Chapter 4: Consents

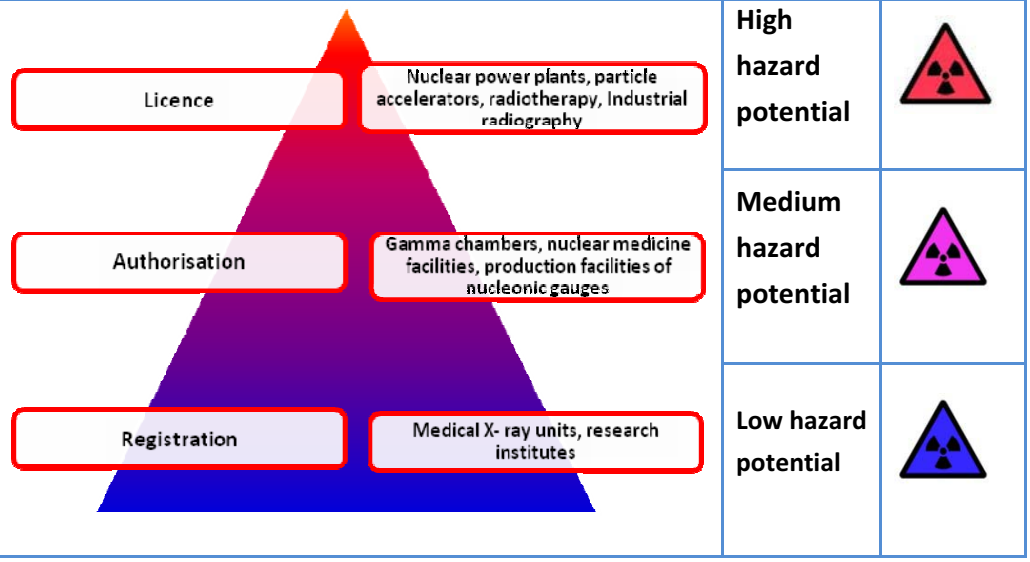
Audit Objective: Whether AERB has been able to effectively regulate nuclear and other radiation utilities through a system of consents

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:

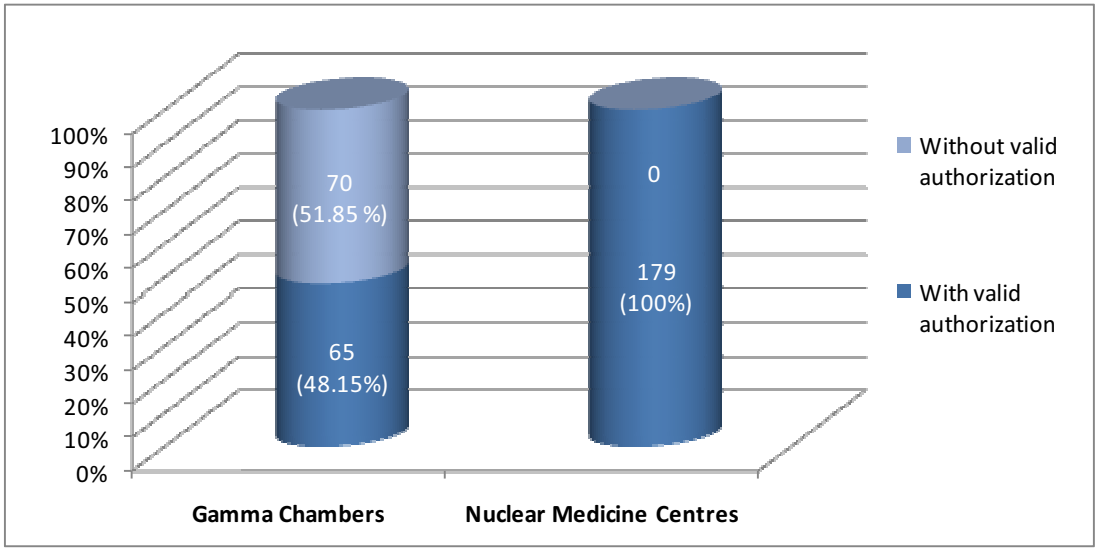
Authorisation
 Radiation hazard potential: Medium

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

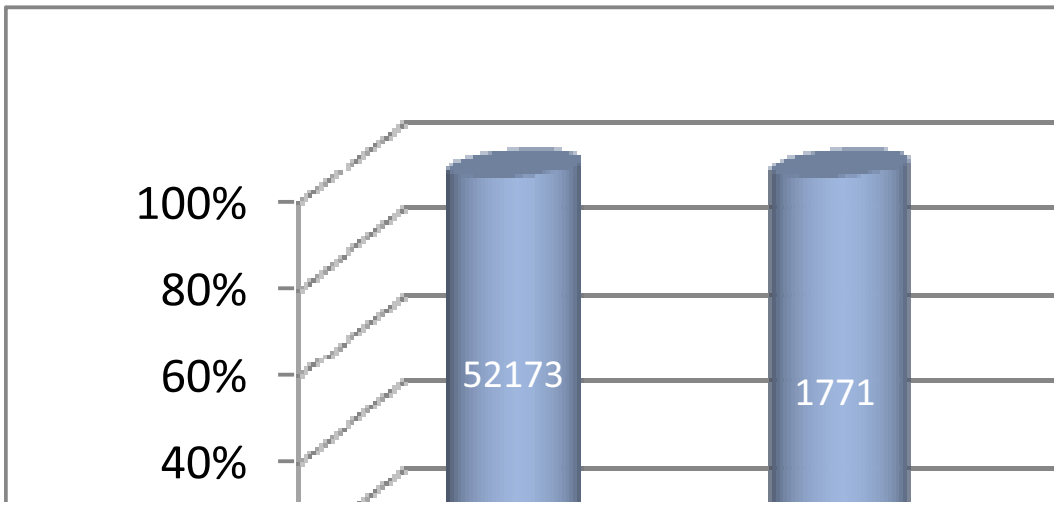
Radiation hazard potential: Low

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.