operating without licences, some with a high radiation potential. Registration of a range of facilities revealed major shortcomings. About 91 *per cent* of the 57,443 medical X-ray facilities operating in the country have no registration. While the Supreme Court had directed the setting up of Directorates of Radiation Safety in all States in 2001 for regulating the use of medical diagnostic X-rays, such directorates have only been set up in Kerala and Mizoram. No rules have been framed to fix fees for recovery of the cost of services rendered by AERB as part of the powers of according licences, authorisations and registrations, even though the Atomic Energy Act, 1962 provides for making such rules. To enforce compliance, periodic inspections by a regulator is essential. While the regime of regulatory inspection has been found to be in conformity with the norms in respect of nuclear power plants, there is a deficiency of over 85 *per cent* in the case of inspection of units relating to industrial radiography and radiotherapy and as much as 97 *per cent* in the inspection of diagnostic radiology facilities like X-rays.

The performance audit revealed that in the area of radiation protection, AERB needs to strengthen its conduct of independent surveillance of exposure control and exposure investigations. There is also an acute shortage of Radiological Safety Officers, in different types of radiation facilities, thereby undermining the safety aspects that need to be adhered to by the licencees.

AERB does not have a detailed inventory of all radiation sources till date to ensure effective compliance for safe disposal of disused sources. A proper mechanism is not in place to verify whether the waste radioactive sources have actually been disposed off safely after their useful lives. There is also no effective mechanism in place to prevent radioactive sources getting out of regulatory control as the events in the case of Mayapuri incident testify. The regulatory response mechanism to trace lost and/or orphan radioactive sources in the country has also found to be ineffective.

With regard to garnering the benefits of international cooperation in the field of nuclear safety, it has been observed that AERB has, in a numbers of instances, not adopted international benchmarks with regard to key areas of nuclear oversight in respect of radiation facilities in the Indian context. It has also not availed of the opportunity of external peer review by IAEA till date, either of a specific activity or of the performance of the body as a whole.

It is evident that AERB is on a very tenuous ground if it has to be judged in terms of benchmarks of what is expected of an independent regulator viz. (a) enactment of appropriate, comprehensive regulations, (b) verification of compliance of such regulations

and (c) enforcement of regulations by imposing appropriate corrective action. There is an urgent need for the Government to bolster the status of AERB if it is to qualify as an independent regulator in a sector which is likely to become increasingly important in meeting India's energy needs, sustaining the growth trajectory and attaining its medium and long term goals.

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Dated: 08 - 08 - 2012

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Dated: 08 - 08 - 2012

Chapter 2: Regulatory framework for nuclear and radiation facilities

Audit Objective: Whether AERB has the necessary legal status, authority, independence and adequate mandate to fulfill the responsibilities expected of a nuclear regulator

2.1 Introduction

The characteristic features of an independent regulator are that it should be created in law, rather than by a decree, legislation, or an executive order, which in turn should provide clarity on the jurisdiction, powers, duties and responsibilities of the regulator. In terms of legal powers, the regulatory body should have the authority to make final decisions on matters within its statutory domain. It should be able to set standards and make rules for the sector for which it has been provided legal authority. It should also be able to enforce its decisions, standards, codes and rules and for this, it should be able to take recourse to a range of remedies, including penalties, appropriate to the severity of violations. It should be able to compel production and provision of information as may be necessary and monitor the performance of the regulated entities.

In this Chapter, we examine whether AERB fulfils the characteristics of an independent regulator and has a clear legal authority and how it is placed in terms of the financial and manpower benchmarks laid down by the IAEA.

2.2 Legal status of Atomic Energy Regulatory Board

In India, the AE Act and the rules framed under it provide the main legislative and regulatory framework pertaining to atomic energy and radiation facilities in the country. As stated earlier, AERB was constituted in 1983 under Section 27 of the AE Act, 1962, which allows the Central Government to delegate any power conferred or any duty imposed on it by this Act to any officer or authority subordinate to the Central or State Government. Section 27 of the Act currently does not provide for constitution of any authority or Board and merely provides for delegation of powers to a subordinate authority. Therefore, the legal status of AERB can be seen to be more of a subordinate authority with powers delegated to it by the Central Government than of a statutory body with independent powers. AERB has thus not been created by any specific legislation.

International practice: International Atomic Energy Agency (IAEA) has recognised the paramount need for independence for regulatory bodies. Its Report of 2003 stresses on the need for regulatory bodies to be able to undertake the functions of developing and enacting

sound regulations, verifying compliance with such regulations and enforcing the established regulations by imposing appropriate measures.

The independent legal status of regulatory bodies has been recognised and a number of countries have conferred legal status to them through laws enacted by their legislatures. Instances of such cases are listed below:

Independent Regulatory Authorities - Cross-country comparisons

Australia	The Australian Radiation Protection and Nuclear Safety Act 1998 established a regime to regulate the operation of nuclear installations. The Australian Radiation Protection and Nuclear Safety Agency is entrusted to perform functions and exercise powers under the Act.
Canada	Canada's Nuclear Safety and Control Act has been in force since May 2000. The Act established the Canadian Nuclear Safety Commission. The Act is binding upon the Crown, both federal and provincial and upon the private sector.
France	The Nuclear Safety Authority, an independent administrative authority, was created by an Act in June 2006.
Pakistan	The Pakistan Government enacted an ordinance in 2001 to establish the Pakistan Nuclear Regulatory Authority for regulation of nuclear safety and radiation protection in Pakistan to the extent of civil liability for nuclear damage resulting from any nuclear incident.
United States	A Nuclear Regulatory Commission was established by the Energy Reorganisation Act of 1974.

In India, the status of AERB is diminished by the fact that it is not a legal entity and is merely a subordinate authority.

The weaknesses in regulatory structures arising out of lack of 'arms length' of regulators has been brought out vividly in the report of the Fukushima Nuclear Accident Independent Investigation Commission which has observed that "the TEPCO Fukushima Nuclear Power Plant accident was the result of collusion between the Government, the regulators and TEPCO and the lack of governance by the said parties. They effectively betrayed the nation's right to be safe from nuclear accidents. Therefore, we conclude that the accident was clearly 'manmade'. We believe that the root causes were the organisational and regulatory systems that supported faulty rationales for decisions and actions."

The failure to have an autonomous and empowered regulator is clearly fraught with grave risks.

2.3 Delays in conferring statutory status with enhanced legal powers to AERB

The actions taken by DAE over the years with regard to dealing with the necessity of conferring statutory status with enhanced legal powers to AERB by amending the AE Act, 1962 as recommended by a number of Committees is set out in the chronology of events detailed below:

Date	Event
February 1981	The Meckoni Committee[3] submits a Report titled 'Reorganisation of Regulatory and Safety Functions' and recommends the creation of AERB as a statutory body under the AE Act to give it a legal status.
November 1983	DAE constitutes AERB under powers conferred under Section 27 of the AE Act, 1962.
May 1987	The Meckoni Committee submits its recommendations and suggests measures relating to effectiveness of the regulatory functions of AERB.
November 1992	DAE introduces a Bill titled 'Atomic Energy (Amendment) Bill, 1992' in the Rajya Sabha for amendment of Section 26 (Cognisance of Offences) of the Atomic Energy Act.

[3] The Meckoni Comiittee report submitted in 1981 was titled 'Reorganisation of Regulatory and Safety Functions'. It recommended the creation of an Atomic Energy Regulatory Board, with powers to lay down safety standards and assist DAE in framing rules and regulations for enforcing the regulatory and safety requirements envisaged under the AE Act. The Committee also recommended that AERB should be a statutory body under the Act (if necessary, by suitable amendment of the Act) to give AERB a legal basis.

January 1997	The Raja Ramanna Committee constituted to review all aspects of regulatory process of nuclear installation.
August 1997	The Raja Ramanna Committee submits its recommendations. It recommends the amendment of the AE Act to increase its effectiveness in the regulation of nuclear safety and changes in the regulatory system so that it becomes more effective.
February 2000	The Cabinet directs DAE to bring up a comprehensive amendment for consideration of the Cabinet.
April 2001	DAE prepares a comprehensive review of the AE Act, 1962.
September 2001	The Atomic Energy Commission considers the proposed amendments including constitution of an Atomic Energy Regulatory Authority (AERA).
June 2002	The Cabinet Committee on Security (CCS) approves the proposal regarding amendment of the AE Act, 1962.
December 2003	DAE submits a draft Bill to the Ministry of Law and Justice for vetting.
July 2004	The Legislative Department, Ministry of Law and Justice advises that as a new Government had taken over, inter-ministerial consultations in the Government of India may be done afresh.
July 2005	DAE submits a draft note to the Prime Minister for approval for placing before the Cabinet.
July 2005	DAE directs the undertaking of a further assessment of the proposed draft amendments, taking into account the requirement of harmonising its provisions with that of weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005, and also implications of a Joint Statement with the US.
October 2005	DAE circulates a revised draft note to all Ministries and Departments concerned for obtaining their views afresh.
March 2006	DAE sends a revised Cabinet note incorporating the comments to the Legislative Department, Ministry of Law & Justice for vetting.
January 2007	Based on the advice of the Legislative Department, DAE again sends a revised note to the Cabinet and submits a revised draft bill to the Legislative Department for vetting.
June 2007	After carrying out the modifications, the draft Bill and Cabinet note are submitted to the Law Ministry for vetting.

August 2007	The Legislative Department vets the Draft Bill and the final note for the Cabinet is sent to the Cabinet Secretariat.
September 2007	The note to the Cabinet is withdrawn.
June 2010	In the wake of the Mayapuri incident,[4] DAE constitutes an Internal Committee to examine the amendment to the Atomic Energy Act, 1962, to suggest necessary modifications in the proposal to strengthen AERB.
December 2010	The Internal Committee submits its report, suggesting various amendments to the Atomic Energy Act, 1962.
September 2011	The Nuclear Safety Regulatory Authority Bill, 2011 (NSRA Bill, 2011) for constitution of a Nuclear Safety Regulatory Authority and other regulatory bodies is introduced in the Lok Sabha on 7 September 2011.

The above chronology of events highlights the delays and lack of adequate priority accorded by the Government of India in amending the AE Act, 1962 to increase its effectiveness in the regulation of nuclear safety by providing for an independent regulator under law. In spite of numerous attempts to bring out legislative changes, the fact remains that the AE Act, 1962 has not yet been amended (July 2012).

DAE stated (February 2012) that the process of improving the existing legal framework for introducing greater clarity in respect of separation of legal responsibilities concerning promotional and regulatory functions, had already been taken up and the Nuclear Safety Regulatory Authority bill had been tabled in Parliament to give enhanced legal status to the existing AERB.

DAE further stated (February 2012) that the Nuclear Safety Regulatory Authority (NSRA) Bill, 2011 introduced in the Lok Sabha envisaged consequential amendments to the AE Act, 1962 insofar as radiation safety was concerned, the provisions of which were related to Sections 16, 17, 23, 26 and 30 and that the Atomic Energy (Amendment) Bill, 2011 had since been drafted and circulated with the approval of the Prime Minister as Minister-in-charge, for the comments of the concerned Ministries. A proposal for introduction of the Atomic Energy (Amendment) Bill, 2011 in the Parliament would be submitted shortly for approval of the Cabinet. DAE also stated that delays in bringing out the Atomic Energy (Amendment) Bill, 2011 had occurred due to unforeseen developments and the intent was that such a Bill would be as comprehensive as possible.

[4] The Mayapuri incident occurred in April 2010, resulting in serious injuries, including the death of a person, due to unsafe and unauthorised disposal of radiation equipment by Delhi University.

The protracted delay in the process of amendment of the Act as brought out in the chronology of events earlier and DAE's replies confirm that adequate priority had not been accorded to the issue for over 30 years since the first recommendation made by the Meckoni Committee in this direction in 1981.

Although international commitments, good practices and internal expert committees' recommendations are available, the legal status of AERB continues to be that of an authority subordinate to the Central Government, with powers delegated to it by the latter.

2.4 Regulatory independence and the clarity of AERB's role

Article 8 of the Convention on Nuclear Safety of the IAEA, ratified by the Government of India on March 31, 2005, stipulates that each contracting party should take appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organisation concerned with the promotion or utilisation of nuclear energy. A regulatory body must be able to exercise its key regulatory functions (standard-setting, authorisation, inspection and enforcement) without pressure or constraint. We made an attempt to assess the status of AERB, based on the criteria laid down by IAEA for achieving effective independence. Our findings are discussed below:

Criteria laid down by IAEA	Present status in India	Audit Observations
1. Institutional separation of regulatory and non-regulatory functions	DAE is responsible for non-regulatory activities of power generation whereas AERB is responsible for regulatory functions of DAE activities. In the present set-up, AERB as well as DAE are responsible to the Atomic Energy Commission (AEC).	The fact that the Chairman, AEC and the Secretary, DAE are one and the same negates the very essence of institutional separation of regulatory and non-regulatory functions.
2. Fixed terms for regulatory officials and constraints on removal of regulatory officials on political grounds	The Chairman is to be appointed for a period of three years or until further orders, whichever is earlier, implying that he can be removed before completion of his term of three years. Currently, however there is no fixed term of office of the Chairman, AERB and	Internationally benchmarked practices have not been adopted.

	extensions are granted on a case to case basis. Three Chairmen worked for periods of three years each during 1990-1993, 1993-1996 and 1996-1999, two for a period of five years each during 2000-2005 and 2005-2010 and one for a period of seven years during 1983 to 1990.	
3. Separate budgetary and employment authority for the regulatory body	As per the Constitution Order of AERB issued in November 1983, DAE provides administrative support with regard to AERB's budget, parliamentary work and matters relating to establishment and accounts. AERB prepares and submits its budgetary requirement to DAE. DAE allocates the budget under separate account heads of AERB.	As against the best practice of the financing mechanism of the regulator being defined in the legal framework, AERB is dependent on DAE for budgetary and administrative support.
4. Reporting to an official or the organisation without conflicting responsibilities	As per the AERB Constitution Order 1983, the Chairman, AERB reports to the Chairman, AEC.	Chairman AERB reports to Chairman AEC. Chairman AEC is also the Secretary, DAE which is one of the bodies regulated by AERB, resulting in conflict of responsibilities and interest.

DAE stated (February 2012) that as per the Constitution Order, the Chairman, AERB had full powers of a head of department under the 'Delegation of Financial Powers Rules' and other relevant rules.

The above tabulation brings out that AERB has no effective independence as per the criteria laid down by IAEA. The Expert Committee headed by Shri Raja Ramanna in 1997 had recommended that the financial powers of Chairman, AERB should be enhanced fully to that of a Secretary of a Department in the Government of India and he should be given full powers to exercise control on the funds allocated under his budget head. However, the Chairman AERB continues to remain subordinate to Secretary DAE in this respect.

DAE further stated (February 2012) that in order to grant de jure autonomy to the regulatory body, a bill viz. Nuclear Safety Regulatory Authority Bill, 2011 had been introduced in the Parliament in September 2011.

AERB's independence is circumscribed by the following aspects: (i) there is no institutional separation of regulatory and non-regulatory functions; (ii) the tenure of the AERB Chairman is not fixed and he works in a capacity similar to any head of department in DAE; (iii) there is no separate budgetary authority; and (iv) AERB reports to an official/organisation whose activities are supposed to be regulated by it i.e. AEC.

2.5 Powers to make Rules

The existing Rules regulating various activities in the field of nuclear and radiation safety are:

- Atomic Energy (Working of the Mines, Minerals and Handling of Prescribed Substances) Rules, 1984,
- Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987
- Atomic Energy (Control of Irradiation of Food) Rules, 1996
- Atomic Energy (Factories) Rules, 1996.
- Atomic Energy (Radiation Protection) Rules, 2004

We, however, observed that none of the above Rules were framed by AERB. They were all framed by DAE.

DAE stated (February 2012) that as per Section 30 of the Atomic Energy Act, 1962, powers to make Rules for carrying out the purposes of the Act were given to the Central Government. However, AERB was always involved in the consultative process while framing/amending rules insofar as they related to issues connected with nuclear and radiation safety. The reply of DAE confirms that AERB had no authority to make Rules.

AERB does not have the authority for framing or revising the Rules relating to nuclear and radiation safety.

2.6 Control weaknesses in framing rules

AERB functions as a 'competent authority'[5] in respect of the Atomic Energy (Radiation Protection) Rules, 2004. It was noticed that while AERB was constituted in 1983 as the safety regulator, it was notified as a 'competent authority' only in December 1987. When the Atomic Energy (Radiation Protection) Rules were replaced in 2004, the Chairman, AERB was notified as the 'competent authority' in October 2006.

DAE has not been prompt in delegation of powers of the competent authority to AERB. As a consequence of the delay, accountability could not have been fixed in the event of any disaster due to absence of such legal authority during the intervening periods.

2.7 Provisions to enforce rules

A regulatory authority should be able to enforce its decisions, standards, codes and rules. Audit noticed instances where the rules were ambiguous.

Clause 30 of the Atomic Energy (Radiation Protection) Rules, 2004 (RPR 2004) empowers *any person,* duly authorised under Sub-section (4) of Section 17 of the AE Act to inspect premises, radiation installations and conveyances. There is a need to eliminate the existing ambiguity caused by the words '*any person'* and replace it with 'AERB' which is a competent authority to bring in more clarity to its powers under Clause 30 of the RPR 2004.

While accepting this observation, DAE stated (February 2012) that though the authority available to AERB as per Clause 30 under RPR 2004 for carrying out inspections was never questioned, greater clarity would be brought in along with other amendments in RPR 2004. It further assured that a new set of rules would be promulgated on enactment of the NSRA Act and the new rules would eventually replace the RPR 2004.

2.8 Penalty provisions

Section 30(3) of the AE Act provides that Rules made under this Act may provide that a contravention of the rules shall, save as otherwise expressly provided in this Act, be punishable with fine, which may extend to five hundred rupees. In this connection, the following are noteworthy:

- The penalty provisions are provided for under the AE Act, 1962, administered by DAE.

[5] Any official or authority appointed, approved or recognised by the Government of India for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

- AERB has no role in deciding the quantum of penalties.
- AERB has no powers with regard to imposition of penalties.
- The maximum amounts of fines are too low to serve as deterrents against offences/contraventions related to nuclear and radiation facilities which involve substantial risks.

Recommendations

1. The Government may ensure that the nuclear regulator is empowered and independent. For this purpose, it should be created in law and should be able to exercise necessary authority in the setting of regulations, verification of compliance with the regulations and enforcement of the same in cases of non-compliance.
2. The maximum amount of fines leviable as per the Atomic Energy Act may be reviewed and AERB as the regulator, may be empowered to take recourse to a range of remedies, including penalties proportionate to the severity of the violations.

Chapter 3: Development of safety policy, standards, codes and guides

Audit Objective: Whether AERB, keeping in view international recommendations and local requirements, has been able to develop safety policies in nuclear, radiological and industrial safety areas and safety codes, guides and standards for siting, designing, constructing, commissioning, operating and decommissioning different types of nuclear and radiation facilities

3.1 National Safety Policy

The IAEA Safety Standards stress the importance of establishing a national policy for safety by means of different instruments, statutes and laws. They specify that the regulatory body, as designated by the Government, has to be assigned with the implementation of the safety policy by means of a regulatory programme and a strategy set forth in its regulations or in the national standards.

As per the Constitution Order 1983, AERB was specifically entrusted with the function of developing safety policies in both radiation and industrial safety areas. It was expected to develop a radiation safety policy under this responsibility, along with next level safety documents in the form of codes, standards, guides and manuals.

While the radiation protection rules had been put in place, AERB had not prepared a radiation safety policy, even after nearly three decades of its existence.

DAE accepted (February 2012) the audit observation. It assured that AERB would initiate the process of consolidating the documents pertaining to its mission, objectives and principles brought out in various policy statements, codes and guides as a separate policy document.

AERB failed to prepare a nuclear and radiation safety policy for the country in spite of a specific mandate in its Constitution Order of 1983. The absence of such a policy at a macro-level can hamper micro-level planning of radiation safety in the country.

3.2 Safety standards, codes and guides

Codes and standards are meant to spell out in detail, the safety requirements to be complied with by consentees at all stages of activity of nuclear facilities, with a view to ensure the safety of the plants, operating personnel, the public and the environment.

IAEA General Safety Requirements stipulate that a regulatory body should establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety, upon which its regulatory judgments, decisions and actions are based.

AERB has been mandated to develop standards[6], safety codes[7], guides[8] and manuals[9] for siting, designing, constructing, commissioning, operating and decommissioning different types of nuclear and radiation facilities, in line with international recommendations and local requirements. Rule 16 under RPR 2004 provides that AERB (competent authority) may issue safety codes and safety standards, from time to time, prescribing the requirements for various nuclear and radiation installations. The licencees should ensure compliance with the same. In this context, we examined the status of development of codes and guides by AERB and our observations are given in the succeeding paragraphs.

3.2.1 Non-development of radiation safety codes, guides and standards

We observed that AERB, after 18 years of its existence, had brought out a Safety Guide in 2001, specifying a provisional list of safety documents which comprised codes, standards and guides to be prepared by it. AERB identified 148 codes, standards, and guides for development under various thematic areas. On a subsequent re-assessment, it deleted 25 safety documents and added another 45 safety documents in the provisional list, for development. We observed that out of 168 safety documents, 51 were issued before release of the Safety Guide in 2001 and 90 were issued during the period 2001 to 2012 as per the following table:

[6] Safety standards contain internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities.

[7] Safety codes are intended to establish objectives and to set minimum requirements to be fulfilled to provide adequate assurance for safety in nuclear and radiation facilities.

[8] Safety guides provide guidelines and make available the methods for implementing the specific requirements prescribed in line with the relevant Safety codes.

[9] Safety manuals are intended to elaborate specific aspects and may contain detailed technical information and/or procedures.

Table – 1
Codes, standards, guides developed as of February 2012

Thematic Area of Code development	Number of Safety Documents					
	Identified in 2001	Identified subsequently	Assessed subsequently as not required	Total codes identified for development	Developed as of February 2012	Not developed as of February 2012
Safety Codes/Standards for Nuclear Facilities	9	1	1	9	9	-
Safety Codes/Standards for Radiation Facilities	33	2	13	22	14	8
Safety Guides for Regulation of Nuclear & Radiation Facilities	8	3	-	11	11	-
Safety Guides for Nuclear Power Plants	68	11	5	74	66	8
Safety Guides for Nuclear Fuel Cycle Facilities other than Nuclear Power Plants	4	7	1	10	7	3
Safety Guides for Radiation Facilities	22	5	4	23	18	5
Safety Guides for Radioactive Waste Management	4	5	1	8	7	1
Safety Manual for Nuclear Power Plants	-	5	-	5	4	1
Safety Manual for Nuclear Fuel Cycle facilities	-	3	-	3	3	-
Safety Manual for Radiation Facilities	-	1	-	1	0	1
AERB Technical Document for Nuclear Power Plants	-	2	-	2	2	-
Total	**148**	**45**	**25**	**168**	**141**	**1**

The table indicates that AERB had developed 141 of the 168 safety documents that it was expected to develop. We observed that the Meckoni Committee in 1987 and the Raja Ramanna Committee in 1997 had stressed upon the need for hastening the process of development of codes and guides. As seen from the table, 27 safety documents relating to safety codes, standards and guides were still to be developed by AERB.

DAE stated (February 2012) that most of the documents that were being developed in AERB dealt with complex, high-end and evolving technology areas as well as related management and regulatory processes. AERB, as a matter of principle, ensured that the views of the relevant stakeholders, experts and the regulators were appropriately considered during the development of regulatory documents. While in most of the cases, the issues or comments were easily resolved, there had been some instances where resolution of contradictory views from the experts and stakeholders on critical issues had taken substantial time, requiring extensive consultations, analytical work and procedural changes in the relevant management and regulatory areas.

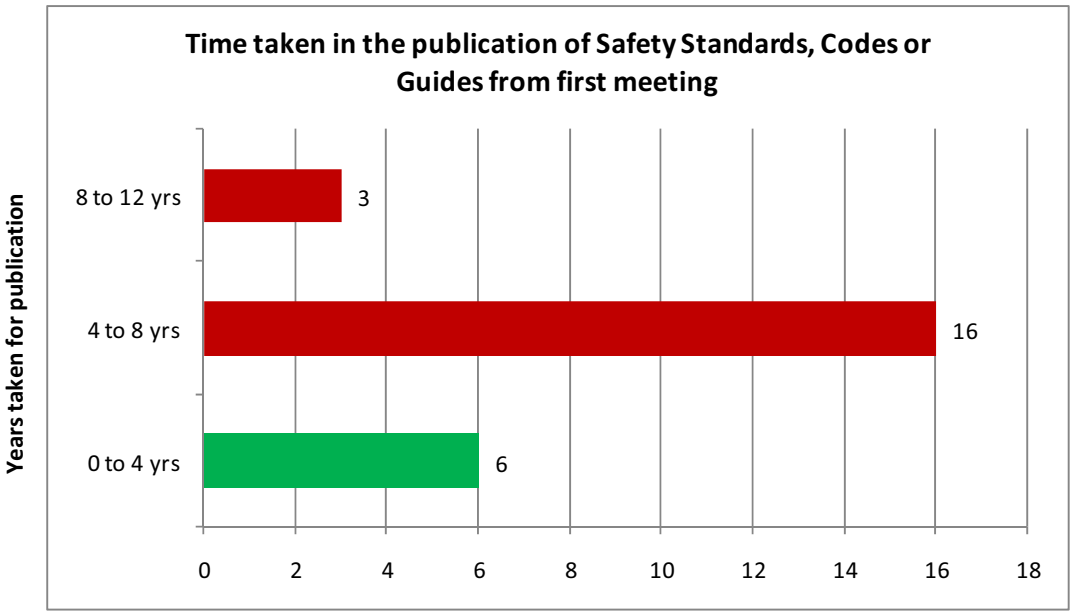
AERB had not brought out 27 required codes and guides relating to nuclear and radiation safety as of March 2012.

3.2.2 Delay in development of safety codes, standards and guides

We reviewed the timeframe within which the codes, standards and guides were developed by AERB in 25 cases. The time taken is depicted in Graph-1.

Graph – 1

Time taken in publication of Safety Standards, Codes or Guide from first meeting



***Cases where time taken to publish safety standards, codes or guides was more than the average period specified are indicated in red, while cases where the time taken was within the prescribed period are indicated in green.**

While the average period of development of the documents was stated to be three to four years, the above graph indicates that only six of the 25 cases were developed within that time frame. Three documents took between eight to 12 years to develop.

AERB stated (October 2010) that the delays were due to various factors such as non-availability of expertise, need for consensus among stakeholders, multiple technical support organisations involved, limited operating experience, feedback from experts, national and international developments etc. The reply of AERB regarding the average time of three to four years taken for development of safety documents needs to be viewed in light of the fact that out of the 25 cases reviewed by us, only six codes, standards and guides had been developed in four years' time.

The Raja Ramanna Committee had recommended (1997) that all codes and guides need not be prepared by AERB and that these could be prepared by other competent agencies and duly approved and adopted by AERB.

DAE stated (February 2012) that the process of document preparation, review and incorporation/disposition of stakeholder views were done through a multi-tier system of expert committees, comprising members drawn from various areas of expertise. Most of the AERB documents were performance based and dealt with very specialised and advanced technology areas which had limited number of individual experts in the related areas.

The fact remains that AERB, even after 15 years of the recommendations of the Raja Ramanna Committee, had not been able to identify external agencies for development of codes and guides.

Recommendations

3. A nuclear and radiation safety policy may be framed in a time-bound manner.

4. The 27 codes and guides required for nuclear and radiation safety, out of which 11 were identified in 2001, may be developed expeditiously.

Chapter 4: Consents

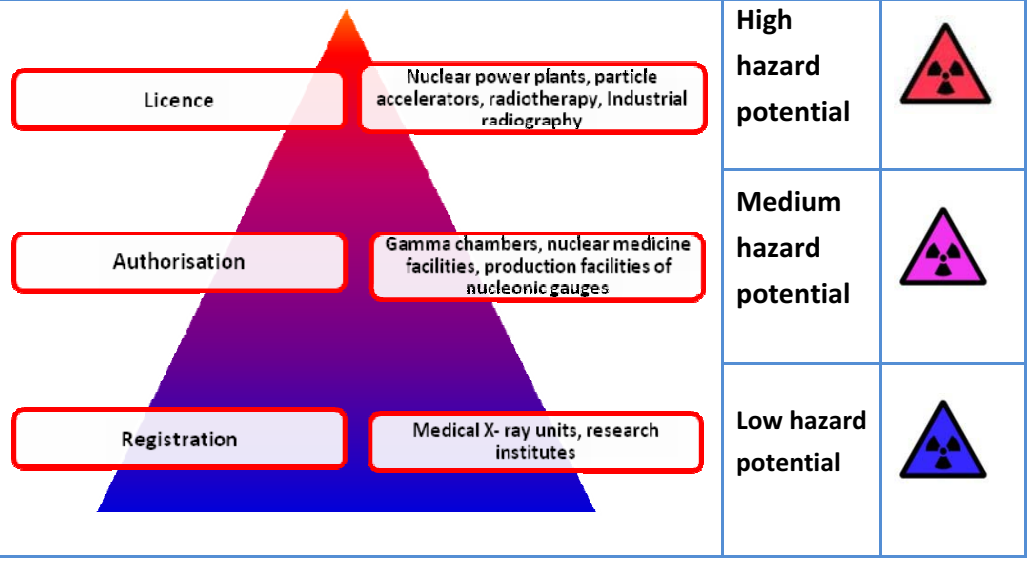
Audit Objective: Whether AERB has been able to effectively regulate nuclear and other radiation utilities through a system of consents

4.1 Introduction

The Code for 'Regulation of Nuclear and Radiation Facilities' of AERB defines 'consent' as a written permission issued to an applicant by the regulatory body to perform specified activities related to nuclear and radiation facilities. The objective of regulatory consent is to secure an effective assurance that the safety of the workers employed and the public at large, of the environment and of plant and equipment is not at risk and that all activities are being carried out in accordance with the prescribed processes and systems, ensuring safety of all.

As per Rule 3 (3) of the RPR 2004, the facilities deploying radiation and/or radioactive sources need consents in the form of licences, authorisations and registrations from the competent authority. These different forms of consents are assigned depending upon the radiation hazard potential (in decreasing order) involved. AERB's regulatory activities of consent have been reviewed vis a vis new projects, operating units, radiation facilities. The various types of facilities and their potential hazards are graded in Chart-1.

Chart 1 : Relation between types of consent, facilities and their hazard potential



The regulator has the responsibility of bringing not only all persons, organisations, equipment or facilities concerned with the atomic energy sector under its regulatory ambit by appropriate consent but also of ensuring that all processes and systems prescribed for securing safety are being followed by the consentees on a continuous and regular basis by adequate and effective regulatory supervision and monitoring.

4.2 Regulatory consent

Regulatory consents are granted in the form of licences, authorisations, registrations, approvals and type approvals[10] depending upon the hazard potential associated with different radiation sources. Licences are applicable to sources with highest radiation hazards and registrations to the lowest.

AERB, being the competent authority, is mandated to grant regulatory consents under RPR 2004. We reviewed the consenting process in AERB for the period 2005-06 to 2011-12 to understand the efficiency and adequacy of the consenting processes. Our observations are discussed in the succeeding paragraphs.

4.2.1 Consents

As per RPR 2004, consents are necessary for the following activities:

- Siting, designing, constructing, commissioning and decommissioning of a radiation installation;
- Procurement of sealed sources, radiation generating equipment and equipment containing radioactive sources, for the purposes of manufacture and supply;
- Package designing for transport of radioactive material;
- Shipment approval for radioactive consignments;
- Procurement of such other source or adoption of such practice as may be notified by the competent authority, from time to time.

The Nuclear Projects Safety Division (NPSD) of AERB processes applications for consents for siting, constructing and commissioning of nuclear projects and carries out required safety reviews and assessments as per the established process for issuance of consents. NPSD had issued 87 consents for siting, designing, constructing and commissioning of nuclear power plants and research reactors. The Radiation Safety Division

[10] Approvals issued by the competent authority, based on evaluation of devices to ensure that they conform to safety standards.

(RSD)[11] had issued 23,440 consents for various facilities under its purview during the period 2005-06 to 2011-12. A detailed break-up of the consents issued by AERB during 2005-06 to 2011-12 is given in Table - 2.

Table – 2
Consents issued by AERB during 2005-12

Year	Consents issued by NPSD	Number of consents issued by RSD for				
		Import of equipment	Number of model types approved	Radiation application	Procurement of radioactive sources	
					Local	Imported
2005-06	9	0	167	0	1331	948
2006-07	19	0	202	0	1304	1047
2007-08	7	68	150	19	1349	978
2008-09	5	64	65	17	2701	1039
2009-10	19	25	97	20	2676	1222
2010-11	**21**	25	102	18	2205	1435
2011-12	**7**	27	127	19	2643	1350
Total	**87**	**209**	**910**	**93**	**14209**	**8019**
		Total number of consents issued by RSD = 23440				

We examined the processes prescribed in issuing consents in the case of nuclear power plants and radiation facilities by AERB and observed that the prescribed process is being followed properly. However, there have been some delays in the cases of siting consents of three nuclear power plants.

DAE stated (February 2012) that siting reviews involved several complex issues. They required investigation of many site-specific issues. During the course of the reviews, certain site-specific investigations were required to be taken up. The pace of the reviews was also governed by the quality of data collected and investigated by various agencies such as National Geophysics Research institute, the Geological Survey of India, the Atomic Mineral Directorate, the National Environment Engineering Research Institute and the National Institute of Oceanography.

[11] The primary responsibilities of RSD were licensing, surveillance and safety review of the Board of Radiation and Isotope Technology facilities and non-DAE radiation installations including accelerators and irradiators; implementation of Atomic Energy (Radiation Protection Rules), 2004 and enforcement of Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987 in non-DAE installations; ensuring safety in transportation of radioactive material in public domain and serving as a Secretariat for SARCAR (Safety Review Committee for Application of Radiation).

The fact of due process being followed is noted. Considering the fact that the lead time had been fixed as nine months, we are of the opinion that AERB should make further efforts to ensure that delays are eliminated or minimised in giving siting consents to avoid time and cost overruns in the construction of nuclear power plants.

4.2.2 Licence

Licences are permissions granted by AERB which are related to the operations of nuclear fuel cycle facilities and certain categories of radiation facilities. RPR 2004 stipulates that no person shall establish or decommission a radiation-generating installation without a licence. A licence can be issued for sources and practices associated with the operation of the following facilities or operations:

Licence
 Radiation hazard potential: High. Description of radiation-generating facilities: ➢ Nuclear fuel cycle facilities ➢ Land-based high intensity gamma irradiators other than gamma irradiation chambers; ➢ Particle accelerators; ➢ Telegamma and accelerators used in radiotherapy ➢ Industrial radiography

As per RPR 2004, AERB is required to issue a licence within 180 days of the receipt of an application, subject to the condition that all requirements for issuance of the licence are fulfilled. The licence so issued is valid for five years from the date of issue. Our observations on the issue of licences for each of the facilities are given below:

4.2.2.1 Nuclear fuel cycle facilities[12]

All documents related to safety review during the project phase are handed over by the Nuclear Projects Safety Division (NPSD)[13] after the commissioning phase to

[12] Nuclear fuel cycle facilities mean all operations associated with the production of nuclear energy, including mining, milling, processing of uranium or thorium; enrichment of uranium; manufacture of nuclear fuel; operation of reactors; reprocessing of nuclear fuel; decommissioning; radioactive waste management and any research or development activity related to any of the foregoing.

[13] The primary responsibilities of NPSD were safety review of nuclear projects, regulatory inspections and enforcement in projects under construction, issue of authorisations at various stages of projects as per established procedures and protocols and review of physical protection aspects in projects.

the Operating Plant Safety Division (OPSD)[14] for safety assessment during the operating phase. Under the existing legal framework, AERB issues a licence for operation of nuclear power plants for a period of five years, which is renewable by a further five years after AERB is satisfied that the nuclear plant continues to be capable of safe operation and will not pose undue risks to the plant, personnel, the public and the environment. AERB also issues licences for operation of fuel cycle facilities of DAE units for a period of five years in terms of Section 6 of the Factories Act, 1948 and Rule 4 of the Atomic Energy (Factories) Rules 1996. An assessment of plant status and performance of in-built safety systems is carried out by AERB every five years. We observed that AERB had issued and renewed 139 licences for operating plants and fuel cycle facilities under nuclear safety and 35 such licences for industrial safety under the Factories Act during the period 2005-06 to 2011-12 as detailed below.

Table - 3
Issue and renewal of licences by AERB

Year	By Operating Plants Safety Division	By Industrial Plant Safety Division	Under Factories Act, 1948
2005-06	6	6	6
2006-07	3	9	4
2007-08	8	14	4
2008-09	4	6	7
2009-10	51	15	1
2010-11	1	7	6
2011-12	3	6	7
Total	**7676**	**63**	**35**

We reviewed the performance of AERB with regard to the issue and renewal of licences and observed that there were no major deviations from the laid-down procedures, except that some units did not submit their applications to AERB within the prescribed time limit of at least 90 days before the expiry of the existing licence.

[14] The primary responsibilities of OPSD were safety reviews and safety surveillances, including health physics aspects and emergency preparedness of operating NPPs and research reactors; regulatory inspections and enforcement in respect of all operating NPPs and research reactors; periodic safety reviews and renewals of authorisation; licensing of operating personnel and management staff; review of physical protection aspects in operating plants; enforcement of Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987; co-ordination with IAEA for International Nuclear Event Scale (INES) based reporting of events and for the Incident Reporting System (IRS) operated by IAEA/ Nuclear Energy Agency and Secretariat of SARCOP.

We observed delays ranging from 10 to 129 days in submission of applications for renewal of licences in the case of 12 units.

DAE explained (February 2012) that even if a licence had expired, the facility continued to be under AERB's continuous regulatory surveillance.

4.2.2.2 Radiation facilities

As per Rule 3 (3) of RPR 2004, the competent authority is required to issue licences to users of radiation sources which would be valid for a period of five years from the dates of issue of such licences. The operation of various radiation facilities was reviewed by Audit. The status of issue of licences as of December 2011 is brought out in Table - 4.

Table - 4
Details and status of functioning radiation facilities - Licencing

Type of Units	Radiation Hazard Potential	No. of facilities	Units operating with licence and comments
Gamma Irradiators		17	All units were operating with valid licences.
Medical Cyclotrons		12	All units were operating with valid licences.
Research Accelerators		12	Out of 12, only one unit was operating with a valid licence.
Industrial Radiography		436	Out of 436, only 110 units were operating with valid licences. 109 files were sought for by Audit. We observed that licence documents in respect of 56 units were not available in the files. The remaining 53 units had not renewed their licences, which were due for renewal during the period between 2005 to 2006. Thus, apart from 326 units operating without any licence, there was evidence of inadequate monitoring and review within AERB with regard to renewal of licences.
Radiotherapy		310	Out of 310, 294 units were operating with valid licences. AERB furnished only 59 out of 294 files related to the units requisitioned in audit. Of these 59 units, 16 had not renewed their licences even though these renewals were due during the years 2005 and 2006.
Computed Tomography (CT)		510	Out of 510 units, only 224 were operating with valid licences.
Interventional Radiological X-ray (Cath lab)		217	Out of 217 units, 194 were operating with valid licences.

From the above table, it is evident that the licencing process for radiation facilities was adequate only in respect of Gamma irradiators and medical cyclotrons. In all other types of units, the licensing and renewal process was unsatisfactory, including units relating to research accelerators, industrial radiography and radiotherapy, all of which were categorised as having 'high' radiation potential hazards. Further, the non-availability of basic licence documents in files and the failure of AERB to monitor the renewal of licences indicated deficiencies in the maintenance of important files relating to licences. As a result, a substantial number of units of radiation installations with high radiation hazard potential, were operating without valid licences.

DAE stated (February 2012) that it began the process of issue of formal licences only in 2006. It further stated that although formal documents were not being issued as licences, various regulatory clearances (in a graded approach) were being issued to the user institutions at various stages and that ensured that user institutions had all pre-requisites prior to commencement of commissioning of the facilities. It added that with the significant increase in its manpower, it expected to complete the backlog of issue of licences by February 2012.

The reply is to be viewed in light of the fact that the RPR 2004 envisaged that AERB would issue licences/ authorisations to users of radiation sources. AERB was, however, slow in bringing all the radiation users in the country under its regulatory control for the last eight years. This indicated lack of sufficient manpower and laxity on the part of AERB in institutionalising the processes and enforcing regulatory control on radiation users.

The consenting process and system for monitoring and renewal are weak in respect of radiation facilities. This has led to a substantial number of units of radiation facilities operating without valid licences. Non-availability of basic licence documents in files also indicates deficiencies in the maintenance of important consent files.

4.2.3 Authorisation

An authorisation is a type of consent granted by AERB for activities relating to the use of radioactive material and radiation-generating equipment. As per RPR 2004, an authorisation is necessary for sources and practices associated with the operation of the following facilities:

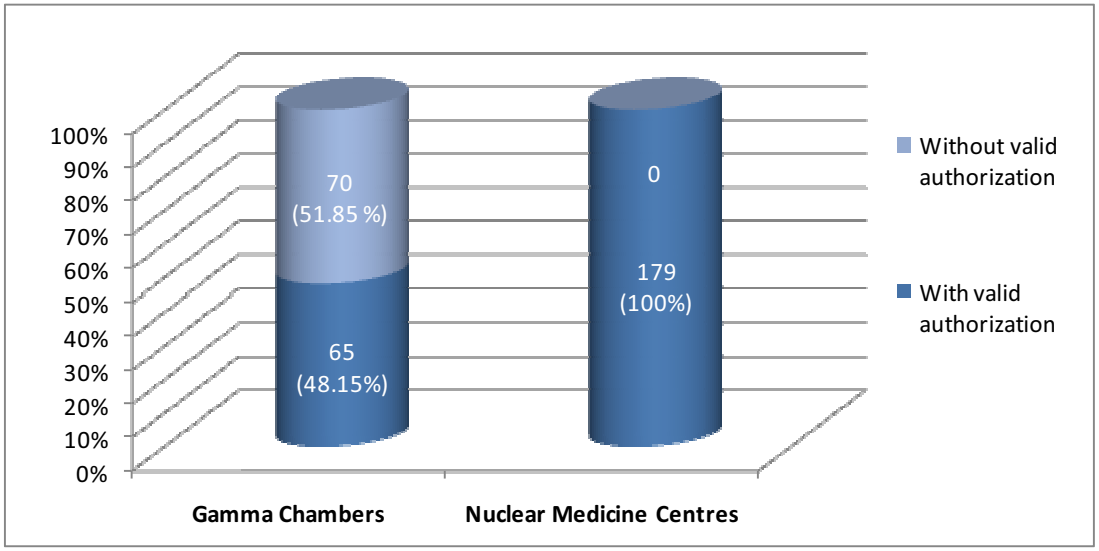
Authorisation
 Radiation hazard potential: Medium

Description of radiation-generating facilities:

- Deep X-ray units, superficial and contact therapy X-ray units
- Gamma irradiation chambers
- Nuclear medicine facilities
- Facilities engaged in the commercial production of nucleonic gauges, consumer products containing radioactive material etc

We observed some instances of radiation facilities functioning without valid authorisations. The status of radiation facilities functioning with and without authorisations is given in Graph-2.

Graph – 2
Units operating with / without authorisation



In the case of Gamma chambers, Audit examined 30 out of the 65 units which had received authorisation. We observed that authorisation documents in respect of 12 units were not available in the relevant files, while the remaining 18 units had not renewed their authorisations, indicating that there was no system in place for monitoring the expiry of authorisations and their renewals. The renewals of these 18 units were due for periods ranging from 1988 to 2009. The problem of protracted delays in renewal of authorisations, for periods as long as 24 years, needs to be urgently addressed.

AERB stated (October 2010) that a circular, along with an application form of authorisation in the revised form had been issued during July-August 2010 to the concerned institutes to send their applications.

The fact, however, remains that even after issue of the circular by AERB in August 2010, there was only a slight improvement in the issue of authorisations and 70 out of 135 Gamma chamber units, continued to function without valid authorisations (December 2011). A regulatory body has the responsibility of verifying compliance with safety regulations. Failure to renew authorisations in a timely manner indicates that there was no system in place for monitoring the expiry of authorisations and their renewals. The non-renewals of authorisations of units could, therefore, result in non-compliance with safety regulations as the units were no longer under the regulatory ambit.

4.2.4 Registration

AERB grants registrations for equipment related to research and medical facilities, whose radiation hazard potential is low. As per RPR 2004, a registration is necessary for sources and practices associated with the operation of the following facilities:

Registration

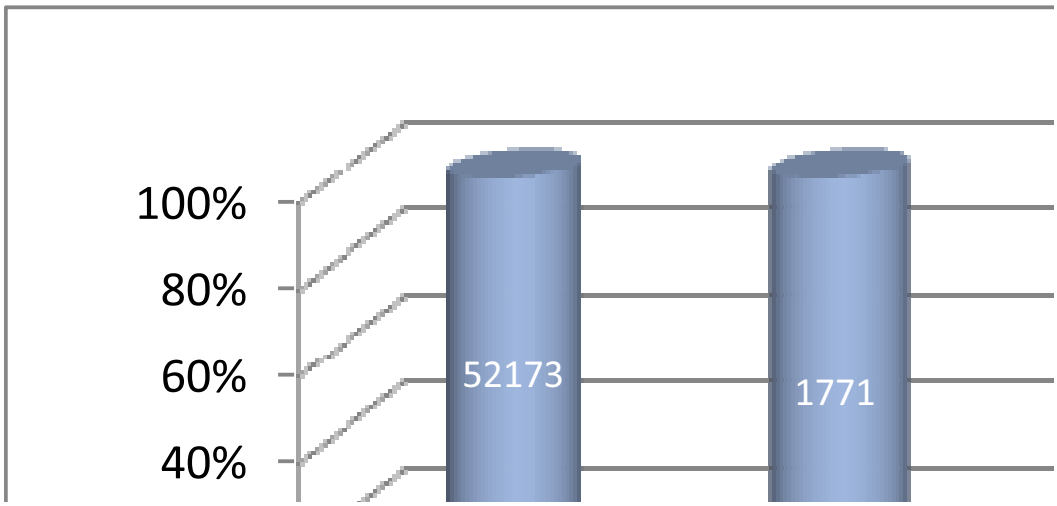
Radiation hazard potential: Low

Description of radiation-generating equipment

- Medical diagnostic X-ray equipment including therapy simulator
- Analytical X-ray equipment used for research
- Nucleonic gauges
- Radioimmunoassay laboratories
- Radioactive sources in tracer studies
- Biomedical research using radioactive material

The position with regard to registration of these facilities was unsatisfactory as detailed in Graph-3.

Graph – 3
Position of registration of units



The above chart shows that 52,173 medical X-ray units, 1771 nucleonic gauge units, 231 radioimmunoassay (RIA) units and 180 research institutions were functioning without valid registrations. We examined the status of medical X-ray units functioning without valid registrations and our observations are discussed below:

4.2.4.1 Medical X-ray units

Ionising radiation, such as medical X-rays, is used in medicine as an essential tool for protecting and improving human health. Over 90 *per cent* of the workload in diagnostic radiology in many countries consists of general radiography, which is a major contributor to the collective population dose[15]. It is, therefore, essential from the point of view of radiological safety, to exercise strict regulatory control over the use of such beneficial applications of ionising radiation.

Recognising the challenges in regulation of medical X-ray units in the country, AERB set up a specialist committee in 1985, to prepare a comprehensive report on the implementation of radiological safety requirements in respect of medical X-ray equipment and installations. Based on the report of this committee, AERB decided (1986) that certain regulatory controls were necessary to ensure safety in the design, manufacture, installation and use of medical X-ray equipment. AERB released (1986) codes intended to govern

[15] Collective population dose is a measure of the total amount of radiation exposure to everyone affected by an activity.

radiation safety in design, installation and operation of X-ray generating equipment for medical diagnostic purposes, which were revised in 2001. The Supreme Court had directed (2001) the setting up of a Directorate of Radiation Safety (DRS) in each State for regulating the use of medical diagnostic X-rays. We observed that DRS had been set up only in Kerala and Mizoram.

We examined the efficiency of registration of medical X-ray units in the country by AERB and the related directions of the Supreme Court and observed the following:

- As of February 2012, there were 57,443[16] medical X-ray facilities operating in the country. Of these, only 5,270 units had been registered and were under the regulatory control of AERB. The balance 52,173 units, constituting 90.82 *per cent* of the total units were functioning without AERB registrations and were, therefore, out of their regulatory control.

With regard to compliance with the Supreme Court directives, it was observed that out of 28 States and seven Union territories, DRS have been set up only in Kerala and Mizoram.

- Kerala had established (1998) a DRS, the set-up of which was delegated with powers to register all radiation installations and equipment in the State. However, this power was withdrawn (1999) and the duties of the DRS were restricted to carrying out inspections of medical diagnostic X-ray installations in the State.

While accepting that not all the units were under its regulatory control, AERB stated (February 2012) that there were challenges on account of the large number of diagnostic X-ray units spread across the country and the accelerated growth in their number. It further stated that it was in the process of establishing an effective regulatory set-up for X-ray units, with the help of State Governments, by forming DRS and devising an improved regulatory model for effective regulatory control of such a large number of X-ray units, through an expert group.

The fact remains that a large number of medical X-ray units were out of regulatory control. This significantly increased the risk of health problems for the workers and the public in the vicinity of these facilities.

[16] As reported by AERB to Audit in February 2012.

Around 91 *per cent* of the medical X-ray facilities in the country have not been registered with AERB and are, therefore, are out of its regulatory control.

4.3 Cost of consenting process

According to Section 30 of the Act, the Central Government had been empowered to make rules to levy fees for issue of licences. The Ministry of Finance, vide an OM dated 24 September 2004, had issued instructions to levy or revise the fees towards the recovery of cost of services rendered for the consenting process. AERB, in the capacity of being the competent authority under RPR 2004 had been authorised to prescribe fees.

It was seen that AERB had not framed any rules to prescribe and fix the fees for recovery of the cost of services rendered for the regulatory and consenting process, as a result of which, it had to bear the cost of the consenting process.

While accepting that fees were not being levied, AERB stated (February 2011) that it was fully funded by the Central Government in the discharge of its regulatory functions.

Recommendations

5. The licensing process for radiation facilities may be strengthened to bring all the radiation facilities in the country under the regulatory control of AERB.
6. Proper maintenance of basic licence documents in respect of radiation facilities may be ensured.
7. The process of setting up Directorates of Radiation Safety in all the States as per the Supreme Court directive may be speeded up.
8. AERB may frame rules for levying suitable fees for recovering the cost of the consenting process from licensees and the amounts of levies so made should be reviewed and revised from time to time.

Chapter 5: Compliance and enforcement of regulatory requirements

Audit Objective: Whether AERB has been able to ensure compliance of the prescribed regulatory requirements by nuclear power plants, other nuclear facilities and radiation facilities through a system of efficient regulatory inspections and enforcement

5.1 Regulatory inspections and prescribed periodicity

According to IAEA Standards, each Government should expressly assign the prime responsibility for safety to an entity and make it responsible for compliance with regulatory requirements. The standards also provide that the regulatory body should carry out inspections of facilities and activities to verify that the authorised parties are in compliance with the regulatory requirements and the conditions specified in the authorisations. Inspections of facilities and activities are to include both announced and unannounced visits.

As per the AERB Safety Code on regulation of nuclear and radiation facilities, the objective of regulatory inspections is to ensure that:

- the operating personnel satisfy prescribed qualifications and are certified, wherever applicable;
- the quality and performance of structures, systems and components are maintained as required for safe operations;
- all prescribed surveillance procedures, codes, standards and rules are complied with by the consentees;
- facilities are operated as per approved technical specifications and as per the conditions stipulated in the consents; and
- deficiencies as noted in the earlier inspections have been rectified.

A safety guide titled '*Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities'* brought out by AERB in September 2002 lays down the procedure for conducting regulatory inspections (RIs) and the enforcement actions to be taken as a follow-up of the inspections.

The inspections are to be carried out as necessary during all stages of the consenting process.

Periodicity: As per the AERB safety manual for RIs and enforcement in NPPs and research reactors, RIs for NPPs under construction as well as operating units should be carried out in the following frequencies:

- NPPs under construction: once in three months (depending on the stage of construction)
- Operating NPPs: once in six months.
- Research reactors: once in six months, but the frequency could be reduced depending upon the design features.

AERB may increase the frequency of these inspections at any time for a particular unit or group of units based on the safety reviews.

In the case of radiation facilities, we observed that AERB had not fixed any frequency for RIs.

5.2 Shortfall in regulatory inspection of radiation facilities

While the process of RIs in respect of nuclear fuel cycle facilities including NPP was being followed as prescribed by AERB, there were significant shortfalls in RIs in the case of radiation facilities.

It was observed that no frequencies of RIs had been prescribed for radiation facilities. In the absence of any benchmark laid down by AERB, we compared the performance of AERB in carrying out RIs of radiation facilities with the periodicity (lowest frequency from the range of frequencies) suggested by IAEA-TECDOC[17]. The suggested inspection frequencies as per the IAEA-TECDOC are given at *Annex 2.* Based on our audit, we observed that there were serious deficiencies and shortfalls in RI of radiation facilities as detailed below:

5.2.1 Industrial radiography and radiotherapy facilities

We reviewed the RI process of the major categories of radiation facilities i.e. industrial radiography and radiotherapy, where annual RIs had been suggested by the IAEA-TECDOC. In the case of both industrial radiography and radiotherapy units, the radiation hazard potential had been rated as 'High'. Year-wise details of RIs of industrial radiography and radiotherapy units for the period from 2005-06 to 2011-12 and the trend of RIs conducted during the period are given in Table - 5.

[17] IAEA technical documents.

Table - 5
Regulatory inspections of Industrial radiography and radiotherapy facilities (2005-06 to 2011-12)

Year	Industrial Radiography			Radiotherapy		
	Total No. of units	No. of units whose RIs conducted	Percentage of RIs not conducted	Total No. of units	No. of units whose RIs conducted	Percentage of RIs not conducted
2005-06	461	126	72.67	218	23	89.45
2006-07	466	74	84.12	231	24	89.61
2007-08	486	42	91.36	230	07	96.96
2008-09	505	39	92.28	249	10	95.98
2009-10	568	57	89.96	266	11	95.86
2010-11	436	78	82.11	306	46	84.97
2011-12	463	61	86.83	317	141	55.52
Total	**3385**	**477**	**85.91**	**1817**	**262**	**85.58**

As seen from the table, the shortfall in RIs was over 85 *per cent* for both industrial radiography and radiotherapy during the seven-year period 2005-06 to 2011-12.

DAE stated (February 2012) that IAEA had not made any recommendations regarding the frequency and scope of RIs to be conducted in respect of radiation facilities. It further stated that different countries had adopted different approaches in carrying out regulatory control of radiation facilities in their countries, including inspections. AERB had steadily improved the RIs carried out. The shortfall in the number of RIs was due to rapid growth in the number of radiation facilities and inadequate infrastructure. In spite of this, AERB continued to monitor these facilities through the safety status reports mechanism. Only sample checks of radiation facilities could be carried out. With augmented manpower, AERB was giving priority towards completion of RIs of these facilities.

As stated earlier, the criteria for audit analysis were drawn from the benchmarks laid down in the IAEA-TECDOC which are the technical documents of IAEA, in view of the absence of similar criteria in AERB.

AERB has not conducted 85 *per cent* of regulatory inspections for both industrial radiography and radiotherapy units even though these have been identified as having a high radiation hazard potential.

5.2.2 Nuclear medicine, nucleonic gauges and diagnostic radiology (X-ray equipment)

We reviewed the RI process of the minor category of radiation facilities i.e. nuclear medicine, nucleonic gauges and diagnostic radiology (X-ray equipment). The suggested inspection frequencies as per the IAEA-TECDOC for these facilities is given below:

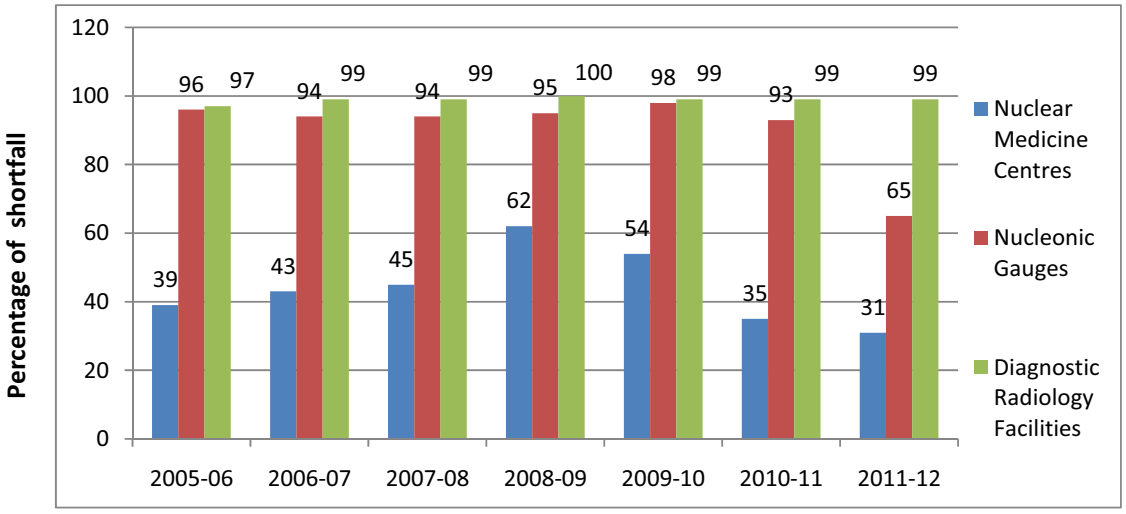
Minimum frequency norms of RIs suggested as per IAEA-TECDOC

Type of facility	Frequency of RIs	Minimum frequency of RIs
• Diagnostic Radiology– Centre with conventional X-ray equipment only	3-5 years	At least once in five years
• Nuclear Medicine	1-2 years	At least once in two years
• Radiation Gauges (Nucleonic Gauges)	3-5 years	At least once in five years

We assessed the adequacy of RIs for nuclear medicine, nucleonic gauges and diagnostic radiology (X-ray equipments) with reference to the minimum frequency of RIs prescribed in IAEA-TECDOC with the data relating to RIs for the same conducted for the period 2005-06 to 2011-12. The details of the inspections are in *Annex 3* and Graph-4 brings out the inadequacy of RIs in these facilities.

Graph – 4

Shortfall in regulatory inspections for nuclear medicine centres, nucleonic gauges and diagnostic radiology facilities (2005-06 to 2011-12)



From the graph, it is observed that in the case of nucleonic gauges and diagnostic radiology (X-ray equipments), there has hardly been any inspection at all.

Shortfall of over 97 *per cent* in regulatory inspections in the case of diagnostic radiology facilities every year shows that AERB is not exercising effective regulatory oversight over units related to the health of the public.

DAE stated (February 2012) that with regard to nuclear medicine and nucleonic gauges, the low hazard potential of the sources and the availability of periodic safety status reports for review were considered while deciding the regulatory control measures. Targeted inspections were undertaken based on these inputs.

With regard to the issue of RIs for all types of radiation facilities, DAE stated that as a part of enhancing the regulatory control for radiation facilities, AERB had undertaken the preparation of a Safety Manual titled 'Regulatory Inspection and Enforcement for Radiation Facilities' which was in the final stage of production. The reply of DAE confirms the lack of commitment and laxity in addressing the issue for over 29 years since the creation of AERB.

AERB has not laid down the periodicity of conducting regulatory inspections of such facilities in spite of the availability of international benchmarks in this regard.

5.3 Delays in issue of regulatory inspection reports

According to the AERB Safety Manual, the final RI reports along with enforcement letters should be issued to the utilities within 15 days from the date of RIs.

Table - 6 gives data relating to the number of RIs conducted and delays in issue of RI reports during 2005-06 to 2011-12.

Table – 6

Delays in issue of Regulatory Inspection Reports

Type of facility	No. of RIs conducted	Units where issue of RI report delayed	Range of delays (in days)
Nuclear Power Projects (under construction)	91	25	1 to 31 days
Nuclear Power Projects/ Research Reactors (operating)	166	21	1 to 13 days
Nuclear Fuel Cycle Facilities	188	99	1 to 38 days
Radiation Facilities	1778	474	1 to 194 days
Total	2223	619	

It was observed that delays impacted the settlement of safety issues as brought out in the RI reports.

AERB stated (February 2012) that after carrying out inspections, the RI teams issued draft reports to the facilities during the exit meetings. The RI draft reports were then submitted to the Director of the concerned division of AERB, and after his review and approval, the final reports were sent to the facilities. In some cases, non-availability of the Director at the office due to subsequent inspections or other official work caused some delay in issue of the reports. It further stated that in the cases of any safety-significant observations, the same were taken up directly with the plant Managements and reviewed by the safety committees.

5.4 Delays in submission of responses to the observations in inspection reports

According to the AERB Safety Manual, responses to the observations in the RI reports should be sent by the utilities within a month from the receipt of the reports. Data relating to non-submission of responses and delays in submission of responses for the period 2005-06 to 2011-12 is given in Table -7.

Table – 7

Responses to the observations in inspection reports

Type of facility	No. of RIs conducted	Failure to submit responses	Delay in submission of responses	Range of delay in number of days	Percentage of delays and non-submission of responses
Nuclear Power Projects (under construction)	91	2	58	1 to 125 days	66
Nuclear Power Projects/ Research Reactors (operating)	166	25	75	1 to 153 days	60
Nuclear Fuel Cycle Facilities	188	Nil	131	1 to 324 days	70
Radiation Facilities	1778	281	115	1 to 561 days	22
Total	2223	281	379		

We observed that in more than 13 *per cent* of the cases, responses to observation of RI reports were not submitted at all. Further, there were delays in submission of responses to RI reports in 17 *per cent* of the cases.

DAE stated (February 2012) that the utilities generally sent responses within three to four months from the dates of issue of the RI reports. However, reminders were sent to the utilities for submitting the responses to RI reports at the earliest. In the case of radiation facilities, it was stated that corrective measures were ordered and implemented on the spot for any deficiency noticed during inspection and an advanced web-based interactive system was being developed to minimise the time lags.

The reply of the DAE confirms the delays, well beyond the prescribed schedule, in the submission of responses.

5.5 Delays in compliance of the recommendations of the Safety Review Committee for Operating Plants

As stated earlier, Safety Review Committee for Operating Plants (SARCOP) monitors and enforces safety regulations in NPPs and other radiation facilities identified by the Central Government. A review of records by Audit revealed that SARCOP had met more than 620

times since its inception in 1987 for safety review of NPPs and other facilities. During these meetings, it had made 3200 recommendations.

The data relating to the SARCOP recommendations, their compliance and pendency are given in Table - 8:

Table – 8
Compliance and pendency of SARCOP recommendations

Year	Nuclear Power Plants			Fast Breeder Test Reactor (IGCAR)[18]		
	Recommend-ations issued	Settled	Pending and in progress	Recommend-ations issued	Settled	Pending and in progress
Upto 2004	2406	2276	130	186	179	7
2005	80	53	27	11	6	5
2006	137	111	26	0	0	0
2007	96	79	17	0	0	0
2008	58	43	15	5	0	5
2009	41	21	20	0	0	0
2010	74	52	22	9	0	9
2011	94	5	89	3	0	3
Total	**2986**	**2640**	**346**	**214**	**185**	**29**

As seen from the table, out of 375 recommendations pending for compliance, 137 pertained to periods prior to 2005.

AERB stated (February 2012) that SARCOP recommendations were mainly for safety improvements and confidence-building measures and followed a graded approach, based on the gravity of the hazards and related actions for enforcement and follow-up of implementation of these recommendations. It further stated that the number of pending recommendations would not represent the safety status of a plant and they dealt with issues which would need time. It assured that a new database, which would be capable of accommodating the specific requirements of follow-ups, was being developed.

AERB's response must be seen in light of the fact that although SARCOP is meant to enforce safety regulations in NPPs and other radiation facilities, it could not ensure compliance of its

[18] Indira Gandhi Centre for Atomic Research, Kalpakkam

recommendations which were pending for several years. As a nuclear safety regulator, AERB should have prescribed timelines for implementation of its recommendations. There was also a need to review all recommendations pending for more than certain threshold periods.

5.6 Non-initiation of regulatory action against defaulting X-ray units in Kerala

The Directorate of Radiation Safety (DRS), Kerala, during its inspections, had reported deficiencies in the operation of X-ray units in Kerala to AERB during the period 2008-10. We, observed that these deviations were in violation of safety provisions which called for penal action as per Rule 35 of RPR 2004 with reference to Section 24 of AE Act. However, no enforcement or penal action was initiated by AERB against the defaulting units.

DAE stated (February 2012) that the deficiencies reported by the DRS were operational discrepancies. The violations observed were mainly practice-specific and not related to built-in safety, which enabled the institution to rectify the deficiencies within the defined period.

The fact remains that AERB had failed to enforce safety provisions and compliance with its own stipulations even when its attention was specifically drawn to deficiencies in the case of units in Kerala.

Recommendations

9. AERB may strengthen the processes of regulatory inspections of nuclear and radiation facilities by:
    - prescribing periodicities of regulatory inspections by after conducting risk analyses and keeping international benchmarks for such inspections in view;
    - undertaking regulatory inspections in terms of the norms prescribed by IAEA for radiation facilities;
    - stipulating the timely issuance of regulatory inspection reports and securing compliance thereof; and
    - laying down timelines for implementation of SARCOP's recommendations based on the relative importance of the various issues.

Chapter 6: Radiation protection

Audit Objective: Whether AERB was monitoring and discharging responsibilities relating to radiation exposure to occupational workers and members of the public and to the release of radioactive substances in the environment in an efficient and effective manner

6.1 Introduction

According to the IAEA Safety Guide, exposure to radiation can occur as a result of various human activities, including work associated with different stages of the nuclear fuel cycle, the use of radioactive sources and radiation in medicine, research, agriculture and industry.

Exposure in excess of the limits prescribed based on medical research, has serious health implications for all living organisms and environment. Radiation protection is thus intended to ensure that the amount of radiation absorbed by an organism does not have negative consequences.

According to the IAEA Handbook, nuclear law must establish a legislative framework for the safe management of all sources and types of ionising radiation. It should, in particular, ensure that individuals, society and the environment are adequately protected against radiological hazards. Finally, it should impose restrictions on the dose that an individual may incur so that no person is subject to an unacceptable risk attributable to radiation exposure.

6.2 Radiation protection in India

The Constitution Order (1983) of AERB vide clause 2 (vii) entrusted the function of prescribing acceptable limits of radiation exposure to occupational workers and members of the public and approve acceptable limits of environmental release of radioactive substances to AERB.

As per the AERB guidelines for an occupational worker, the annual dose limit is 30 mSv[19], with the condition that it should not exceed 100 mSv in a span of five years. Authorised regulatory limits of radioactive effluents for the public are based on the apportionment of an effective dose limit of one mSv per year.

[19] Milli-Sievert (mSv) – derived unit of dose equivalent radiation which attempts to quantitatively evaluate the biological effects of ionising radiation.

As per the provisions of the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, the responsibility for safe disposal of radioactive waste is placed on the licencees and AERB has the mandate of ensuring that the licencees perform their responsibilities. RPR 2004 also specifies the responsibilities of various parties, viz. the employers, licencees, Radiological Safety Officers and workers, with respect to radiation protection. The Rules also specify the powers of the competent authority (AERB) with respect to (i) specifying requirements in respect of safety, health surveillance of workers, radiation surveillance and records to be maintained; (ii) issuing directives; (iii) inspections and (iv) enforcement actions.

6.3 Radiation protection in nuclear and radiation facilities

6.3.1 Nuclear Power Plants

We reviewed the adequacy and effectiveness of the procedures and practices in respect of radiological protection of workers, the public and the environment in respect of NPP, other nuclear fuel cycle facilities and other radiation facilities. We also reviewed the adequacy and effectiveness of the radioactive waste management system, which was one of the most vulnerable aspects of radiation protection. Our observations are as follows:

6.3.1.1 Radiological protection of workers

Each NPP has a Health Physics Unit (HPU) which is entrusted with the responsibility of providing radiological surveillance and safety support functions; monitoring of areas, personnel, systems and effluents, as well as exposure control and exposure investigations. These HPUs were initially part of the BARC and were independent of the NPPs, with direct channels of communication with the top plant Management of the Nuclear Power Corporation of India Ltd (NPCIL) in enforcing the radiation protection programme.

The HPUs in all NPPs were transferred from BARC to NPCIL in May 2009 by DAE. This meant that the functions of monitoring of radiological exposure as well as the responsibility of radiological surveillance of NPPs now lay with NPCIL which was an operator of NPPs.

In respect of the critical issues of radiological protection of workers, AERB's role in verification of compliance, an essential requirement for any regulator, has not been provided for, in a direct way. In view of AERB's role as the nuclear regulator of India, independent assessments and monitoring can be ensured only if these HPUs are placed under its direct control.

6.3.1.2 Radiological protection of public

The discharge of radioactive waste from NPPs is governed by the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 issued under the AE Act. It is mandatory for an NPP to obtain authorisation under the above rules from AERB for disposal of radioactive wastes. AERB prescribes the regulatory limits of radioactive effluents based on the apportionment of an effective dose limit of one mSv per year to the public, arising from nuclear facilities at a site, considering all the routes of discharges and significant radionuclides[20] in each route of discharge.

AERB reported that during the period from 2005 to 2010, the effective dose to the public was far less than the prescribed annual limit of one mSv in all the sites.

6.3.1.3 Radiological protection of environment

The Environmental Survey Laboratories (ESLs) of the Health, Safety and Environment Group, BARC carry out environmental surveillance over an area of 30 km radius around the nuclear reactors at all the operating NPP sites. They provide AERB with periodic reports on radiological conditions of the NPPs and the results of environmental surveillance. The ESLs are, therefore, not under the direct control of AERB.

DAE stated (February 2012) that initially all the activities related to operation of NPPs and radiation protection functions were discharged by the Government. In 1987, the operation and maintenance of NPPs were transferred to NPCIL but the functions relating to occupational radiation protection and environmental surveillance continued to be discharged by BARC. In 2009, these functions were transferred to an Environment Group set up within the Safety Directorate of NPCIL. This arrangement provided for independent environmental surveillance by the ESLs established by the Health, Safety and Environment Group of BARC. Subsequent to this reorganisation, AERB had undertaken the process of authorising Radiological Safety Officers (RSO) at the NPPs and radiation facilities within the Government. The responsibilities of the employers, licencees and RSOs were clearly specified in RPR 2004.

DAE further stated that to fulfill their responsibility, AERB had instituted an aggressive inspection programme for checking compliance of the requirements by the utilities.

[20] A **radionuclide** is an atom with an unstable nucleus. The radionuclide is said to undergo radioactive decay, resulting in the emission of gamma ray(s) and/or subatomic particles and occur naturally, or can be produced artificially and present both real and perceived dangers to health.

The reply of DAE once again confirms the absence of any direct role of AERB in verification of compliance with regard to environmental surveillance issues. AERB, as is essential for any independent regulator, should have the authority to monitor the performance of the regulated entity. Accordingly, it should strengthen its role with adequate infrastructure and manpower to conduct independent surveillance of exposure control and exposure investigations.

6.3.2 Radiation facilities

As per RPR 2004, AERB has the responsibility for ensuring radiation protection by prescribing collective dose budgets[21], reviewing excess exposure cases, conducting regulatory inspections and reviewing radiological safety aspects of radiation facilities, mainly based on the prescribed reports submitted by the Radiological Safety Officers (RSO)[22] of the facilities. Our observations are discussed in the following paragraphs:

6.3.2.1 Radiological protection from occupational exposure

As per AERB guidelines, the annual dose limit for an occupational worker is 30 mSv, with the condition that it should not exceed 100 mSv in a span of five years.

We observed that there were 89 cases of excess exposure, i.e. exceeding 30-mSv at radiation facilities during the period from 2005 to 2010. Out of this, the exposure was more than 50 mSv in 41 cases. This indicated that wrong work practices were prevalent among radiation workers and the excess exposures would have negative consequences and adverse effects on the health of workers in the short as well as long term.

Insofar as the verification of exposure to workers in a radiological facility is concerned, the RPR, 2004 envisages that the RSO should be responsible for radiological surveillance, including those relating to personnel. He is to accordingly furnish periodic reports on safety status to AERB.

DAE stated (February and June 2012) that the number of cases of doses exceeding the AERB limit had come down drastically in the recent years. They further stated that in case the specified annual dose limit was exceeded in the case of a worker, the case was reviewed to

[21] AERB approves the annual collective dose budget for each NPP. In the beginning of a calendar year, NPPs present the budget proposal along with planned activities for the year. These proposals are reviewed and approved by relevant AERB committees.

[22] A person who is so designated by an employer with the approval of the competent authority i.e. AERB under the Atomic Energy (Radiation Protection) Rules, 2004 and Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987.

ensure that the dose received by the worker remained within the limit of 100 mSv over a period of five years.

It was also stated that in case the annual limit of 30 mSv was exceeded for a worker, he was engaged in non-radiation areas for the remaining period to keep the five yearly total dose within the limit of 100 mSv. For investigation of cases of overexposure, AERB took the help of RSOs appointed in the radiation facilities. Reports of the preliminary investigations carried out by the RSOs were first scrutinised and reviewed by AERB. AERB carried out further inspections and undertook investigations for the cases as necessary. Based on these investigations, improvements in the working conditions and safety culture at the facilities were considered. DAE further stated that the number of overexposures had been less than 0.1 *per cent* of the total number of radiation workers in the last five years.

The reply of DAE addresses post-exposure measures rather than preventive action. There is a shortage of RSOs and inadequacy in respect of RI of radiation facilities, impacting independent verification and review of radiological safety aspects in respect of the large number of radiation facilities available in the country. Thus, there is a need for efforts to prevent even a single case of over-exposure which could impair the health of the people in the affected areas. Further, insofar as the responsibility of reporting by RSOs is concerned, there was an acute shortage of such officers, particularly in the case of diagnostic radiology and nucleonic gauges, both of which are radiation facilities.

6.4 Radioactive waste management

As per the IAEA Handbook, when a sealed radiation source reaches the end of its useful life, it should be disposed off or returned to the manufacturer for recycling. However, at times, disused sources are often discarded and may give rise to accidents. It is, therefore, essential that the regulatory body be provided with the means necessary for effectively controlling all major sources in the country. It is also essential that the regulatory body maintains effective communication with the holders of licences for these sources.

The discharge of radioactive waste[23] from radiation installations in India is governed by the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987. It is mandatory for every radiation installation to obtain authorisation under these rules from the competent authority, i.e AERB, for disposal of radioactive waste.

We examined the effectiveness of the systems and processes of disposal of radioactive waste i.e. disposal of sources that had outlived their utility (disused sources), radioactive

[23] Any waste material containing radionuclides in quantities or concentrations as prescribed by the competent authority by notification in the official gazette

sources that had gone out of regulatory control (orphan sources) and other waste including effluents. Our findings are discussed in the succeeding paragraphs.

6.4.1 Management of disused radiation sources:

6.4.1.1 Disposal of sources that have outlived their utility (Disused sources)

According to Rule 3 of the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, no person should dispose of radioactive waste

(a) unless he has obtained an authorisation from the competent authority under these rules;

(b) in any manner other than in accordance with the terms and conditions specified in the authorisation issued under these rules;

(c) in any location different from those specified in the authorisation;

(d) in quantities exceeding those specified in the authorisation.

While the systems and procedures for the disposal of disused sources in respect of NPP and other nuclear fuel facilities were in place, the same were not so in the case of other radiation facilities due to inadequate monitoring on account of shortfalls in RIs and inadequate strength of RSOs in these facilities. This was also evident in case of the radiation incident in Mayapuri mentioned earlier, which is described below:

Radiation incident in Mayapuri

The University of Delhi procured radiation equipment containing a gamma cell in 1970, which was operated till 1985. AERB stated (June 2010) that this unused equipment containing the gamma cell was sold to a local scrap dealer in a public auction. Thereafter, the equipment was dismantled and the source assembly was handled by persons with bare hands. This resulted in serious radiation injuries to these persons, including the death of a person. These casualties occurred due to unsafe and unauthorised disposal of radiation equipment at Mayapuri, New Delhi in April 2010. It is apparent that the accident was the result of ignorance about practices for safe disposal of radioactive waste. AERB confirmed that Delhi University was not aware of the provisions of the Atomic Energy (RP) Rules, 2004 and the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules,

1987. The nature of the incident was classified as level 4[24]. The AERB version of the incident is given in *Annex 4*.

AERB replied (February 2012) that the incident occurred primarily due to violations by Delhi University of the clear and unambiguous requirements specified in the applicable rules, about safe disposal practices of radioactive wastes.

The fact, however, remains that the sources mixed with scrap metal used for subsequent recycling, can lead to contamination of industrial plants and the environment. The contamination can possibly result in serious consequences.

6.4.1.2 Database relating to radiation facilities

As stated earlier in para 6.4, the IAEA Handbook states that a regulatory body is to be provided with the means necessary for effectively controlling all major sources in the country. It is also essential that the regulatory body maintains effective communication with the holders of licences for these sources.

Prior to the establishment of AERB, radiation facilities were under the regulatory control of BARC. AERB did not obtain sufficient data relating to radiation facilities operating in the country when the regulatory work was assigned to it.

AERB stated (February 2012) that following the Mayapuri incident in April 2010, it had undertaken a vigorous campaign to establish and maintain an inventory of all the radiation sources used in the country and to improve their regulatory control. The measures taken as part of this included (i) sensitising all academic, medical and R&D institutions to prepare inventories of radiation sources under their possession and review their existing safety procedures, (ii) asking all the suppliers/manufacturers for details of the sources supplied by them till date, (iii) strengthening the AERB data base on source inventory by identifying and bringing on record, the legacy sources. AERB further stated that it had initiated a process of developing an advanced web-based interactive system for managing the regulation of radiation sources and facilities.

The fact remains that AERB still does not have an effective system in place to ensure continuous collection and updating of its inventory of all radiation sources, to ensure effective compliance of regulations for safe disposal of disused sources.

[24] The nature of radiation events are classified by IAEA under seven levels on the International Nuclear and Radiological Event Scale (INES) depending on the gravity of the incidents, with level seven being the highest level. Level four signifies accidents with local consequences

AERB does not have a detailed inventory of all radiation sources to ensure effective compliance of regulations for safe disposal of disused sources. No proper mechanism is in place to ensure that waste radioactive sources have actually been disposed off safely after utilisation.

6.4.1.3 Absence of a proper mechanism to monitor safe disposal of radioactive material

AERB issues consents for disposal of decayed radioactive materials from medical, industrial and research institutes for safe disposal to the original supplier or to one of the approved radioactive waste disposal facilities[25] in India.

We observed that although a large number of consents for transport of radioactive material for safe disposal had been given so far, there was no proper mechanism in place to verify whether the sources had actually been disposed off in accordance with the safeguards prescribed in the consent letter. Records for all the sources disposed off so far at their facilities were being maintained by the National Waste Management Agency.

DAE stated (February 2012) that a computerised database of the sources disposed of at an authorised waste management agency with prior permission from AERB is maintained both at the waste management agency and AERB. It assured that once the advanced web-based interactive system for the management of radioactive sources (currently in advanced stage of development) became operational in AERB, it would be easier to track and complete the cradle to grave cycle of a radioactive source. This system would integrate the management of the sources by the user, AERB and the waste management agency.

Though a large number of consents for transport of radioactive material for safe disposal have been given so far, there is no proper mechanism to verify whether the sources have actually been disposed off or not.

The existing mechanism for safe disposal of radioactive material reveals weakness in verification of compliance and the lack of enforcement by AERB. This indicated departure from features that are essential for the functioning of a regulator.

[25] National Waste Management Agency, BARC

6.4.2 Orphan sources

The IAEA Safety Glossary defines an 'orphan source' as a radioactive source which is not under regulatory control, either because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation. The issue has engaged international attention, especially after the terrorist attack of 11 September 2001, in USA with the concern that such sources may be acquired and used for malicious purposes.

As per the provisions of RPR 2004, an employer has to inform AERB about losses of radiation sources under their custody. AERB included such cases in their reports as 'unusual occurrences'.

During the period 2005-06 to 2011-12, AERB had reported the following instances:

- Forty eight cases of loss, theft or misplacement of radioactive sources since 2000, in which radioactive material found its way into the environment and 15 cases where the source was never found. Details of these are listed in *Annex 5.*
- Several incidents of radioactive packages remaining uncollected at airports, including 67 unclaimed packages found at Chennai, Delhi, Kolkata and Mumbai airports in 2001.
- The mistaken handing over of a radioactive package containing 6.539 GBq[26] Y-90[27] to a waste disposal agency in 2004-2005, by the staff at Mumbai airport.

AERB stated (February 2012) that the radioactive sources in use in the country were large in number and were regulated through a graded approach, commensurate with their hazard potential. AERB dealt with cases of loss, theft and misplacement of sources through regulatory action, awareness programmes and help from the police and IG security (DAE). The reported cases of loss and theft of sources were mainly from radiation facilities having low hazard potential. AERB ensured that all the licencees immediately reported any incident of loss and theft or misplacement of sources to enable prompt action for tracing and recovering the sources. If the cases of loss, theft or misplacement of the sources were known to be due to negligence from the side of the licencees, appropriate regulatory action was initiated against them.

[26] Gigabecquerel (GBq) is a measurement unit of radioactivity.

[27] Yttriga-90 is a solution of Yttrium [90Y] chloride, which is a β-emitting radionuclide radiopharmaceutical.

AERB further stated that due to the increased awareness regarding radiation safety amongst airport Managements, Customs officials, importers and exporters, AERB got information on time and took prompt action to resolve the issues. AERB had been undertaking many campaigns through various awareness programmes about the safety and security of radioactive sources used in the country. In view of this, such incidents were expected to come down in the near future with proper monitoring of the sources with the help of the advanced web-based active system.

AERB should strengthen its current approach to deal with the issue of orphan sources. The IAEA Safety Guide envisages development of a national strategy for regaining control over orphan sources and improving control over vulnerable sources. AERB should adopt the best practices laid down by the IAEA.

There is no effective mechanism in place to prevent radioactive sources from getting out of regulatory control. The regulatory response mechanism to trace and discover lost and/or orphan radioactive sources in the country is also not effective.

6.5 Acute shortage of Radiological Safety Officers

According to Rule 7 of RPR 2004, no licence to handle radioactive material or to operate radiation generating equipment, should be issued to a person unless, in the opinion of the competent authority, an RSO is designated in accordance with Rule 19 of RPR, 2004.

The duties and functions of an RSO are defined in Rule 22 of RPR, 2004 and Rule 13 of Safe Disposal of Radioactive Waste Rules, 1987 as detailed in Annex *6*. We observed that RSOs had been assigned enormous responsibilities under these rules for radiation protection and safe disposal of radioactive waste and they were vital links between the licencees and the regulator in securing compliance of the rules for radiation protection and safe disposal of radioactive waste. The regulator was mainly dependent on the RSOs in ensuring the compliance of various provisions under these rules.

We observed that the total number of RSOs finally approved for various types of nuclear and radiation facilities was not adequate to cover all the units of nuclear and radiation facilities. The number of RSOs approved by AERB and the number of similar units of nuclear and radiation facilities as on 31 March 2012 are given in Table – 9.

Table - 9

Number of RSOs approved by AERB and number of units of nuclear and radiation facilities as on 31 March 2012

Sl. No.	Type of facility/ Application	No. of registered units	No. of approved RSOs
1.	Nuclear Power Plants and Research Reactors	19	34
2.	Other DAE facilities	3	3
3.	Nuclear Fuel Cycle Facilities	15	7
4.	Non-DAE Facilities (Beach Sand Mineral Facilities)	23	21
5	Radiotherapy	319	363
6	Industrial Radiography	472	689
7	Nucleonic Gauges	1710	628
8	Nuclear Medicine	179	247
9	Research Applications	288	279
10	Diagnostic Radiology	6041	395
Total		**9069**	**2666**

As may be seen from the above table, there was an acute shortage of qualified RSOs in comparison to the total number of registered units, indicating that most of the units of radiation facilities were working without RSOs.

DAE stated (February 2012) that the country had been facing a shortage of RSOs for a larger number of facilities like nucleonic gauges and diagnostic X-ray units etc. where, however, the radiation hazard was low. Training courses for RSOs were conducted by the Radiological Physics & Advisory Division of BARC, Mumbai, with lectures from AERB officers on radiation safety, but there were constraints in terms of limited space, manpower and long waiting lists. AERB was also exploring other ways of spreading awareness on radiation protection, especially to the users of diagnostic X-ray equipment.

The fact remains that RSOs have been assigned enormous responsibilities under these rules for radiation protection and safe disposal of radioactive waste and they are a vital link between the licencees and the regulator in securing the compliance of the rules for radiation

protection and safe disposal of radioactive waste. In the absence of this link, the effectiveness of the safety procedures followed cannot be ensured in these facilities.

There is an acute shortage of Radiological Safety Officers, who should be designated for all radiation units as per the Rules.

Recommendations

10. The regulatory role of AERB may be strengthened by bringing the monitoring agencies viz. Health Physics Units, Environmental Survey Laboratories etc. under the direct control of AERB.

11. AERB needs to strengthen its infrastructure and manpower to conduct independent surveillance of exposure control and exposure investigation.

12. AERB may strengthen its system to ensure continuous updating of its inventory of all radiation sources till date to prevent radioactive sources from going out of regulatory control and ensure safe disposal of disused sources.

13. AERB may enhance awareness regarding safe handling and disposal of radioactive waste in the country.

14. AERB may take proactive action to ensure that the existing acute shortage in designating Radiological Safety Officers for radiation installation is addressed.

Chapter 7: Emergency preparedness for nuclear and radiation facilities

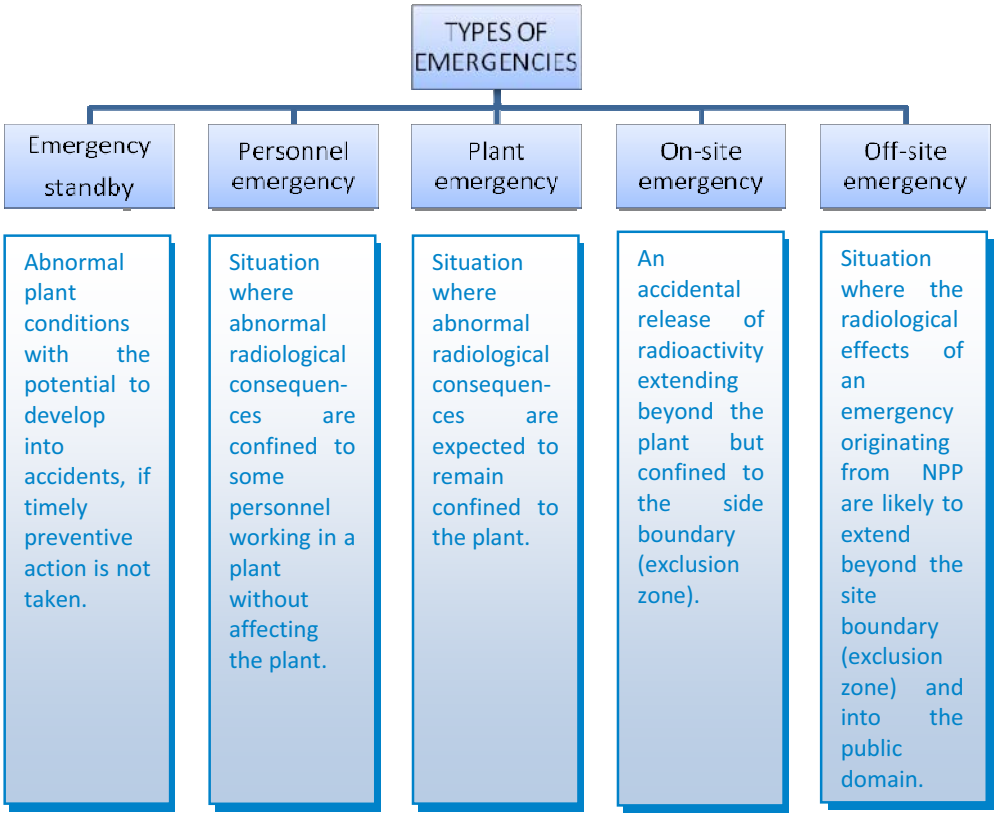
Audit Objective: Whether emergency preparedness plans are in place for nuclear and radiation facilities and during transport of large radioactive sources, irradiated fuel and fissile material

7.1 Introduction

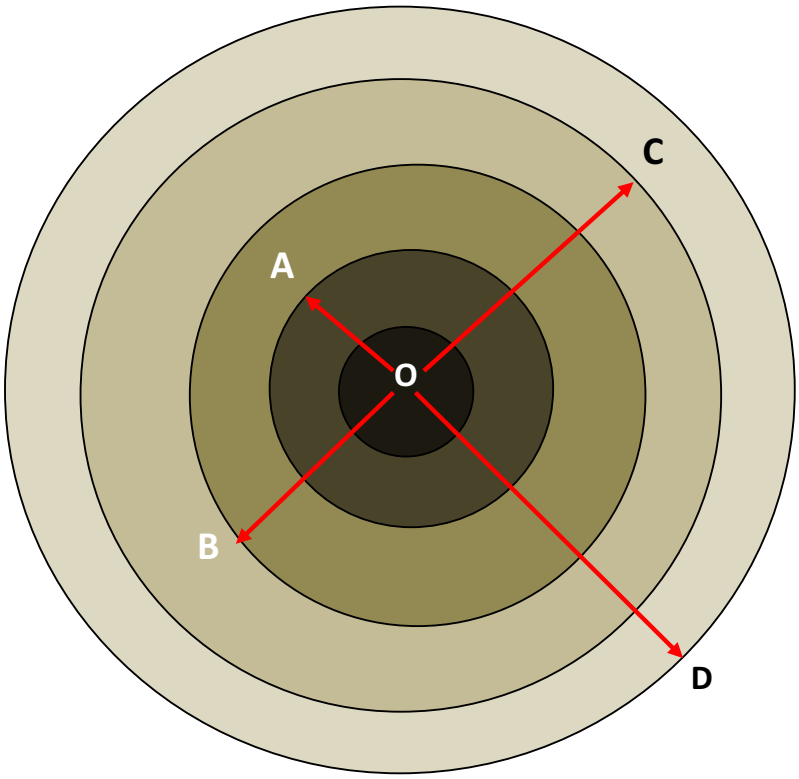
In addition to the safety standards to be adopted for creating and operating nuclear and radiation facilities, as per Article 16 of the Convention on Nuclear Safety of IAEA, AERB has to ensure development of emergency response plans in conformity with international practices so that any eventuality with a potential to result in undue radiological risks to plant, personnel and the public, is handled effectively.

Based on the radiological conditions and their consequences, emergencies at nuclear facilities are categorised as emergency standby, personnel emergency, plant emergency, on-site emergency and off-site emergency. These are explained in Chart – 2 below.

Chart - 2



The exclusive zones for emergency preparedness are depicted in the diagram below:



OA: plant area, OB: 1.6 km, OC: 5 km, OD: 16 km

Type of emergency	Affected zones	Responsible agency
Emergency standby	Stack location (O)	Plant Management
Emergency standby	Plant area (OA)	Plant Management
Personnel emergency	Plant area (OA)	Plant Management
Plant emergency	Plant area (OA)	Plant Management
On-site emergency	Exclusion zone (OB)	Plant Management
On-site emergency	Sterilised zone (OC)	Plant Management
Off-site emergency	Emergency planning zone (OD)	Plant Management, district authorities, State government and NDMA

Source : AERB Safety Guide no. AERB/SG/O-6 titled 'Preparedness of the operating organisation for handling emergencies at nuclear power plants'

7.2 International scenario vis-à-vis the Indian scenario

Article 16 of the Convention of Nuclear Safety of the IAEA, ratified by the Government of India on March 31, 2005, stipulates that each contracting party should take appropriate steps to ensure that there are on-site and off-site emergency plans that are routinely tested for nuclear installations and cover the activities to be carried out in the event of an emergency. For any new nuclear installation, such plans should be prepared and tested by the regulatory body, before it commences operations. Each contracting party should take appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of the nuclear installation are provided with appropriate information for emergency planning and response.

The IAEA Handbook on Nuclear Law corroborates the above by providing the three aspects of emergency planning relating to regulatory bodies requiring specific inclusion in national nuclear legislations. The comparative position of the legislative framework on emergency planning stipulated by IAEA and as followed by India is detailed below:

Stipulation as per IAEA	As followed in India
1. The role of the regulatory body in approving emergency response plans for facilities utilising nuclear material or radiation sources should be spelt out.	Emergency preparedness plans prepared by the plant Management of NPPs and nuclear fuel cycle facilities should be approved by AERB.
2. The role of the regulatory body in providing expert information and assistance to other governmental bodies and the public in the case of emergencies involving radioactive material should be spelt out.	As per the Constitution Order dated 15 November 1983, AERB should take such steps as is necessary to keep the public informed about major issues of radiological safety significance. As regards off-site emergency response plans, the responsibility rests with district authorities, with assistance from the facility operators, AERB, and the Crisis Management Group (CMG[28]) under the overall coordination of the National Disaster Management Authority (NDMA).
3. The role of the regulatory body in implementing certain international legal commitments such as those under the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear	India is party to the Convention on Early Notification of a Nuclear Accident (1986), the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1986), the Convention on the Physical Protection of Nuclear Material (1979) and the International Convention

[28] Crisis Management Group is immediately activated in the event of any nuclear/radiological emergency in the public domain and would coordinate the additional technical resources required by the affected NPP to handle the emergency and is chaired by Additional Secretary, DAE.

Accident or Radiological Emergency should be spelt out.	for Suppression of Acts of Nuclear Terrorism (2005), Convention on Nuclear Safety (ratified in 2005) and complies with their obligations. However, the role of AERB in relation to implementing international legal commitments has not been specifically defined in its constitution order.

7.3 Emergency preparedness plans for nuclear power plants

Preparedness and responses to emergencies are important responsibilities of an operating organisation, which has to establish and maintain the necessary emergency plans and procedures for all emergencies by having an on-site emergency preparedness plan and an off-site emergency preparedness plan. The off-site emergency plan is the combined responsibility of the operator, the district authorities and other associated authorities such as NDMA, the CMG of DAE, etc. The other emergency plans fall within the domain of responsibility of the operator. AERB has the responsibility to ensure that these emergency preparedness plans are submitted by the operators to it for approval, review and updation.

We reviewed the regulatory effectiveness of systems and procedures relating to emergency preparedness, both on-site and off-site and the general adequacy of emergency preparedness and coordination between various authorities, without going into the effectiveness of emergency preparedness plans as they are technical in nature. Our findings in respect of both on-site and off-site preparedness are detailed in the succeeding paragraphs:

7.3.1 On-site emergency preparedness

On-site emergency preparedness plans are put in place by the plant Managements of NPPs and nuclear fuel cycle facilities. These emergency preparedness plans are tested by actual periodic exercises prescribed, based on the types of emergencies, by the plant Managements of NPPs. Plant emergency exercises (PEE) are conducted once in a quarter, while site emergency exercises (SEE) are conducted once a year. AERB only reviews the reports of these exercises conducted by the plant Managements and does not directly associate itself in these exercises, even as observers of PEE and SEE.

As the nuclear safety regulator, AERB should associate itself as an observer in these exercises on selection basis to exercise adequate regulatory supervision in these exercises.

DAE welcomed the suggestion of Audit, stating (February 2012) that AERB was contemplating deputing observers during on-site exercises on a sample basis.

7.3.2 Off-site emergency preparedness

For the purpose of planning an off-site emergency, an emergency-planning zone (EPZ) is specified up to a 16 km radius from the plant. The Emergency Response Manual of AERB specifies the criteria to determine an off-site emergency. The protective measures in the public domain are also specified in the Manual. These measures have to be implemented by the district officials under the direction of the district authority, who is designated as the Off-Site Emergency Director (OED). The OED is the chairman of the Off-Site Emergency Committee (OEC) and is responsible for convening the OEC when the report of the initiation of an emergency is received. Its members include the chiefs of all public services relevant to the management of any emergency in the public domain.

The State Governments approve and issue the off-site emergency plans after review by AERB. The emergency response plans provide guidance to ensure that the NPPs and off-site authorities develop and maintain compatible emergency plans. In order to test these plans, periodic off-site emergency exercises (OSEE) are carried out, involving the station authorities, district administrations and members of the public.

Review in audit of off-site emergency preparedness in the country revealed the following:

(a) In the case of NPPs, the OSEE are conducted once in two years, in coordination with district authorities and the public. We observed that there was no significant deviation in the conduct of OSEE and AERB was associated with these exercises as an observer. In all, 26 such emergency exercises were conducted during the period 2005-2011 in various NPPs and AERB submitted observer's reports to the plant authorities and the CMG for taking necessary action to rectify/revise the offsite emergency plans.

(b) Low population density in emergency zones and proper approach roads to plant sites enable effective responses in case of any emergencies. We reviewed the NPP sites at Tarapur, Kalpakkam and Kaiga and observed that there was no proper approach road from the Palghar Tahsildar Office to the Plant site of the Tarapur Atomic Power Station and also that the population had increased manifold in the emergency zone at the site due to large scale industrial activity in the Maharashtra Industrial Development Corporation area at Tarapur. These bottlenecks would pose serious impediments in speedy responses for rescue of affected people in case of any emergency.

AERB stated (February 2012) that presently, it was not mandated to take follow-up action with the district / State authorities on deficiencies in emergency preparedness pointed out by it. However, it was considering asking the plant Managements to obtain and submit

information on the status of corrective measures taken subsequent to the OSEEs by the local authorities.

The reply confirms the weakness in the regulatory regime since the AERB has no authority to enforce rules in the instances of malpractices and departures from the approved plans.

Off-site emergency exercises carried out highlighted inadequate emergency preparedness. AERB is not empowered to secure compliance of corrective measures suggested by it.

7.4 Emergency plans for radiation facilities

It was observed that codes for emergency preparedness plans for NPPs and nuclear fuel cycle facilities of DAE had been framed and issued, but no specific codes on emergency preparedness plans for other types of radiation facilities such as industrial radiography, radiotherapy and gamma chambers etc had been brought out even though the hazard potential of these were rated as high. We observed that the number of radiation applications in various areas has grown continuously and high strength radioactive sources were being used extensively in industry, hospitals and other irradiation facilities.

DAE stated (February 2012) that though in their assessment, emergency preparedness in radiation facilities had been addressed adequately in the present system of regulation, the suggestion could be examined.

Recommendations

15. AERB may be more closely associated with on-site emergency preparedness exercises.

16. AERB may be empowered to secure compliance of the corrective measures suggested by it for strengthening the emergency preparedness of plant sites.

17. AERB may strengthen the regulatory aspect of emergency preparedness in the area of other radiation facilities by prescribing codes for emergency preparedness plans based on the assessment of risk factors of each facility and suitable procedures for securing compliance to the requirements prescribed in the codes.

Chapter 8: Decommissioning of nuclear and radiation facilities

Audit Objective: Whether there exists an adequate and effective regulatory system in the country for the decommissioning of nuclear and radiation facilities as well as a system for creation of decommissioning reserves

8.1 Introduction

At the end of the life of any NPP, nuclear fuel cycle facility or radiation facility, it needs to be decommissioned[29], decontaminated and demolished so that the site is made available for other uses.

The decommissioning activity for a NPP may be divided into three phases i.e. initial activities[30], major decommissioning as well as storage and licence termination activities.

With a view to ascertaining the adequacy of the regulatory system with regard to units relating to decommissioning, Audit mapped the institutional arrangements in India vis-à-vis the recommended practices by IAEA, examined the status of decommissioning plans of units and the issues relating to funding of decommissioning of nuclear power plants.

8.2 International scenario vis-à-vis the Indian scenario

The comparative position of the legislative framework on provisions for the safe decommissioning of facilities, safe management and disposal of radioactive waste arising from facilities and activities and safe management of spent fuel is discussed in Table 10.

[29] Discontinuation of the use of radiation equipment or installation on a permanent basis, with or without dismantling the equipment, including removal or containment of radioactive material. The term includes all clean-up of radioactivity and progressive dismantling of the plant in case of a nuclear power plant.

[30] Shut down activities like removal of radioactive fuel, study of environmental impact and identification of site-specific decommissioning activities.

Table -10

Stipulated as per IAEA	Followed in Indian context	Audit's Remarks
i. Role of the regulatory body should be clearly delineated, including the need to develop regulatory requirements and procedures for all stages of the decommissioning process. This is particularly important since decommissioning can extend over lengthy periods of time during which there should be no gaps in regulatory supervision and control.	AERB's Constitution Order of 1983 empowers it to issue codes and guides for nuclear and radiological safety, including those on decommissioning and advise AEC/DAE on technical matters including decommissioning of the plants under DAE.	-
ii. The basic structure and contents of the decommissioning plan should be codified. In view of the importance of the decommissioning plan, legislation can usefully identify key elements, although specific technical requirements could be left for implementing regulations.	The AERB Safety Manual on decommissioning of nuclear facilities has codified the basic structure and contents of decommissioning plans.	There is no legislative framework in India for decommissioning of nuclear power plants.
iii. There should be provision in law for regulatory approval for any change in ownership of a facility and responsibility of decommissioning.	There is no specific provision in law for regulatory approval for any change in ownership of a facility and responsibility of decommissioning.	Internationally benchmarked practices have not been adopted.
iv. The law should make clear how financial arrangements for decommissioning are to be handled. The law must also reflect as to how the costs of decommissioning are to be assessed, funded and managed till the time required for decommissioning.	There are no specific arrangements in law in India with regard to funding of decommissioning activity.	Internationally benchmarked practices have not been adopted.

DAE further stated (February 2012) that the Atomic Energy Act, 1962 was for all aspects of handling, use and disposal of radioactive substances, which would encompass decommissioning also. It stated that the broad scope of decommissioning was already covered in various codes and guides of AERB.

The reply of DAE needs to be viewed in the light of international practices followed in other countries i.e., USA, UK, Canada, Spain, France, etc., including countries where nuclear energy is totally under the public sector. These countries have designated competent authorities, which are often nuclear regulators, who play a major role in approving the decommissioning strategies selected; review the cost estimates developed and also review the funding mechanism used to assure adequate funding for decommissioning. While the role of regulators is generally defined by law, the roles and duties of other interested parties are generally defined by the regulator.

There is no legislative framework in India for decommissioning of nuclear power plants and AERB does not have any mandate except prescribing of codes, guides and safety manuals on decommissioning.

8.3 Non-submission of proposal for decommissioning of any nuclear facility

As per IAEA safety standards, a decommissioning plan should be developed for each nuclear facility to show that decommissioning could be accomplished safely. Further, all aspects should be taken into account for the eventual need to decommission a facility at the time it is being planned and constructed. The AERB Safety Manual on 'Decommissioning of Nuclear Facilities' was published in March 1998, to assist DAE units in formulating a decommissioning programme and in furnishing the required information to the regulatory body for authorisation for decommissioning. The manual stipulated that facilities which were already in operation should prepare preliminary decommissioning plans and submit them to AERB within five years of publication of the manual and new facilities, should do the same before the construction licences or operation licences were issued.

Of the 20 units of NPPs operating in the country at present, 10 plants came into operation before the publication of the AERB Safety Manual on 'Decommissioning of Nuclear Facilities'. None of these 10 plants had prepared preliminary decommissioning plans so far.

Ten plants, which came into operation after publication of the Safety Manual had also not prepared their decommissioning plans despite the requirement that these were to be prepared and submitted to AERB before the construction licences or operation licences were issued. This indicated that licences for operation were issued without AERB insisting upon

the submission of decommissioning plans. All NPPs in the country were operating without any decommissioning plans.

We observed that even after the lapse of 13 years from the issue of the Manual, NPCIL, the agency responsible for drawing up decommissioning plans for nuclear power plants, had not submitted decommissioning plans for any of its plants despite the fact that Tarapur Atomic Power Station (TAPS)-1 and 2 had already completed over 30 years of operation and the Rajasthan Atomic Power Station (RAPS)-1 was under shutdown condition since 2004.

AERB replied (February 2011) that the Manual published by it was advisory and neither mandatory nor recommendatory in nature.

It further stated (February 2012) that NPCIL had submitted notes on decommissioning aspects for TAPS-3 & 4, Kaiga-3 & 4, Rajasthan Atomic Power Project (RAPP)-5 & 6, Kakrapar Atomic Power Project (KAPP)-3 & 4 during the design review stage itself to AERB. As regards RAPS-1, the techno-economic feasibility of further operations was under review. As and when a decision was taken for decommissioning, detailed plans would be submitted to it for approval.

The reply of AERB only confirms that AERB does not have an adequate mandate in respect of decommissioning of NPPs, research reactors and other nuclear fuel cycle facilities. The fact remains that all the NPPs and research reactors in the country are operating without decommissioning plans and AERB, as a regulator, is not in a position to secure compliance with the provisions of its Manual on the plea that the safety of operating units does not get jeopardised in the absence of decommissioning plans. Inaction on the part of NPCIL reflects the lack of effectiveness of the regulator as there are no provisions in the Act or in the Constitution Order or in the rules which empower the regulator to ensure compliance.

Even after the lapse of 13 years from the issue of the Safety Manual by AERB, none of the NPPs in the country, including those operating for 30 years, and those which have been shut down, have a decommissioning plan.

8.4 Adequacy of decommissioning of reserves and investment of Decommissioning Fund

As per the IAEA Safety Standards/Guides, a mechanism for providing adequate financial resources should be established to cover the costs of radioactive waste management and, in particular, the cost of decommissioning. It should be put in place before operation and should be updated as necessary. Consideration should also be given to providing the necessary financial resources in the event of premature shutdown of a facility.

DAE had issued a notification in December 1988 to levy a decommissioning charge of 1.25 paise per KWH energy sold from the nuclear power stations in the country. It had revised (October 1991) the levy of decommissioning charges to 2 paise per KWH energy sold. The notification stipulated that the receipts on account of decommissioning charges should be credited to a separate fund to be known as the 'Decommissioning Fund', to be maintained by NPCIL.

We observed that NPCIL had accumulated ₹920.22 crore in the Decommissioning Fund as of March 2011, along with a corresponding earmarked investment. As per a notification dated December 1988, NPCIL was to hold and manage the Decommissioning Fund on behalf of the Government.

While reviewing the adequacy of the decommissioning reserve, we observed that the Organisation for Economic Co-operation and Development (OECD) had published a study of decommissioning of nuclear plants, in which decommissioning cost estimates by various member countries such as Belgium, Germany, Italy, USA etc had been indicated. We also observed that considering the span of the decommissioning periods, the cost of decommissioning could exceed the cost of construction of such facilities, after providing for inflation. AERB had not worked out the decommissioning cost formula in any of its documents.

We observed that NPCIL was collecting the levy amounts for decommissioning of power plants on behalf of the Government and these were being credited to the Decommissioning Fund account. An expert committee had been constituted (September 2006) by the Government to judge the adequacy of the Decommissioning Fund, among its other responsibilities.

We observed that this Committee had, in its recommendations of June 2009, expressed its inability to accurately estimate the decommissioning levy since the calculations were very sensitive to the assumptions regarding the escalation rate and the interest rate. The committee, therefore, recommended retention of the levy of 2 paise/kWh and recommended that a review should be undertaken in future when better estimates were

available for future expenditure on decommissioning at the end of reactor lives. However, no further action on the same had been taken since 2009.

Neither the Atomic Energy Act, 1962 nor the Rules framed under it had any provisions for creation and calculation of decommissioning reserves by the utilities. Besides, AERB had no role to play either in the creation of the Fund or in ensuring the adequacy of the Fund**.** We observed that DAE was continuing with the policy domain of decommissioning even after formation of AERB, which clearly indicated that the role of AERB was limited to prescribing standards, codes and guides.

DAE stated (February 2012) that the issue of decommissioning charges could be looked into.

Neither the Atomic Energy Act, 1962 nor the Rules framed thereunder have any provision for creation of decommissioning reserves by the utilities. Besides, AERB has no role to play in ensuring availability of adequate funds in it. Decommissioning charges had not been revised since 1991.

Recommendations

18. The Government may set up clear timelines within which Nuclear Power Plants, which are in operation and those which are in the course of being set up, should prepare and obtain approval for their decommissioning plans.

19. The role of AERB with reference to decommissioning may be strengthened in terms of the guidelines of the International Atomic Energy Agency in the matter.

20. The financial arrangements for decommissioning may be laid down more clearly and the decommissioning charges reviewed on a periodic basis, with a view to ensuring their adequacy.

Chapter 9: Maintaining liaisons with international bodies dealing with nuclear regulatory issues

Audit Objective- Whether the regulator has taken adequate measures for maintaining liaison with international bodies dealing with nuclear regulatory issues

9.1 India, IAEA, and international cooperation

IAEA, set up as the world's 'Atoms for Peace' organisation in 1957, has played a central role in international nuclear safety. India has been one of the member States of the agency since 1957. Article 2 of the statute of IAEA provides that it shall seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity, throughout the world.

A Handbook on Nuclear Law by IAEA stresses the need for the users of nuclear techniques and their regulators to maintain close relationships with relevant international organisations and counterparts in other States. It also stipulates that national nuclear energy legislation should make adequate provision for cooperation due to the following factors associated with nuclear activities:

- The potential for trans-boundary impacts, which require Governments to harmonise policies and develop co-operative programmes so as to reduce the risks of damage to their citizens and territories, the global population and indeed, to the planet as a whole.

- The use of nuclear material involves security risks that do not respect national borders.

After the Chernobyl nuclear accident in 1986, the global safety regime underwent vast changes. Worldwide consensus emerged on two issues relating to nuclear safety. Firstly, the need for effective international cooperation and secondly, the need to effectively separate nuclear power development from nuclear safety oversight functions. India became a signatory to different conventions and agreements, which placed obligations on it towards nuclear safety and regulation. India is currently a party to the following conventions:

In this chapter, we examine the nature of engagement by AERB with international bodies dealing with nuclear regulatory issues and the benefits that have emerged therefrom.

9.2 AERB and benefits from international cooperation

A large number of international legal instruments have been promulgated to codify the obligations of States in the nuclear field. The terms of those instruments require Governmental compliance, but may limit the discretion of legislators in framing national legislation.

In India, the Atomic Energy Act, 1962 provides that the Central Government may, by notification, make rules for carrying out the purposes of the Act, which also provides for generally promoting co-operation with other countries in the production, use and application of atomic energy as well as in research and investigations in that field. We observed that rules made thereunder such as the Radiation Protection Rules, 1971 revised as RPR 2004 and the Safe Disposal of Radioactive Waste Rules, 1987 etc. did not mention international co-operation or adherence to mutually agreed international guidelines on radiation safety.

We observed that Para 2(vi) and (xiii) of the AERB's Constitution Order provided for adopting radiological and other safety criteria recommended by the International Commission on Radiological Protection, the International Atomic Energy Agency and such other international bodies to suit Indian conditions and thereby evolving major safety policies and maintaining liaison with statutory bodies in the country as well as abroad, regarding safety matters.

We further observed that AERB was associated with the following International agencies/fora related to nuclear and radiation safety:

- International Atomic Energy Agency

- Forum for the Canada Deuterium Uranium Senior Regulators for exchange of information on issues specifically related to safety of Pressurised Heavy Water Reactors.
- United States Nuclear Regulatory Commission.
- Directorate General for Nuclear Safety and Radiation Protection, France.
- Radiation Safety Authority, Russia.

We, however, observed that though AERB maintained liaisons with international nuclear organisations, it was slow in adopting international benchmarks and good practices as has been suitably pointed out in Chapters 2, 3 and 5.

DAE stated (February 2012) that DAE and AERB were involved in IAEA's activities related to enhancement of nuclear and radiation safety. The knowledge and experience brought back by the Indian experts, who participated in the IAEA activities had a significant impact in shaping AERB's regulatory approach and framework. India had also presented its national report under the convention, for peer reviews in 2008 and 2011, wherein member states had accepted the safety record of the Indian NPPs and the efforts and initiatives of AERB, its technical support organisations and the plants for achieving the international benchmarks on safety. AERB stated that it was the first regulatory body to adopt the recommendations of the International Commission of Radiation Protection (ICRP).

DAE has mentioned the impact of the involvement of DAE and AERB with IAEA activities. However, on the key issues of regulatory independence, underpinned by the enactment of comprehensive regulations, the verification of compliance of regulation and enforcement of regulations, which are the key characteristics for an independent nuclear regulator, the AERB has been found to be sharply out of alignment with its international peers.

We have commented earlier on the fact that in contravention of the IAEA Safety Standards, AERB had not yet developed a radiation safety policy even after nearly three decades of being entrusted with this function.

Although AERB maintains liaisons with international nuclear organisations, it has been slow in adopting international benchmarks and good practices in the areas of nuclear and radiation operation.

9.3 IAEA Integrated Regulatory Review Service

IAEA, as a part of its mandate, provides safety review and appraisal services at the request of member States. In the regulatory framework and activities of the regulatory bodies, 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) service 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) service that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

IAEA's safety review and appraisal services, called the Integrated Regulatory Review Service (IRRS) aims at the following:

- to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognising the ultimate responsibility of each State to ensure the safety of nuclear facilities, protection against ionising radiation, safety and security of radioactive sources, safe management of radioactive waste and safe transport of radioactive material,

- to carry out comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues and

- to provide an opportunity for a balance between technical and policy discussions among senior regulators; sharing of regulatory experiences; harmonisation of regulatory approaches among member States and mutual learning opportunities among regulators.

IAEA offers external peer review services either of a specific regulatory activity or of the performance of a regulatory body as a whole.

We observed that 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. Sixteen countries including Canada, China, France, Pakistan, UK and USA have availed of the opportunity of benefits of IRRS missions as of 2010.

We, however, observed that AERB had not availed of the opportunity of the peer review services of IRRS to get its regulatory framework and effectiveness reviewed so far. AERB had not even conducted any self-assessment regarding its regulatory practices against the IAEA safety standards.

DAE stated (February 2012) that the Government of India had already committed to host an IRRS mission of IAEA for peer review of AERB in the near future. AERB had initiated a self-assessment exercise in 2010 in preparation of the peer review and the self-assessment was presently at an advanced stage of its regulatory framework.

The fact remains that the Committee constituted by AERB in November 2010 for internal assessment of the preparedness of AERB for IRRS had not submitted their report till date. Also, India has fallen behind many countries in availing of the opportunities of peer review of its regulatory framework by IRRS.

AERB has not yet availed of the opportunity of the peer review and appraisal services of IAEA to get its regulatory framework and its effectiveness reviewed by them.

Recommendations

21. AERB may avail of the peer review and appraisal services of IAEA to help make the nuclear regulatory infrastructure effective and sustainable.

Annex 1: AERB's regulatory and safety functions envisaged under Sections 16, 17 and 23 of the AE Act, 1962 (Refer Paragraph 1.2)

Section 16 of the AE Act, 1962: Control over radioactive substances: The Central Government may prohibit the manufacture, possession, use, transfer by sale or otherwise, export and import and in an emergency, transport and disposal, of any radioactive substances without its written consent.

Section 17 of the AE Act, 1962: Special provisions regarding safety:

(1) The Central Government may, as regards any class or description of premises or places, being premises or places, in which radioactive substances are manufactured, produced, mined, treated, stored or used or any radiation generating plant, equipment or appliance is used, make such provision by rules as appear to the Central Government to be necessary - (a) to prevent injury being caused to the health of persons employed at such premises or places or other persons either by radiations, or by the ingestion of any radioactive substance; (b) to secure that any radioactive waste products resulting from such manufacture, production, mining, treatment, storage, or use as aforesaid are disposed of safely; (c) to prescribe qualifications of the persons for employment at such premises or places and the regulation of their hours of employment, minimum leave and periodical medical examination and the rules may, in particular and without prejudice to the generality of this subsection provide for imposing requirements as to the erection or structural alterations of buildings or the carrying out of works.

(2) The Central Government may, as respects the transport of any radioactive substance or any prescribed substance specified by an order issued under this Act as being dangerous to health, make such rules as appear to be necessary to prevent injury being caused by such transport to the health of persons engaged therein and other persons.

(3) Rules made under this section may provide for imposing requirements, prohibitions and restrictions on employers, employed persons and other persons.

(4) Any person authorised by the Central Government under this section, may, on producing, if so required, a duly authenticated document showing his authority, enter at all reasonable hours any premises, or any vehicle, vessel or aircraft for the purpose of ascertaining whether there has been committed, or is being committed, in or in connection with the premises, vehicle, vessel or aircraft, any contravention of the rules made under this section.

(5) In the event of any contravention of the rules made under this section, the Central Government shall have the right to take such measures as it may deem necessary to prevent further injury to persons or damage to property arising from radiation or contamination by radioactive substances including, without prejudice to the generality of the foregoing provisions, and to the right to take further action for the enforcement of penalties under section 24, the sealing of premises, vehicle, vessel, or aircraft, and the seizure of radioactive substances and contaminated equipment.

Section 23 of the AE Act, 1962: Administration of Factories Act, 1948: Notwithstanding anything contained in the Factories Act, 1948, the authority to administer the said Act, and to do all things for the enforcement of its provisions, including the appointment of inspecting staff and the making of rules thereunder, shall vest in the Central Government in relation to any factory owned by the Central Government or any authority or corporation established by it or a Government Company and engaged in carrying out the purposes of this Act.

Annex 2 : Suggested inspection frequencies as per 'IAEA-TECDOC-1526' (Refer paragraph 5.2)

Use	Inspection frequency (in years)
Dental radiography	5
Nuclear medicine	1-2
Radiotherapy	1
Diagnostic radiology – centres with complex equipment (e.g. computed tomography, interventional radiology, fluoroscopy, mammography)	2-3
Diagnostic radiology – centres with conventional X-ray equipment only	3-5
Industrial radiography	1
Irradiators (i.e. industrial)	1
Irradiators (i.e. research)	3-5
Radiation gauges	3-5
Well logging	1-3

Annex 3: Data relating to regulatory inspection for nuclear medicine, nucleonic gauges and diagnostic radiology (X-ray equipment) conducted during the period 2005-06 to 2011-12 (Refer paragraph 5.2.2)

Diagnostic Radiology Facilities						
Year	Total No. of units	Frequency of inspection as suggested by IAEA	No. of units of RI mandated to be done	No. of RI conducted	shortfall in RI	%age of shortfall of RI
2005-06	40000	once in five years	8000	208	7792	97.40
2006-07	40000		8000	80	7920	99.00
2007-08	40000		8000	80	7920	99.00
2008-09	40000		8000	0	8000	100.00
2009-10	40000		8000	46	7954	99.43
2010-11	40000		8000	41	7959	99.49
2011-12	40000		8000	67	7933	99.16
Total	280000		56000	522	55478	99.07
Nuclear Medicine Centres						
2005-06	131	Biennial	66	40	26	39.39
2006-07	140		70	40	30	42.86
2007-08	145		73	40	33	45.21
2008-09	155		78	30	48	61.54
2009-10	177		89	41	48	53.93
2010-11	162		81	53	28	34.57
2011-12	179		90	62	28	31.11
Total	1089		547	306	241	44.06
Nucleonic Gauges						
2005-06	1386	once in five years	277	11	266	96.03
2006-07	1435		287	18	269	93.73
2007-08	1464		293	18	275	93.86
2008-09	1485		297	16	281	94.61
2009-10	1572		314	7	307	97.77
2010-11	1638		328	24	304	92.68
2011-12	1696		339	117	222	65.49
Total	10676		2135	211	1924	90.12

Annex 4: Incident of high radiation exposures in metal scrap market in Mayapuri, Delhi (Refer Paragraph 6.4.1.1)

Incident Reported

An incident involving high radiation exposure unfolded, when a message from Indraprastha Apollo Hospital, Delhi was received by Atomic Energy Regulatory Board (AERB) on 7 April, 2010. The message stated that a patient – a scrap dealer from the Mayapuri Industrial area- who was admitted in the hospital since 4 April developed symptoms suspected to be indicative of high radiation dose.

Immediate Follow Up

After confirming the information, within a few hours on the same day (7 April), two officers from AERB rushed to the Mayapuri area to assess the situation at ground zero. They carried out an extensive radiation survey in and around the scrap shop which belonged to the affected patient and identified the shops and adjoining areas where high radiation levels were prevailing. As an immediate measure, they provided shielding by covering the identified radiation hot spots to reduce radiation levels. The entire affected area was cordoned off.

On 8 April, in a joint effort, the officers of AERB, Emergency Response Centre of DAE, Narora Atomic Power Station (NAPS), National Disaster Response Force (NDRF) and Radiation Safety Systems Division of BARC, assisted by local police carried out combing operations through extensive radiation surveys. This led to the identification and recovery of most of the radioactive sources. The sources were safely recovered and transported to NAPS for safe and secure storage. By forenoon of 9 April, the area which was cordoned off earlier was cleared off radioactive materials and rendered safe as no unacceptable radiation levels in these areas were observed.

Following these events, a quick survey of the entire market area encompassing several hundred shops was carried out on 13 April to rule out the presence of additional sources. Elevated radiation level was noticed near another scarp shop, around 500 m away from the earlier shop. This led to recovery of two more radioactive sources. The sources were transported to the site of the NAPS for safe and secure storage.

Another occurrence came to light on 15 April after another shop owner of the same scrap market was admitted to a hospital in Delhi. A small Co-60 source was recovered from him.

While radiation surveys indicated absence of any more radiation sources some low level contamination left by dust particles of cobalt was detected in a number of spots.

An awareness programme was also conducted on May 6, 2010 for the Mayapuri scrap dealers on the safety aspects along with legal and regulatory requirements in possessing and handling radioactive sources.

By May 2010 the entire Mayapuri scrap market area were cleaned up - including removal of contaminated soil-and declared open for public access and habitation. By June 14, 2010, the final clean up operations at the affected shop was completed and the shop was handed over to the owner by the police. Thereafter, concretization of the road in front of the affected shops was completed.

Throughout this period, AERB issued periodic press releases to allay the apprehensions of the public and apprise them of the situation in perspective.

Furthermore, a public Notice was also issued by AERB through leading newspapers about the legal/statutory and regulatory requirement of possession, handling and disposal of radioactive sources stating clearly that possession of radioactive sources without proper licence/ authorisation / registration is an offence.

A rating of Level 4 in the International Atomic Energy Agency (IAEA) International Nuclear and Radiation Event Scale was accorded to this incident. Information regarding the above incident was also provided to the Illicit Trafficking Data Base (ITDB).

Facts Emerging From Investigations

Investigations carried out at the site of incident, discussions with the affected personnel and the inspections carried out at NAPS by officers of AERB, Board of Radiation and Isotope Technology (BRIT) of DAE and Delhi police, it was established that the radioactive Cobalt-60 (Co-60) sources recovered from the Mayapuri scrap market in Delhi were from an old gamma cell (Model No 220) made by Atomic Energy Canada Ltd which was purchased by the Chemistry Department of Delhi University in 1969. The gamma cell was being used by a Chemistry professor till his retirement. Since then it remained disused in the same room for more than 15 years till it was auctioned by the Delhi University in Feb 2010 and reached the hands of the scrap dealer who purchased it through this auction.

The whole event came to light when the gamma cell was dismantled by local workers at the metal scrap shop, leading to the highly radioactive Co-60 pencil sources coming out of the cage, causing unwarranted high exposure to seven persons (who were admitted to various hospitals in Delhi with radiation induced symptoms) of whom one succumbed to radiation sickness.

Regulatory Enforcement Actions Taken

All the radioactive sources originally present in the gamma cell of the Delhi University were recovered and accounted for their number and source strength. These sources will continue to remain in safe and secure custody of the Department of Atomic Energy. Recovery of the entire inventory present in the gamma cell was confirmed by counting of the recovered cobalt slugs in the hot cells in BARC.

The unauthorized disposal of the gamma cell by the Delhi University as a scrap is in violation of the Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987 and the RPR 2004. In view of this, AERB issued a show cause notice to the Delhi University and in the interim, advised the university to suspend forthwith all activities involving the use of radiation sources. The preliminary response submitted by the University is currently under review by AERB.

Reinforcement of Regulatory Mechanism and other

Following the Mayapuri incident, following actions have been initiated by AERB to reinforce and further strengthening of its regulatory enforcement mechanism:

- **Sensitizing all the academic, medical and R&D institutions to undertake inventory of radiation sources under their possession and review their existing safety procedures.**
- **Issuing guidelines and stipulations regarding the use and disposal of radioactive sources and making the training on radiation emergency management to be part of curriculum in medical education.**
- **Improving and intensifying the public awareness on legal, regulatory and general safety requirements vis-à-vis radioactive sources by way of issuing notices through print media and knowledge sharing through its website.**
- **Further strengthening the AERB database system of records on source inventory.**
- **Pursuing with the State Governments for the formation of Directorate of Radiological Safety and enhancing the coverage and effectiveness of inspections of radiation facilities all over the country.**
- **Instituting the Regional Regulatory Centres (RRC) in the country. RRC in East and South have been formed already. Formation of RRC in North is planned in the immediate future.**
- **Based on lessons learnt from this experience the system of response to radiation source related emergencies is further strengthened in collaboration with National Disaster Management Authority (NDMA).**

  Though not directly related with this incident, following additional actions are being pursued:

  - **Ongoing program to install radiation detection equipment at all sea ports is being re-emphasized.**
  - **Metal recycling industry has again been mobilized to install radiation detection equipment at various processing points in handling of scrap metal.**

Annex 5: Details of 'unusual occurrences' relating to 15 cases which were not recovered/found (Refer Paragraph 6.4.2)

Sl.No	Period	Details of the event
1	November 2011	M/s Petrocon Engg. & Inspection Co., Navi Mumbai reported an incident involving theft of Industrial Gamma Radiography Exposure Device (IGRED) model Delta-880 which was kept inside a four wheeler. In spite of extensive search operation conducted by M/s Petrocon Engg. & Inspection Co., and local police, exposure device could not be recovered so far. The main cause of the incident was the improper storage of the radiography exposure device.
2	January 2011	Theft of 15 nucleonic gauge sources took place from M/s Durgapur Steel plant (DSP), Durgapur. The sources were stolen by breaking the source storage room. In the search that followed, two were recovered from scrap shops at Durgapur. The main cause of the incident was the improper storage of the disused nucleonic gauge sources. AERB directed DSP to enhance their efforts to trace the remaining 13 nucleonic gauge sources and initiate corrective measures for the security of the sources in their possession.
3	October 2010	An incident of missing of five nucleonic gauges from M/s National Aluminum Company Limited (NALCO), Damanjodi, Koraput, Orissa, was reported on 5 October 2010. The five gauges were found to be missing after they were dismantled and stored for safe disposal. A show-cause notice was issued on 21 October 2010. M/s NALCO replied to show cause notice vide letter dated 2 November 2010. Efforts are still on to locate and recover the sources.
4	July 2009	On 29 July 2009, a vehicle containing IGRED model Roli-1 belonging to M/s. Indian NDT Centre (INDTC), Ghaziabad was snatched by robbers while travelling from Ghaziabad to Dehradun for carrying out radiography work. The missing IGRED could not be located despite extensive surveys.
5	September 2008	A radiographer boarding a train at Hazrat Nizamuddin railway station in New Delhi carrying an IGRED reported that it was stolen from him. The devices, and the sources within, were never found.
6	May 2008	Loss of a decayed radiography source from Perfect Metal Testing and Inspection Agency in Kolkata.
7	August 2007	An IGRED was stolen from General Industrial Inspection Bureau in Jamshedpur. The source could not be recovered 'inspite of extensive search operations by using high sensitivity radiation survey instruments'.
8	2006	A trainee radiographer and his assistant left an IGRED in an auto rickshaw. The machine was never recovered.
9	November 2006	An IGRED was stolen from a radiography agency after the machine was left lying unattended outside a dark room. The missing IGRED was never located.

10	November 2006	A nucleonic gauge was reported to be missing from a coal washery that had not been in operation since 2003. It was reported that the electronic parts associated with the gauge were stolen in 2005. Despite 'extensive radiation detection surveys' around the plant and in all scrap yards in the unspecified city, the material was never found.
11	May 2005	Two exposure devices were lost from a user's premises and were never recovered.
12	August 2005	An employee of a radiography agency steals an pigtail from a rival radiography agency in Mumbai and throws it into the Vashi creek. The source was thought to have flowed down to the sea, and was never recovered.
13	July 2002	A radiography camera was lost while being carried by a radiographer on a public bus. The device was either stolen or slipped from the improperly locked luggage compartment, and was never traced.
14	2001	A density gauge was lost in a coal washery, and never retrieved.
15	2000	A 'premier medical hospital' lost a radiation source due to 'procedural lapses'. Despite systematic search, the AERB was unable to recover the source.

Source : Annual Reports of AERB

Annex 6: Duties and functions of Radiological Safety Officers under various rules

(Refer Paragraph 6.5)

Atomic Energy (Radiation Protection) Rules, 2004 (Rule 22)

The Radiological Safety Officer shall be responsible for advising and assisting the employer and licencee on safety aspects aimed at ensuring that the provisions of these rules are complied with.

The Radiological Safety Officer shall:-

- **carry out routine measurements and analysis on radiation and radioactivity levels in the controlled area, supervised area of the radiation installation and maintain records of the results thereof;**
- **investigate any situation that could lead to potential exposures;**
- **advise the employer regarding (i) the necessary steps aimed at ensuring that the regulatory constraints and the terms and conditions of the licence are adhered to; (ii) the safe storage and movement of radioactive material within the radiation installation;(iii) initiation of suitable remedial measures in respect of any situation that could lead to potential exposures; and (iv) routine measurements and analysis on radiation and radioactivity levels in the off-site environment of the radiation installation and maintenance of the results thereof;**
- **ensure that (i) reports on all hazardous situations along with details of any immediate remedial actions taken are made available to the employer and licencee for reporting to the competent authority and a copy endorsed to the competent authority; (ii) quality assurance tests of structures, systems, components and sources, as applicable are conducted; and (iii) monitoring instruments are calibrated periodically.**
- **assist the employer in (i) instructing the workers on hazards of radiation and on suitable safety measures and work practices aimed at optimizing exposures to radiation sources; and (ii) the safe disposal of radioactive wastes; and (iii) developing suitable emergency response plans to deal with accidents and maintaining emergency preparedness;**
- **advise the licencee on (i) the modifications in working condition of a pregnant worker; and (ii) the safety and security of radioactive sources;**
- **furnish to the licencee and the competent authority the periodic reports on safety status of the radiation installation; and**
- **inform the competent authority when he leaves the employment.**

Atomic Energy (Safe Disposal of Radioactive Waste) Rules , 1987 (Rule 13)

- **to advise the employer regarding the safe handling and disposal of radioactive wastes and on the steps necessary to ensure that the operational limits are not exceeded;**
- **to instruct the radiation workers engaged in waste disposal on the hazards of radiation and on suitable safety measures and work practices aimed at minimising exposures to radiation and contamination, and to ensure that adequate radiation surveillance is provided for all radiation workers and the environment;**
- **to carry out such tests on conditioned radioactive waste, as specified by the competent authority;**
- **to ensure that all buildings, laboratories and plants wherein radioactive waste will be or are likely to be handled/produced, conditioned or stored or discharged from, are designed to provide adequate safety for safe handling and disposal of radioactive waste;**
- **to assess the radiation protection instruments required for an installation and to keep such instruments in use under proper calibration;**
- **to help investigate and initiate prompt and suitable remedial measures in respect of any situation that could lead to radiation hazards;**
- **to ensure that reports on all hazardous situations (including situations of the type referred to in rule 14 or as laid down by the competent authority regarding operational limits) along with details of any immediate remedial measures that may have been initiated are made available immediately to his employer and a copy thereof to the competent authority;**
- **to ensure that the provisions of the Radiation Protection Rules, 1971 are followed properly.**

Glossary of Terms

AE Act	Atomic Energy Act 1962
AEC	Atomic Energy Commission
AERB	Atomic Energy Regulatory Board
ARPANSA	The Australian Radiation Protection and Nuclear Safety Agency
ASN	Nuclear Safety authority of France
BARC	Bhaba Atomic Research Centre
BRIT	Board of Radiation and Isotope Technology
C&SED	Civil and Structural Engg. Division
CANDU	Canada Deuterium Uranium
CCS	Cabinet Committee on Security
CNSC	Canadian Nuclear Safety Commission
CSS	Commission on Safety Standards
CT	Computed tomography
CWMF	Central Waste Management Facility
DAE	Department of Atomic Energy
DGSNR	Directorate General of Nuclear Safety and Radiation Protection
DRS	Directorate of Radiation Safety
ESL	Environmental Survey Laboratory
FCF	Fuel cycle facilities
GBq	Gigabecquerel
GSR	General Safety Requirement
HPU	Health Physics Unit
IAEA	International Atomic Energy Agency
IAEA-CRP	IAEA Coordinated Research Programme
IAEA-TECDOC	IAEA technical documents
ICRP	International Commission on Radiological Protection
IGRED	Industrial Gamma Radiography Exposure Device
INES	International Nuclear Event Scale
IPSD	Industrial Plants Safety Division
IRRS	Integrated Regulatory Review Service
IRS	Incident Reporting System
ITSD	Information and Technical Services Division
KAPP	Kakrapara Atomic Power Project
KGS	Kaiga Generating Station
KWH	Kilowawtt hour
MAPS	Madras Atomic Power Station
NAPS	Narora Atomic Power Station

NPCIL	Nuclear Power Corporation of India Ltd.
NPP	Nuclear Power Plants
NPSD	Nuclear Projects Safety Division
NRF	Nuclear and Radiation Facilities
NSC	Nuclear Safety Commission of Japan
NSRA	Nuclear Safety Regulatory Authority
OECD	Organisation for Economic Co-operation and Development
OPSD	Operating Plants safety Division
PHWRs	Pressurised Heavy Water Reactors
PNRA	Pakistan Nuclear Regulatory Authority
RAPP	Rajasthan Atomic Power Project
RAPS	Rajasthan Atomic Power Station
RI	Regulatory Inspection
RIA	Radioimmunoassay
RPM	Radiation Protection Manual
RPR 2004	Atomic Energy (Radiation Protection) Rules, 2004
RRC	Regional Regulatory Centres
RSD	Radiological Safety Division
RSO	Radiological Safety Officer
SAAD	Safety Analysis and Documentation Division
SARCAR	Safety Review Committee for Application of Radiation
SARCOP	Safety Review Committee for Operating Plants
SRC	Safety Review Committee
SRI	Safety Research Institute
TAPS	Tarapur Atomic Power Station
US	United States of America
USNRC	United States Nuclear Regulatory Commission
WMD	Waste Management Division
WMD	Weapon of Mass Destruction