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:

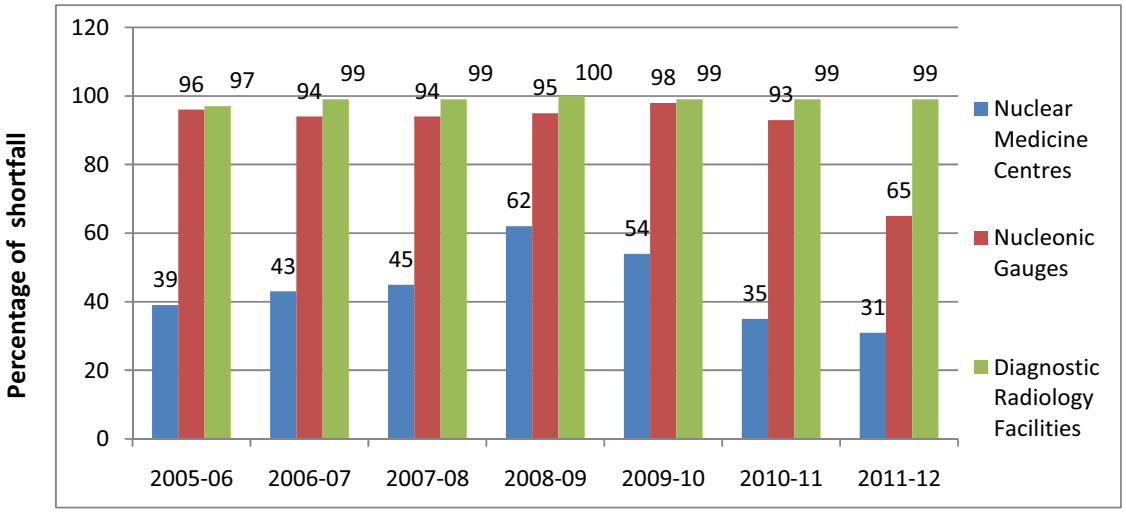
Minimum frequency norms of RIs suggested as per IAEA-TECDOC

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.