

ACTIVITIES OF ATOMIC ENERGY REGULATORY BOARD

[Action Taken by the Government on the Observations/Recommendations of the Committee contained in their 90th Report (15th Lok Sabha)]

DEPARTMENT OF ATOMIC ENERGY

**PUBLIC ACCOUNTS COMMITTEE
(2019-20)**

SEVENTH REPORT

SEVENTEENTH LOK SABHA



**LOK SABHA SECRETARIAT
NEW DELHI**

PAC NO. 2188

SEVENTH REPORT

PUBLIC ACCOUNTS COMMITTEE **(2019-20)**

(SEVENTEENTH LOK SABHA)

ACTIVITIES OF ATOMIC ENERGY REGULATORY BOARD

[Action Taken by the Government on the Observations/Recommendations of the Committee contained in their 90th Report (15th Lok Sabha)]

DEPARTMENT OF ATOMIC ENERGY



सत्यमेव जयते

Presented to Lok Sabha on:

Laid in Rajya Sabha on:

04 FEB 2020

**LOK SABHA SECRETARIAT
NEW DELHI**

February, 2020 /Magha, 1941 (Saka)

CONTENTS

	PAGE
COMPOSITION OF THE PUBLIC ACCOUNTS COMMITTEE (2019-20)	(iii)
INTRODUCTION	(iv)
CHAPTER I Report	1
CHAPTER II* Observations/Recommendations which have been accepted by the Government	
CHAPTER III* Observations/Recommendations which the Committee do not desire to pursue in view of the replies received from the Government.....	
CHAPTER IV* Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration	
CHAPTER V* Observations/Recommendations in respect of which the Government have furnished interim replies	

APPENDICES*

- I Minutes of the 11th sitting of the Public Accounts Committee (2019-20) held on 28th January, 2020.
- II Analysis of the Action Taken by the Government on the Observations/Recommendations of the Public Accounts Committee contained in their Ninetieth Report (15th Lok Sabha)

**Not appended to the cyclostyled copy of the Report*

COMPOSITION OF THE PUBLIC ACCOUNTS COMMITTEE
(2019-20)

Shri Adhir Ranjan Chowdhury - Chairperson

MEMBERS

LOK SABHA

2. Shri T. R. Baalu
3. Shri Subhash Chandra Baheria
4. Shri Sudheer Gupta
5. Smt. Darshana Vikram Jardosh
6. Shri Bhartruhari Mahtab
7. Shri Ajay (Teni) Misra
8. Shri Jagdambika Pal
9. Shri Vishnu Dayal Ram
10. Shri Rahul Ramesh Shewale
11. Shri Rajiv Ranjan Singh alias Lalan Singh
12. Dr. Satya Pal Singh
13. Shri Jayant Sinha
14. Shri Balashowry Vallabhaneni
15. Shri Ram Kripal Yadav

RAJYA SABHA

16. Shri Rajeev Chandrasekhar
17. Prof. M. V. Rajeev Gowda
18. Shri Naresh Gujral
19. *Vacant**
20. Shri C. M. Ramesh
21. Shri Sukhendu Sekhar Ray
22. Shri Bhupender Yadav

SECRETARIAT

- | | | |
|----|-------------------------|--------------------|
| 1. | T.G. Chandrasekhar | - Joint Secretary |
| 2. | Shri M.L.K. Raja | - Director |
| 3. | Smt. Alok Mani Tripathi | - Deputy Secretary |

* Shri Bhubaneswar Kalita ceased to be a Member of Committee consequent upon his resignation from Rajya Sabha on 05 August, 2019

INTRODUCTION

I, the Chairperson, Public Accounts Committee (2019-20), having been authorised by the Committee, do present this Seventh Report (Seventeenth Lok Sabha) on Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Ninetieth Report of the Public Accounts Committee (Fifteenth Lok Sabha) on **"Activities of Atomic Energy Regulatory Board"** relating to Department of Atomic Energy.

2. The Ninetieth Report was presented to Lok Sabha/laid in Rajya Sabha on 9th December, 2013. Replies of the Government to all the Observations/Recommendations contained in the Report were received. The Public Accounts Committee considered and adopted the Seventh Report at their sitting held on 28 January, 2020. Minutes of the sitting are given at Appendix-I.

3. For facility of reference and convenience, the Observations and Recommendations of the Committee have been printed in thick type in the body of the Report.

4. The Committee place on record their appreciation of the assistance rendered to them in the matter by the Office of the Comptroller and Auditor General of India.

5. An analysis of the action taken by the Government on the Observations/Recommendations contained in the Ninetieth Report of the Public Accounts Committee (Fifteenth Lok Sabha) is given at *Appendix-II*.

NEW DELHI;
30 January, 2020
10 Magha, 1941 (Saka)

ADHIR RANJAN CHOWDHURY
Chairperson,
Public Accounts Committee

CHAPTER - I

REPORT

This Report of the Public Accounts Committee deals with action taken by the Government on the Observations/Recommendations of the Committee contained in their Ninetieth Report (Fifteenth Lok Sabha) on “**Activities of Atomic Energy Regulatory Board**” based on C&AG's Report No. 9 of 2012-13 relating to the Department of Atomic Energy (DAE).

2. The Ninetieth Report (Fifteenth Lok Sabha) was presented to Lok Sabha/laid in Rajya Sabha on 9th December, 2013. It contained 18 Observations/Recommendations. Action Taken Notes in respect of all the Observations/Recommendations have been received from the Department of Atomic Energy and are broadly categorized as follows:

- (i) Observations/Recommendations that have been accepted by the Government:

Paragraph Nos. 1, 6, 7, 8, 9, 12, 13, 16 and 18

**Total: 09
Chapter- II**

- (ii) Observations/Recommendations which the Committee do not desire to pursue in view of the replies received from the Government:

-NIL-

**Total: 00
Chapter- III**

- (iii) Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration:

Paragraph Nos. 2, 4, 5, 10, 14, 15 and 17

**Total: 07
Chapter- IV**

- (iv) Observations/Recommendations in respect of which the Government have furnished interim replies:

Paragraph Nos. 3 and 11

**Total: 02
Chapter- V**

3. Action Taken Notes (ATNs) in respect of all the Observations/Recommendations are to be submitted by the concerned Ministry/Department i.e. Department of Atomic Energy within six months of presentation/laying of the Ninetieth Report to the Parliament i.e. by 9th June, 2014. However, the ATNs were received after a lapse of four years and five months, after a series of correspondences and were furnished in the first instance by the Office of the C&AG of India vide their letter dated 25.09.2018 and then by the Department of Atomic Energy vide their letter dated 08.01.2019.

4. The Action Taken Notes furnished by the Department of Atomic Energy on the Observations/Recommendations of the Committee contained in their Ninetieth Report (Fifteenth Lok Sabha) have been reproduced in the relevant Chapters of this Report. The Committee will now deal with the Action Taken by the Government on some of their Observations/Recommendations which either need reiteration or merit comments.

5. The Committee desire that the Department of Atomic Energy should ensure timely submission of Action Taken Notes in future and recommend that final Action Taken Notes in respect of Observations/Recommendations contained in Chapter I and final action taken replies in respect of Observations/Recommendations contained in Chapter V for which interim reply had been given by the Government be furnished within six months of the presentation of the Report to the House. The Committee further desire that clarifications sought for by audit on the Observations/Recommendation of Public Accounts Committee contained in Paragraphs numbers 8,9 and 13 of their 90th Report may be furnished.

**I. Grant of Independent status to AERB
(Recommendation Para No. 2)**

6. In their earlier Report, the Committee found that while Countries such as Australia, Canada, France, United States of America, etc. had already conferred legal status to their nuclear regulating bodies by enacting appropriate laws in recognition of the paramount need for independent and empowered regulatory bodies as stressed by the International Atomic Energy Agency (IAEA), the legal status of AERB of India remains that of a mere subordinate Authority with powers delegated to it by the Central Government. The Committee observed that the failure to have an autonomous and independent regulator was clearly fraught with grave risks as brought out poignantly in the report of the Fukushima Nuclear Accident Independent Investigation Commission. The Committee were dismayed to find protracted delays in the DAE's efforts to confer statutory status with enhanced legal powers to AERB. The Committee also noted that under the AE Act, 1962, the powers conferred for imposition

of penalty vests with the Central Government and not with the AERB. Moreover, the process of enforcement as available under penal Sections 24 and 30 (3) of the Act were also available with the DAE and not with AERB. Mindful of the fact that an independent regulator should have adequate powers to frame rules, enforce compliance and impose appropriate penalties, the Committee observed that such systemic lacunae in the legislative framework stands in the way of AERB being truly an independent and effective regulator. The Committee further noted with profound concern that even after a lapse of more than three decades after the Meckoni Committee Report of 1981, which recommended creation of AERB with statutory status and powers to lay down safety standards, the matter continued to hang in the balance. Admittedly, while AERB never found its present status to be an impediment in the discharge of its assigned responsibilities in an autonomous, professional and effective manner as was evident from the numerous regulatory enforcement actions taken by it with respect to nuclear power plants and radiation installation with even shutdown orders of plants or suspension of their activities, the Nuclear Safety Regulatory Authority Bill (NSRA), 2011 which seeks to confer statutory status to the regulator was introduced in Lok Sabha on 7 September, 2011. The Department related Parliamentary Standing Committee (DRSC) on Science and Technology in their 221st Report on the NSRA Bill, 2011 observed that the Bill by and large seemed to meet three out of the four core values viz. competence, stringency and transparency, but it still lacks somewhat on the count of independence. The dissenting minute appended to the said report of the Standing Committee pointed out categorically, that unless clauses 14, 42 and 48 of the Bill were fully deleted or drastically amended, the NSRA would have no meaningful autonomy. The Committee were assured that the Department of Atomic Energy have initiated the process of formulating amendments to accommodate the recommendations of the Standing Committee in consultation with the Ministry of Law and Justice. Taking note of the grave structural lacunae and weaknesses in the legislative framework intended to avert nuclear accidents, the Committee concurred with the recommendation of the Standing Committee on Science and Technology that the Regulating Authority should be more independent and autonomous so that it functions effectively, builds greater credibility and inspires public trust. The Committee, therefore, recommended that the DAE should seriously re-examine the provisions of the Bill and take necessary steps urgently so as to ensure that the nuclear regulator becomes an independent and credible body at par with similar regulators in other Countries.

7. The Department, in their Action Taken Note, have submitted as under:

"The Nuclear Safety Regulatory Authority Bill, 2011 (NSRA Bill) was introduced in the Lok Sabha on 7 September 2011. The Bill was examined by the Department related Parliamentary Standing Committee on Science and Technology. The observations/recommendations of the Department-related Parliamentary Standing Committee on the said Bill were carefully noted and studied, based on which certain official amendments were proposed to the Bill with the approval of the Union Cabinet. Notifications to the Lok Sabha Secretariat for consideration of the amendments and the passing of the Bill were duly issued during the Budget, Monsoon and Winter sessions of Parliament in 2013.

Subsequently, after fresh rounds of consultations the Department proposes to move the NSRA Bill 2015 in the Parliament shortly.

The Department is in the process of obtaining necessary administrative approvals before re-introduction of the Bill in the Parliament. On receipt of the requisite clearances, the Bill will be introduced immediately.

The final outcome in respect of the Bill can be reported after introduction of the Bill in the Parliament.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. On receipt of recommendations of internal Committee, a new NSRA Bill, will be considered for introduction in the Parliament after observing all necessary formalities.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. The internal Committee constituted under the chairmanship of Dr. R.B. Grover, former DAE Homi Bhabha Chair Professor and Member, Atomic Energy Commission (AEC) to re-examine the draft Bill, submitted its report and is being examined."

8. The Committee note with deep concern that till the above cited reply was submitted the Government has not conferred legal status to the Atomic Energy Regulatory Board (AERB) by enacting laws for the regulatory body's independence and autonomy as per the laid down rules/guidelines by the International Atomic Energy Agency (IAEA). They are disconcerted to note that Government has not taken any cognizance of the Meckoni Committee Report, 1981, which specifically stipulated statutory status and laying down of safety standards. The Nuclear Safety Regulatory Authority Bill (NSRA), 2011, which was introduced in Lok Sabha in September, 2011 lacked independence thereby contravening its autonomy as rightly pointed out by the Department related Parliamentary Standing Committee (DRSC) on Science and Technology in their 221st Report. Moreover, they would specifically like to point out

that the bill was re-introduced in the Parliament in 2013 as well as in 2015 with amendments but eventually it could not be enacted as legislation. They would like to know the reasons for which the Department withdrew the bill for re-examination and desire that they be apprised of the Grover Committee Report on the Nuclear Safety Regulatory Authority (NSRA) Bill. The Committee, while reiterating their earlier recommendation, desire that the Government should introduce the amended NSRA Bill at the earliest available opportunity so that the AERB is conferred legal status which may effectively empower the regulator to frame rules, enforce compliance and impose appropriate penalties. They would like to impress upon the Government that being an independent regulator, IAEA would solicit international cooperation in nuclear energy field, which is in consonance with the guidelines of IAEA.

II. Nuclear and Radiation Safety Rules

(Recommendation Para No. 4)

9. In their Ninetieth Report the Committee were concerned to note that AERB did not have any authority for framing rules relating to nuclear and radiation safety as the rule-making power under Section 30 of the AE Act, 1962 vests with the Central Government, that is, with the DAE and the AERB is involved in the consultative process. The Committee had also noted delay by the DAE in designating AERB as the Competent Authority in respect of the Atomic Energy (Radiation Protection) Rules, 2004 leaving gaps in the accountability regime during the intervening period. The Committee further noted the ambiguity in the Atomic Energy (Radiation Protection) Rules, 2004 wherein the word 'any person' in Rule 30 left the definition of competent authority to inspect premises, radiation installation and conveyances rather vague and unspecific. In terms of the oft-repeated recommendation of the Committee on Subordinate Legislation, Lok Sabha (COSL) provisions in rules should not be vague or ambiguous capable of tolerating different interpretations. The Committee had hoped that as assured by DAE, a new set of rules devoid of such lacunae would be promulgated on enactment of the NSRA Bill, replacing the RPR, 2004. The Committee also desired that the DAE should take appropriate steps to review and scrutinize all their existing rules and regulations and confer necessary powers on the AERB so that all such lacunae were corrected expeditiously.

10. The Department, in their Action Taken Note, have submitted as under:

"The views of the Committee have been noted and, as advised, these aspects will be addressed in the new set of rules that would be promulgated after enactment of the NSRA Bill.

The Rules will be framed after passage and enactment of the NSRA Bill in the Parliament and notification thereafter.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. On receipt of recommendations of internal Committee, a new NSRA Bill, will be considered for introduction in the Parliament after observing all necessary formalities.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. The internal Committee constituted under the chairmanship of Dr. R.B. Grover, former DAE Homi Bhabha Chair Professor and Member, Atomic Energy Commission (AEC) to re-examine the draft Bill, submitted its report and is being examined."

11. The Committee highlight the fact that AERB is still not been vested with powers for regulating nuclear and radiation safety in the Country. Rather, the Union Government is mandated by the internationally constituted guidelines to entrust an independent and a specialized agency with necessary authority that is required for enactment of rules, verification for compliance and strict enforcement of rules. The Committee are unable to understand reasons for such inordinate delay on the part of the Union Government to bring in the NSRA Bill inspite of the fact that Dr. R.B. Grover Committee re-examined the Bill and submitted its report for further scrutiny of the Bill. They, therefore, once again re-iterate that the Government expeditiously bring the NSRA Bill in the Parliament for conferring the necessary powers to AERB.

**IV. Need for a Deterrent Fine
(Recommendation Para No. 5)**

12. The Committee noted with deep concern that in terms of Section 30 (3) of AE Act, 1963, the penalty for contravention of the provisions of the Act and Rules made thereunder remained abysmally low at a maximum fine of Rs. 500. Obviously, such undetering penalties for contraventions related to nuclear and radiation facilities involving substantial risks only points to the systemic weakness in the legal framework of the Country's nuclear

regulatory oversight mechanism. Surprisingly, the Committee found that in 50 years of operation of DAE and 29 years of existence of AERB, the penal provisions under Section 24 or 30 (3) of AE Act, 1962 were never invoked, rendering the penal provision virtually a dead letter. The Committee were informed that AERB had been using far more effective enforcement actions such as suspension/withdrawal of consents and curtailment of operations as the preferred tool for ensuring compliance, the economic penalty of which was huge with potential of seriously affecting the financial health of stakeholders. Apparently, such a contention of AERB makes the penal provision relating to fine redundant compared to the economic penalty. The Committee, therefore, recommended that the penal provisions in the NSRA Bill, 2011 may be relooked so that the proposed new law contains a sound provision to act as an effective deterrent against the violators. The Committee further desired that such provisions should be adequately published and made known to all concerned including Institutes, Academicians, Facilities as well as the public in general.

13. The Department, in their Action Taken Note, have submitted as under:

"Suitable penal provisions will be incorporated in the NSRA Bill.

Presently, in addition to section 30(3) of the Atomic Energy Act, 1962, AERB is empowered to act against offenders in terms of section 24 of the said Act that deals with "Offences and Penalties" and provides for imprisonment or fine, or both for certain violations.

Steps being taken by AERB to bring the Enforcement and Penal Provisions to the attention of Stakeholders:

AERB is currently taking following steps towards publicising that non-adherence to the conditions of license, safety codes and standards and applicable Rules would invite enforcement action by AERB.

- The licenses issued by AERB currently for radiation facilities include a specific clause to the effect that deviating from the license conditions, the provisions of the Atomic Energy (Radiation Protection) Rules, 2004 and the applicable Codes and Standards of AERB, would invite enforcement action by AERB.
- The communications / directives sent to the licensees of radiation facilities also include a very clear statement that failure to comply with the directives / licensing conditions would invite enforcement measures such as suspension of the activity / withdrawal/ modification of license, etc.
- The licenses as well as the directives issued by AERB to the licensees presently include advisory to the licensees regarding the penal provisions applicable for violation of the provisions of the Act, Rules and regulatory requirements.
- AERB has also put out notices in the leading newspapers, notifying the users of radiation sources and radiation generating equipment, with the aim of giving publicity to the importance of adherence to the legal and safety requirements as well as the regulatory enforcement and penal provisions for contravention.
- WARNING was put out in leading newspapers specifically, to target the stakeholders of X-ray equipment including the (manufacturers, suppliers and utilities for enforcement actions in case of non-compliance with regulatory requirements.

Following this AERB has carried out special inspections in different parts of the country since April 2015 and has sealed X-ray equipment in 68 medical diagnostic facilities, which were not complying with AERB requirements.

- AERB is taking up revision of the relevant formats for issuance of license (included in the AERB Safety Guide AERB/SG/G-7 on "Regulatory Consents for Nuclear and Radiation Facilities: Contents and Formats", to include this aspect suitably in the format.

- AERB is planning to include the aspect of enforcement and penal provisions that would be applied for violation of the legal provisions, licensing condition and / or requirements of safety codes / standards, prominently in its public website."

14. The Committee observe that Sections 24 and 30 (3) of the Atomic Energy Act, 1962, provide for imprisonment and fine or both for certain violations. In their Action Taken Notes, the Ministry has further informed the Committee that AERB was taking up revision of the relevant formats for issuance of license. They also noted that AERB was planning to include the aspect of enforcement and penal provisions that would be applied for violation of the legal provisions, licensing condition and/or requirements of safety codes/standards that are prominently displayed in its website. They observe that the Ministry has conveyed that the 1962 Act covers all aspects for the regulation of atomic energy. However, as per its own submission the Ministry have proposed to Cabinet to revise and include new aspects in NSRA Bill. This, the Committee feel are contradictory. The Committee are of the opinion that the Atomic Energy Act, 1962 has become archaic in the present times and desire that suitable amendments be carried out in the Act and a new NSRA Bill be brought urgently to address the issues and to streamline nuclear energy regulation.

V. Monitoring of Medical X-ray Units
(Recommendation Para No. 10)

15. The Committee were deeply concerned to note that the regulatory mechanism concerning X-ray units was virtually non-existent. Out of a total of 57,443 medical X-ray facilities operating in the Country, only 5270 units had been registered and were under the regulatory control of AERB, leaving the balance 52,173 units constituting almost 91% of the total units without registrations. The representatives of AERB admitted that with its centralized workforce of 300 engineers and scientists, it was impossible to regulate 57,443 odd X-ray machines. The marked accelerated growth of ionising radiation such as medical X-rays used as an essential diagnostic tool pose risks to health of workers and the public in the vicinity of these facilities. Surprisingly, even after the Supreme Court directive for setting

up a Directorate of Radiation Safety (DRS) in each State for regulating the use of medical diagnostic X-rays, the Committee find that out of 28 States and 7 Union Territories, DRS have been set up only in Kerala and Mizoram. The Committee were however, assured that the roadmap to bring medical X-ray facilities under AERB's regulatory control includes inter-alia steps to enhance awareness levels on regulatory requirements related to diagnostic x-ray facilities, through advertisements in the newspapers, awareness programmes and information provided in AERB website; simplification of regulatory requirements for the end-users of diagnostic x-ray facilities; regulatory control on manufacturers/suppliers, through type approval of the equipment and arrangements for sharing information on the purchasers/users of x-ray equipment; development of an easy and approachable interface for the users to facilitate online filing of application for obtaining Registration, using the new web based interactive system (e-LORA i.e. e-licensing of radiation applications); establishment of an accreditation programme for the agencies involved in providing quality assurance services; decentralisation of regulatory functions with the establishment of Regional Regulatory Centres (RRCs) and State level Directorates of Radiation Safety (DRS); rationalization and simplification of the existing regulations for users in diagnostic x-ray practice, by way of amendments of AERB Safety Code; enhancing regulatory control on manufacturers/suppliers as well as users; etc. The Committee hoped that the AERB's roadmap for regulating control of Medical X-ray units, hitherto effectively out of their ambit would fructify in the near future. The Committee also urged that the process of setting up Directorates of Radiation Safety in all the States as per the Supreme Court directive may be expedited. Taking note of lack of proper linkage between AERB and the Ministry of Health on issues related to Public Health due to radiation, the Committee desired that appropriate institutional mechanism be set up providing for healthy exchange of information and the Committee apprised.

16. The Department, in their Action Taken Note, have submitted as under:

"Implementation of Roadmap for Regulation of Diagnostic X-ray Facilities:

In 2012, AERB had drawn out a road map to achieve effective regulation of the Xray units over the past 3-4 years. The actions points included:

- i) Building of infrastructure,
- ii) Streamlining of regulations,
- iii) Spreading of Awareness and support in organising training programs and
- iv) Surprise inspections and Enforcement Actions

The detailed actions carried out in the recent past is given below:

A) Building of infrastructure:

a) E-Licensing of Radiation Facilities: e-Licensing of Radiation Applications (eLRA) has been made functional for faster and easy on-line processing of licensing applications. Presently, more than 35,000 x-ray equipment have got declared through this system and Licence/ Registration of more than 23,500 equipment were issued

b) Establishment of Regional Regulatory Centres (RRC) of AERB and State level Directorate of Radiation Safety (DRS). The RRC will ensure effectiveness in implementation of regulation in and around the region. Presently, the Northern, Eastern and Southern RRCs are functional.

c) Authorisation of 79 Service agencies many of whom carry out Quality Assurance of diagnostic x-ray equipment, at the utility end. It is mandatory to have a valid and acceptable QA report of medical diagnostic x-ray equipment in order to obtain an AERB License/Registration

d) AERB is in the process of bringing the Manufacturers and Suppliers under regulatory control, which would ensure only AERB Type approved (design approved) equipment are being marketed in the country.

e) AERB is also in the process of instituting the requirement of import permission for all X-ray equipment/X-ray tubes being brought into the country, through interaction with the Director General of Foreign Trade (DGFT).

ii) Streamlining of regulatory requirements for X-ray Facilities

AERB has streamlined and reviewed the regulatory requirements for all facilities for which a directive has been issued indicating optimized layout, shielding and RSO requirements. The guidelines are also put up on the AERB website. AERB has recently revised the safety code on medical diagnostic X-ray facilities, incorporating the revised requirements. The document is under publication.

iii) Spreading awareness:

a) AERB is continuing with an outreach programme directed at communicating the regulatory and safety requirements to all the stakeholders.

b) AERB has put out many notices in the newspapers in the past one year and have extended advertisements to health magazines and associations related to Medical physics and Medical imaging to further enhance awareness about the AERB requirements to all stakeholders.

c) AERB has put out warning-notices in the leading newspapers for the stakeholders, who have not obtained AERB licences, iv) Surprise Inspections and Enforcement Actions:

AERB recently conducted many campaigns of surprise inspections of the medical diagnostic facilities at Mumbai, Jaipur, Raipur, Pune, Nagpur, Chennai, Bengaluru, Hyderabad, New Delhi, Kolkata, Patna, Ranchi, Gaya, Goa, and Ahmedabad during April 2015 to January, 2016. During these inspections, AERB noted that some of the X-Ray facilities were not possessing the requisite License/Registration' from AERB and were also not conforming to radiation safety requirements specified by AERB. AERB has sealed medical diagnostic equipment in 68 medical diagnostic facilities and issued warnings to 60 medical diagnostic X-ray facilities to comply with the requirements. AERB would be continuing similar surprise inspections of Medical diagnostics X-Ray facilities in other areas in the country in a phased manner.

Setting up of Directorates of Radiation Safety(DRS) at States:

As of February, 2016, DRS have been established in six states, i.e. Kerala, Mizoram, Chhattisgarh, Tripura, Punjab and Arunachal Pradesh. In addition, AERB has signed MoUs with the Governments of (1) Madhya Pradesh, (2) Tamil Nadu, (3) Punjab, (4) Himachal Pradesh, (5) Gujarat, (6) Maharashtra and (8) West Bengal. AERB is

pursuing for signing of MoU for establishment of DRS with the remaining State/UT Governments, of which Haryana and Uttar Pradesh are in an advanced stage. AERB is also pursuing with the Governments that have already entered into MOUs to establish the respective DRS as early as possible.

In addition, a letter was written by Secretary, AERB on Nov.7, 2013 to all States/UTs for sending a list of diagnostic x-ray facilities in their States/UTs. A few States/UTs responded as on date (Daman & Diu, Goa, Lakshadweep, West Bengal, and Dadra & Nagar Haveli).

The practical issues identified in relation to the formation of DRS are generally related to the respective State governments. They are as follows:

- Financial burden to the State Governments/UTs
- The frequent change of Principal Secretaries of the Health and Family Welfare department of the States/UTs
- The administrative delays in processing and getting financial sanctioning from the respective State Governments /UTs
- The undue delay in the recruitment process of DRS staff

AERB is continuing to follow-up with the State/UT Governments further to speed up the process.

Recently, in a meeting arranged by the Cabinet Secretary (on March 25, 2014), Ministry of Home Affairs was requested join DAE and AERB in following up the issue with the State Governments.

Institutional Mechanism for linkages between AERB and the Ministry of Health:

Currently there are mechanisms with the AERB officers participating in certain activities coming under the Ministries of Health and Family Welfare, like the Technical Committee of National Accreditation Board for Hospitals and Healthcare providers (NABH) and the National Technical Committee for Development and Review of Standards for Diagnostic Centres and the Technical committee of the National Health Scheme Resources centres etc. Similarly, the officials from the Ministry of Health are also being inducted into certain committees of AERB.

AERB has also extended the current level of interaction and is identifying a list of issues of common interest to both AERB and the Ministry of Health. Some of the issues identified in this regard include (a) radiation safety of the patients, (b) support from the Health Ministry for ensuring compliance to regulatory and radiation safety requirements (c) use of refurbished equipment for diagnostic and interventional radiology, etc.

AERB also represents in various technical committees set by Bureau of Indian Standards (BIS), for adopting international standards.

A formal exchange mechanism with Ministry of Health is in place as one of the senior official of DHS is a member of AERB Apex committee. This has ensured exchange of information and sharing of expertise on issues of common interest.

AERB has also participated in the Vice chancellor conclave, Association of Indian Health Sciences universities, AIHSU. in Delhi to discuss the importance of implementation of mandatory rules and regulations of AERB in health care institutions of India. The participation paved way for putting across AERBs position on the incorporation of radiation safety as part of the curriculum in various medical and para-medical courses held by Health Sciences Universities.

Presently Directorate of Radiation Safety (DRS)/ Radiation Safety Agency (RSA) is functioning in six states viz. Kerala, Chhattisgarh, Tripura, Arunachal Pradesh, Mizoram and Punjab. In addition, MoU was signed by AERB with Department of

Health & Family Welfare in seven states viz. Gujarat, Maharashtra, Orissa, Tamil Nadu, West Bengal, Himachal Pradesh and Madhya Pradesh. The status of formation of DRS in some states is as follows:

a) Madhya Pradesh and Tamil Nadu are in the process for recruitment of staff for DRS. b) Daman and Diu had communicated for attaching their DRS activities with Gujarat.

Meanwhile, AERB had brought about radical initiatives for regulation of medical diagnostic X-ray facilities in the country, which are proving to be extremely effective. While, DRS was conceived in the year 1992, with availability of advanced communication/ IT technology, AERB has devised and implemented in 2013, an easy and approachable interface for the user in the new web based system. Due to proactive approach of AERB, several institutions have come forward and initiated the process to acquire the registration/license for operating the medical diagnostic equipment. The following are in the initiatives.

a) e-LORA (e-Licensing of Radiation Applications e-LORA) which is fast and facilitates on-line processing of licensing applications b) Establishment of Northern, Eastern and Southern AERB Regional Regulatory Centres which carry out Regulatory inspections c) Wide coverage and outreach through media d) Enforcement actions on non-compliant institutions.

These efforts and actions are indicating satisfactory effectiveness as seen by the rise in the number of Licences (as given in para 8)

Towards DRS/RSA, following efforts/actions have also been taken:

a) AERB had sent a booklet to the Principal/Chief Secretary (Health) of all States detailing the requirements of DRS in October 2002. Information on the Kerala model of DRS was also sent to all the States.

b) AERB communicated again to all the states in 2010 for formation of DRS. DRS/RSA of five states were authorized by AERB during 2011-15.

c) AERB has organised periodic workshops in 2005, 2009 and the latest in 2015, for voluntary participation of all the States to discuss on the issues of formation of DRS.

d) The states where DRS is functional have also been provided with access to AERB's e-LORA system.

Presently Directorate of Radiation Safety (DRS)/ Radiation Safety Agency (RSA) is functioning in six states viz. Kerala, Chhattisgarh, Tripura, Arunachal Pradesh, Mizoram and Punjab. In addition, MoU was signed by AERB with Department of Health & Family Welfare in eight states viz. Gujarat, Maharashtra, Orissa, Tamil Nadu, West Bengal, Himachal Pradesh, Madhya Pradesh and Andhra Pradesh. The status of formation of DRS in some states is as follows:

a) Madhya Pradesh and Tamil Nadu are in the process for recruitment of staff for DRS.

b) Daman and Diu had communicated for attaching their DRS activities with Gujarat.

These efforts and actions are indicating satisfactory effectiveness as seen by the rise in the number of Licences (as given in para 8)

Towards DRS/RSA, following efforts/actions have also been taken:

a. AERB had sent a booklet to the Principal/Chief Secretary (Health) of all States detailing the requirements of DRS in October 2002. Information on the Kerala model of DRS was also sent to all the States.

b. AERB communicated again to all the states in 2010 for formation of DRS. DRS/RSA of five states were authorized by AERB during 2011-15.

c. AERB has organised periodic workshops in 2005, 2009 and the latest in 2015, for voluntary participation of all the States to discuss the issues of formation of DRS. The states where DRS is functional have also been provided with access to AERB's eLORA system.

DRS has been established in the state of Andhra Pradesh. However, States/UTs, in general, are not responding to AERB for formation of DRS. Even the states which had earlier signed MoU on formation of DRS, have not approached AERB for renewal. The difficulties stated by the State Governments are financial constraints and lack of requisite trained manpower to sustain the state DRS.

AERB, in parallel, as part of its efforts towards 'Maximum Governance, Minimum Government' has established other effective regulatory and monitoring mechanisms to meet the intent as follows:

a) Deployment of a web-based interactive licensing system for radiation facilities including medical x-ray facilities named as eLORA, i.e. e-Licensing of Radiation Applications, which can be accessed by every X-ray facility owner all over the country. As the entire on-line system is transparent, user friendly, the process of filing of applications and obtaining licences is extremely simplified.

b) AERB has already established three Regional Regulatory Centres at Chennai, Kolkata and New Delhi to provide effective radiation surveillance to radiation facilities and conducts inspections for better regulatory coverage and oversight on x-ray facilities in the regions. Further, AERB, as a campaign, carried out enforcement actions such as "Seal of the equipment" to non-compliant institutions, in different states across the country. This has impacted positively for compliance of regulatory requirements by x-ray institutions.

In view of the above initiatives, the objective of monitoring of X-ray installations across the country from radiological safety view point is being achieved even when States/UTs are not showing much interest in formation of DRS."

17. The Committee appreciate the steps taken by the Ministry for regulating diagnostic X-ray facilities in the country such as e-licensing, establishment of Regional Regulatory Centres (RRC) of AERB and State level Directorate of Radiation Safety (DRS), authorisation of 79 Service agencies to carry out Quality Assurance of diagnostic x-ray equipment at the utility end, bringing the manufacturers and suppliers under regulatory control, which would ensure only AERB approved equipments are marketed in the country and instituting the requirement of import permission for all X-ray equipment/X-ray tubes being brought into the country, through interaction with the Director General of Foreign Trade (DGFT). However, they feel that more concerted efforts are still required to streamline the regulatory requirements for medical X-ray facilities as the Directorate of Radiation Safety (DRS) has been established only in six states *viz.* Kerala, Chhattisgarh, Tripura, Arunachal Pradesh, Mizoram and Punjab as of February 2016 inspite of the fact that AERB had communicated to all States regarding requirement of DRS way back in October 2002

and again in 2010. The Committee would like to register their disquiet over the fact that despite such measures taken, the States/UTs, in general, were not responding to AERB for formation of DRSs and even the States which had earlier signed the MoU on formation of DRSs, had not approached AERB for renewal. The Committee also take note of the difficulties such as financial constraints and lack of requisite trained manpower to sustain the DRSs faced by the State Governments/UTs. The Committee are of the considered view that continuous follow-up is required by AERB with the State/UT Governments to speed up the process of DRS formation in the remaining states. The Committee opine that a new law was needed for effective regulatory and monitoring mechanisms and recommend that the Government should bring the NSRA Bill at the earliest so that a new law is brought into effect which is in consonance with the changing times.

**VI. Framing of Rules Prescribing Fee for cost of Services
(Recommendation Para No. 11)**

18. In their earlier Report, the Committee were concerned to note that AERB had not framed any rules to prescribe and fix fee for recovery of the cost of services rendered for the regulating and consenting process as a result of which it had to bear such costs despite clear provision in Section 30 of the AE Act read with the RPR, 2004 framed thereunder. The Committee impressed upon the AERB not to undermine the importance of revenue generation through recovery of requisite cost of services and urged the AERB to frame requisite rules for levying suitable fees for recovering the cost of the consenting process for licenses with appropriate provision for periodic review and revision.

19. The Department, in their Action Taken Note, have submitted as under:

"Preparatory work in regard to levying of licence fees for facilities and activities regulated by AERB was undertaken. Since at that stage the NSRA Bill had already been tabled in Parliament, it was felt that it may be more appropriate to allow the new regulatory authority to make a decision on the matter.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. On receipt of recommendations of internal Committee, a new NSRA Bill, will be considered for introduction in the Parliament after observing all necessary formalities.

The relevant rule making process will be initiated after passing of the NSRA Bill."

20. The Committee note that AERB, taking cognizance of their recommendation, undertook preparatory work for levying of licence fees for facilities and activities regulated by it. However, according to AERB, it would be more appropriate to allow the new regulatory authority to make a decision on the matter by tabling the NSRA Bill in Parliament for enactment of a new law. It is a matter of serious concern that till date no new rules have been framed for prescribing fees for availing services from AERB despite clear provision in Section 30 of the AE Act read with the RPR, 2004 framed thereunder. The Committee have been given to understand that the relevant rule making process would be initiated after passing of the NSRA Bill. In view of the fact that since 2010, the NSRA Bill has been undergoing modifications but yet to be tabled in Parliament, the Committee recommend that expeditious steps be taken to frame rules for levying suitable fee for recovering the cost of the consenting process for licenses under appropriate provision of NSRA, Bill.

VII. Shortage of RSOs
(Recommendation Para No. 14)

21. In their Ninetieth Report the Committee were concerned to note that there was an acute shortage of Radiological Safety Officers, who were required to be designated for all radiation units in accordance with the provisions in Rule 22 of RPR, 2004 and Rule 13 of Safe Disposal of Radioactive Waste Rules, 1987. In view of the fact that RSOs were assigned enormous responsibilities for radioactive protection and safe disposal of radioactive waste, the Committee observed that effectiveness of safety procedures remained deeply compromised due to their acute shortage. Further Observing that that there was acute shortage of not only RSOs but also of trained manpower in general in AERB, the Committee, had, recommended that:

- (i) the DAE should take proactive measures for augmentation of RSOs and other requisite trained human resource at all levels of recruitment at various levels;
- (ii) impart appropriate training and also launch talent search to attract students from Universities for their appropriate orientation for posts in AERB; and
- (iii) considering the fact that fundamental science of today is the technology of tomorrow, the DAE should incentivize nuclear research by having appropriate linkages with the Universities/IITs.

22. The Department, in their Action Taken Note, have submitted as under:

"Status RSOs in the Nuclear and Radiation Facilities:

It may be noted that adequate number of RSOs are available at the nuclear power plants, nuclear fuel cycle facilities and the higher category radiation facilities, which is ensured at the licencing stage itself. The shortfall with respect to RSOs is limited only to low hazard facilities like, nucleonic gauges and research institutes handling very small amount of radioactivity.

The responsibility of appointing RSO of requisite qualification and experience is with the facility. AERB as the regulator has specified the requirements with respect to educational qualifications, training curriculum and experience, for appointment of personnel as RSOs for different type of facilities. The training courses for RSOs of different facilities are provided by BARC.

Recently, AERB has conducted a detailed study of the status of availability of RSOs for various types of facilities, including the possible future requirement owing to the steady growth of facilities using radiation sources. The study has indicated that with the current rate of training provided for different category of facilities, the number of personnel being qualified to be RSOs would actually be more than the projected requirement, considering the growth of facilities.

As mentioned earlier, there is no shortfall of RSOs in the installations with higher category sources (Category 1 & 2). The current shortfall is with respect to some of the smaller sources of Category 3, 4 & 5 like, nucleonic gauges and research institutes handling very small amount of radioactivity. Currently AERB is authorising the institutions to procure the Nucleonic Gauges only after ensuring availability of trained RSO or after obtaining commitment from the institution for RSO training within one year period. In the case of existing installations, this aspect is specifically addressed during renewal of license. In parallel RPAD, BARC has been taking action for conducting about 7 training courses per year wherein around 250 candidates are qualified to cater to requirements of RSOs for the present facilities and the expected growth in the future.

For the Diagnostic Radiology facilities under the Registration category, the RSO norms have been relooked. Considering that knowledge of radiation protection and familiarity with the regulatory requirements, are adequate to perform the responsibilities of RSO for such facilities, AERB has revised the guidelines so that the Registrant of the facility can also be assigned the responsibilities of RSO. Based on training provided by supplier and undertaking to that effect, the revised guidelines have been published on AERB website and the facilities are being advised to follow these guidelines.

Attracting and Orienting Students from the Universities with the aim of absorbing them for posts in AERB:

As reported in response to the recommendation no. 8 above, AERB already has put in place such a scheme under its Postgraduate Fellowship Scheme.

Incentivising Nuclear Research by having linkages with Universities/IITs:

Department of Atomic Energy (DAE) is involved in the production of safe and economical nuclear power, using indigenous uranium and thorium resources. Towards this end, it is involved in developing, (a) different types of power reactors with associated fuel cycle facilities for the purpose of carrying Basic research and (b) research reactors for production of radioisotopes for medical, agriculture and other societal benefits. DAE is also involved in the development of advanced technology in areas such as accelerators, lasers, control and instrumentation, computers,

biotechnology, information technology and materials technology. While bulk of the development is carried out by different units of DAE, it also derives support from various IIT'S, NIIT's, IISC, academic institutions and other R&D laboratories for some of the basic research and small developments. This support to Non-DAE units is conducted through the Board of Research in Nuclear Sciences (BRNS) which is extra-mural funding agency of DAE formed in August 1954.

BRNS supports high quality 3 year R & D projects to individual faculties and scientists. It also provides institutional support in the form of MOUs in the areas of relevance to its programme. BRNS lays emphasis on collaborative programmes between the DAE scientists and the scientific community outside the DAE family. At any point of time, the number of ongoing projects is —700 and the number of MOUs is 15 to 20.

Efforts have been made to address the shortage of RSOs in a) Nucleonic Gauge (NG) practice handling most of the Category 3, 4 & 5 sources. b) Research Institutions.

a) There are about 1000 institutions possessing Nucleonic Gauge sources (Category 3 & 4). Some of these institutions possess sources which are no longer being used (disused) and are required to be disposed of as per AERB regulations. Trained RSOs are available in almost all the above Nucleonic Gauge facilities. In addition, there are nearly 700-800 nucleonic gauges which are of low beta activity, the employer himself can be designated as RSO, owing to the very low activity and risk potential involved. AERB has carried out the following efforts: i) Enhancement of number of RSO training courses for Nucleonic Gauge practice. Presently in a year, 10 such courses are being conducted and about 300 RSOs are successfully trained annually.

ii) Issuance of circular by AERB to institutions in possession of Nude= Gauges for availability of trained RSOs in the facility.

iii) AERB ensures the availability of trained RSOs in the upcoming N institutions (New), prior to permission for procurement of NG devices.

iv) There are few institutions who possess disused NG devices/sources and do not have RSOs. AERB has written to DAE for necessary guidance/actions for disposal of such disused sources.

b) There is no shortage of RSOs in the research institutions wherein unsealed radioisotopes are being handled. Research institutions use sealed radio isotopes normally of very low activity (of gCi levels). The sources used are discrete and in non-dispersible form. In view of the activity and the physical form, use of such sources pose very low potential hazard.

Efforts have been made to address the shortage of RSOs/certified radiation professional in (a) Nucleonic Gauge (NG) practice handling most of the Category 3, 4 & 5 sources and (b) Research Institutions.

c) There are about 1000 institutions possessing Nucleonic Gauge sources (Category 3 & 4). Some of these institutions possess sources which are no longer being used (disused) and are required to be disposed of as per AERB regulations. RSOs/certified radiation professional are available in almost all the above Nucleonic Gauge facilities and as on date about 1167 RSOs/certified radiation professional are available in such facilities. In addition, there are nearly 700-800 nucleonic gauges which are of low beta activity. Although RSOs/certified radiation professional are available in many of the institutions possessing such Gauges, for other inst. employer himself can be designated as RSO, owing to the very low activity and risk potential. AERB has carried out the following efforts:

- i) Enhancement of number of RSO training courses for Nucleonic Gauge practice. Presently in a year, 10 such courses are being conducted by BARC and about 300 RSOs are successfully trained annually.
- ii) AERB ensures the availability of trained RSOs in the upcoming NG institutions (New), prior to permission for procurement of NG devices.
- iii) AERB used to raise Non-compliances in online regulatory system (e-LORA) against the inst., if RSOs/certified radiation professional leave the institution.
- iv) Issuance of circular by AERB to Nucleonic Gauge institutions which are not registered in online regulatory system (e-LORA) and for availability of trained RSOs in the facility.
- v) There are institutions which possess only disused NG devices/sources and do not have RSOs. AERB has written to DAE for necessary guidance/actions for disposal of such disused sources. Moreover, AERB has initiated regulatory inspection of such institutions.

There is no shortage of RSOs in the research institutions wherein unsealed radioisotopes are being handled. Research institutions use sealed radio isotopes normally of very low activity (of pCi levels). The sources used are discrete and in non-dispersible form. In view of the activity and the physical form, use of such sources pose very low potential hazard.

BRIT is presently pursuing the disposal of such sources. A special drive in consultation with BARC has been undertaken to recover the disused neutron sources from used Nucleonic Gauges.

Further, on persuasion of AERB, Nucleonic Gauges suppliers have also shown willingness to assist the institutions possessing disused Nucleonic Gauges for safe disposal."

23. The Committee appreciate that adequate number of Radiological Safety Officers (RSOs) are now available at the nuclear power plants, nuclear fuel cycle facilities and the higher category radiation facilities, which is ensured at the licencing stage itself. However, the shortfall of RSOs is limited only to low hazard facilities like nucleonic gauges and research institutes handling very small amount of radioactivity which might result in non-compliance of rules/regulations at low hazard facilities and be prone to theft, irregular maintenance and improper disposal of nuclear waste. The Committee, therefore, recommend that earnest and immediate efforts be made to address the shortage of Radiological Safety Officers (RSOs) in installations dealing with low level nuclear radiation. In view of the fact that even low level nuclear radiation has the potential of causing considerable health hazard, the Committee desire that AERB should actively pursue the matter with the DAE for disposal of such disused sources at the earliest and make immediate arrangements to post adequate number of RSOs so as to ensure safe disposal of disused devices/sources.

● VII. Preparation of Emergency Responses
(Recommendation Para No. 15)

24. In their earlier Report the Committee had noted with profound concern that off-site emergency exercises carried out highlighted inadequate emergency preparedness even for situations where the radiological effects of an emergency originating from NPP were likely to extend beyond the site and affect the people around. Article 16 of the Convention on Nuclear Safety of IAEA, ratified by the Government of India in 2005, stipulates 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. The Committee found that while emergency preparedness plans were to be approved by AERB, it had no authority to enforce rules in instances of malpractices and departures from approved plans. The Committee also found that as regards off-site emergency response plans, the responsibility rested with district authorities under the overall coordination of the National Disaster Management Authority (NDMA). Notably, the cardinal principle in safety management was that the operator had the prime responsibility for safety. Having regard to the fact that the number of radiation applications in various areas had grown continuously and high strength radioactive sources were being used extensively in industry, hospitals and other irradiation facilities, the Committee recommended that the AERB need to:

- (i) strengthen the regulating aspect of emergency preparedness in the area of other radiation facilities as well which is almost non-existent;
- (ii) prescribe mandatory safety codes/procedures and emergency preparedness plan based on strict assessment of risk factors; and
- (iii) put in place effective control mechanism for securing compliance to the prescribed safety codes.

25. The Department, in their Action Taken Note, have submitted as under:

"Emergency Preparedness and Response for radiation facilities:
AERB has established a set of clear requirements with respect to emergency preparedness and response plans that should be followed for the radiation facilities. These requirements are part of the respective Safety Codes for the specific radiation facility and are specified based on assessment of the threat category of source in question. AERB has also established the mechanisms for ensuring compliance to these requirements as part of licensing of the facilities and subsequently during the regulatory inspections.

AERB has published a number of safety codes for specifying the safety and regulatory requirements applicable for the respective practice. All these codes include a separate chapter on "emergency preparedness", which specify the emergency situations to be considered, the preparedness aspects and the actions to be taken in case of emergencies and aspects related to training.

It is mandatory to display the emergency procedure to handle the situation and important telephone numbers near the control console and train the associated staff in emergency handling. These aspects are already included in all the existing codes relating to radiation facilities and would be part of the ones that are being prepared. AERB also brought out a Safety Guide in 1990, on 'Medical Management of Persons Exposed in Radiation Accidents'.

Emergency situations envisaged in the case of radiation facilities such as gamma irradiators, tele-gamma therapy equipment and industrial radiography do not foresee any major off-site impact. To address the emergency preparedness, the topic is included in the professional course curriculum of the respective practices and emphasised while assessing the suitability of the candidate to work as Radiological Safety Officer (RSO) and Operator. It is mandatory to have a qualified RSO to operate a radiation facility and the RSO is competent to handle the emergency situations. The radiation facilities are also advised to have a local safety committee in which Employer acts as Chairman and RSO acts as Member Secretary, which meets periodically to address issues related to safety and emergency situations.. Emergency Preparedness of the facility is reviewed by AERB at the time of Regulatory Inspections also.

As per the terms and condition of license, in line with the requirements stipulated in Atomic Energy (Radiation Protection) Rules- 2004, any kind of unusual occurrence including theft of source need to be reported to AERB and Emergency Control Centre, DAE within 24 hours of occurrence. Based on the kind of unusual occurrence, regulatory support is extended to the radiation facilities to mitigate the consequences. Emergency Preparedness and Response for Transport of Radioactive Materials:

The emergency response plan and preparedness during transport of radioactive material is also in place. Emergencies during transport of radioactive material are handled in accordance with the procedures in the document entitled, "Response Plans to Handled Emergencies During the Transport of Radioactive Material (2000)", published by the Crisis Management Group (CMG) of the Department of Atomic Energy (DAE). The consignor is responsible for the emergency response actions, if any as directed in the TREMCARD (Transport Emergency Card in English and Hindi) which contains emergency action plan for the vehicle crew or any person at the scene of an accident. This also includes telephone numbers of concerned authorities. This TREMCARD accompanies the consignment during en route.

In this regard, DAE and AERB have constituted a Task Force for updating the following documents the following transport safety related documents

- a) Guidelines for the Transport of spent nuclear fuel by Road (issued in January 2002)
- b) Response plans to handle emergencies during transport of radioactive materials (issued in April 2000)
- c) Guidelines to handle reported presence or suspected presence of radioactive material in public domain (issued by CMG, DAE in Sept 1999)

The Task Force is in the process of incorporating the latest requirements in the documents.

Ensuring physical security of radioactive sources is an important part of prevention of untoward incidents in public domain. AERB has published safety documents AERB/RF/SG-1 and AERB/NRF-TS/SG-10 in this regard. It is mandatory for the Category 1 and 2 facilities to submit security plans as per the guidelines prescribed in the above AERB documents. One way AERB ensures the physical security of sources is by insisting on the police verification certificate of "employer" and ensuring all employees of the radiation facility have had similar background checks. AERB further verifies these aspects during Regulatory inspection of these facilities. In addition, Circulars were also sent out directing utilities handling Category 1 and 2 sources to comply with the AERB requirements, AERB has organised five awareness programmes on safety and Security of sources with participation from employers/ licensees of radiation facilities and law enforcement authorities of different parts of the country. More such programs are being planned by AERB in various major cities, in the coming months.

Crises Management Group, DAE is entrusted with the task of preparation and updation of transport safety related documents. Presently, there are two documents which are under preparation and the same are on the verge of finalisation.

The Task Force constituted by Crises Management Group- DAE for revising/updating the two documents related to transport safety of radioactive materials viz. i) "Guidelines for the transport of spent nuclear fuel by road" and ii) "Response plans to handle emergencies during transport of radioactive materials"; submitted the documents for approval of Crises Management Group in June 2017. While reviewing the documents, revision being a continuous process, CMG felt a need for further improving the guidelines on aspects related to physical security during transport. Revision of the documents incorporating elaborate security related guidelines is expected to be completed by May 2018.

The response given earlier is reiterated. The revision of documents was expected to be completed in May 2018. However, the deadline could not be met due to functional reasons and the matter is being pursued for completion of the process expeditiously."

26. The Committee take note of AERB's efforts in establishing a set of clear-cut requirements on emergency preparedness and response plans that should be followed for the radiation facilities and are part of the respective Safety Codes for the specific radiation facility, based on assessment of the threat category of source in question. The Committee desire that the Ministry should take more stringent measures to regulate the lower level radiation facilities as per the established norms/guidelines so that the protracted hazards due to Lower Level Radiation (LLR) are obviated.

The Committee are concerned to note that two documents relating to "Guidelines for the transport of spent nuclear fuel by road" and "Response plans to handle emergencies during transport of radioactive materials", which were submitted for approval in June 2017, could not be completed till May 2018 due to revision of the documents incorporating elaborate security related guidelines. Since, both the

documents provide for exigencies during transport of spent nuclear fuel, the Committee are of the considered view that these documents be finalised at the earliest so as to provide a clear and detailed road map of action in case of any emergency/disaster as well as for safe transport of spent nuclear fuel.

VIII. Adoption of International Benchmarks and Peer Review
(Recommendation Para No. 17)

27. In their earlier Report, the Committee took note of the fact that although AERB maintained liaison with international nuclear organization, it had been slow in adopting international benchmarks and good practices in the areas of nuclear and radiation operation. The role of AERB in relation to implementing international legal commitments had not been specifically defined in its Constitution Order. Further, the AERB had not yet availed of the opportunity of peer review and appraisal services of IAEA to get its regulatory framework and its effectiveness reviewed by them. The Committee found that though AERB had initiated a structured process of self-assessment of its regulating framework, processes and systems, which was statedly in an advanced stage, had not yet hosted the Integrated Regulatory Review Services (IRRS) of IAEA for peer review though committed to the mission. Admittedly, AERB was awaiting the completion of the legislative process of the NSRA Bill, presently in Parliament, to host the IRRS Mission for peer review. The Committee hoped that once the law was enacted, then AERB would start peer review and appraisal services of IAEA to help make the nuclear regulatory infrastructure effective, sustainable and more creditable. The Committee also desired that loopholes in the existence legal framework be addressed appropriately for speedy and effective implementation of the international legal commitments.

28. The Department, in their Action Taken Note, have submitted as under:

"Adoption of International Benchmarks:

Since its inception in 1983, AERB has been involved in the IAEA's activities related to enhancement of nuclear and radiation safety and its regulation. Indian contribution in development of the IAEA codes and standards, which constitutes the IAEA's basic framework regarding safety regulation was existing from the beginning. The knowledge and experience brought back by the Indian experts, who participated in the IAEA activities had a significant impact in shaping the AERB's regulatory approach and framework.

The codes, guides and standards developed by AERB, which sets the benchmark for safety regulation in India are in fact adoption of the IAEA standards for the Indian context. The majority of the areas where AERB developed its own codes and guides,

are to adopt the IAEA benchmarks while addressing the specific aspects related to the technology being pursued (eg. Indian PHWR) and the legal framework of India. AERB continues to use the IAEA Safety Documents in areas where AERB has not developed its own document so far. Thus, AERB has actually been in tune with the IAEA's benchmarks for safety.

AERB has in fact been very prompt in adopting some of the landmark international developments related to nuclear and radiation safety.

- AERB was one of the first regulators to adopt the recommendations of the International Commission for Radiological Protection (ICRP) on radiation dose limits to the occupational workers and members of public. The AERB safety directive regarding dose limits was issued in 1990, soon after publication of ICRP recommendations. The limits on radiation exposures to occupational workers established by the AERB safety directive is in fact more conservative than the ICRP recommendation.

- AERB is the first regulator internationally to adopt the system of Periodic Safety Review (PSR) as a basis for renewal of operating license of NPPs. AERB has been one of the founder participants in the international ventures for sharing of safety and operating experience, under IAEA initiative, namely the IAEA-IRS (Incident Reporting System) programme started in 1983. Active participation by AERB in this programme has helped in taking prompt measures safety improvements for the Indian NPPs. A few examples of such measures worthwhile mentioning here are

- o Programme for health assessment and life management of coolant channels of PHWRs.

- o Preemptive action for inspection and health assessment of health of feeder pipe fittings in the primary heat transport system in PHWRs, in view of the experience of feeder thinning in the Canadian reactors.

- o Enhancement of inspection of secondary system piping at the NPPs, by introducing thickness monitoring to guard against failures due to flow assisted corrosion.

- AERB has been the founder participant in the IAEA's programme, International Nuclear Event Scale (INES) in 1990, currently known as International Nuclear and Radiological Event Scale, and soon after, AERB has introduced the system of INES rating of all events in the Indian plants. Later the system of INES rating was introduced for events in domain of applications of radiation.

Additional testimony of the promptness of adoption of international benchmarks for the Indian plants comes from the feedback of the international peer reviews carried out under the Convention of Nuclear Safety. After ratification of the Convention, India had presented its national report for peer reviews, in 2008, 2011, 2014 and in August 2012 (second extraordinary review meeting of the contracting parties, for review of safety enhancement measures in NPPs subsequent to the Fukushima accident), wherein the Contracting Parties have accepted the safety record of the Indian NPPs and the efforts/initiatives of AERB, its technical support organisations and the plants for achieving the international benchmarks on safety. AERB participated in a Diplomatic Conference held in February, 2015 wherein the Vienna Declaration on Nuclear Safety was adopted. The Vienna Declaration calls for enhanced safety objectives and requirements and bringing out the national safety requirements commensurate with these objectives, in light of the lessons learned from the accident at Fukushima-Dai-ichi. By the time the Vienna Declaration was adopted by the Diplomatic Conference, AERB had already put in place the regulatory/safety

requirements commensurate with the objectives of the Vienna Declaration. AERB was one of the first regulators in the world to do so.

International Peer Review of AERB:

During March 16 — 27, 2015, AERB underwent an international peer review by the IAEA's Integrated Regulatory Review Services Mission, in which a team of 16 experts from IAEA and senior regulators from other countries including Canada, US, UK, Finland, Czech Republic, Hungary, Netherlands, etc. participated and carried out the peer review of the legal and regulatory system established in India with respect to the safety regulation of nuclear power plants. The IRRS mission after having reviewed and verified the working of AERB closely over a period of two weeks, issued a detailed report (available to public on AERB web site).

The IRRS Team while acknowledging the functional independence of AERB, made the recommendation "The Government should embed in law, the AERB as an independent regulatory body separated from other entities having responsibilities or interests that could unduly influence its decision making". (IRRS Report on AERB, Chapter — 1, page 10), to ensure de-jure independence for the regulatory body.

The IRKS report identifies several strengths of the regulatory system established by AERB as good practices including the unique role played by the nation-wide educational and training system in supporting the competence building at AERB, continual improvement of the regulatory framework and processes based on the regulatory and operational feedback and R&D infrastructure established to support the regulatory review and assessment activities. The report further acknowledges the scope and depth of the AERB recruitment and training programme as being worthy of the attention of other regulatory bodies.

After closely reviewing the processes established by AERB for development of regulatory documents, the IRRS team observed in its report that AERB follows a robust development and revision process of its regulatory documents, that is based on IAEA approach and acknowledged that in principle, AERB adopts, with country specific modifications, all relevant IAEA standards.

With respect to the actions taken in the aftermath of accident at Fukushima Daiichi, Japan, the IRRS report made few salient observations, e.g., :

"The IRRS team concludes that in response to the TEPCO Fukushima Daiichi accident the AERB acted responsibly and expeditiously. It initiated a thorough re-assessment of the safety of the Indian nuclear power plants both operating and under construction, and requested in a timely manner the implementation of the measures deemed necessary to avoid the possibility of consequences similar to those in the Fukushima event". (IRRS Report on AERB, Chapter — 11, page 82, Conclusion — I).

"The IRRS team considers that the Government of India is fully committed to act in light of the TEPCO Fukushima Daiichi accident. Appropriate technical reviews have been conducted to confirm the adequacy of the existing measures and to identify areas where improvements are required. The actions to improve safety have been or are being implemented for all identified safety issues. Implementation of these actions is being tracked". (IRKS Report on AERB, Chapter — 11, page 86, Conclusion — 7).

In addition to the aforementioned strengths of the regulatory system, the IRRS report identified a few recommendations and suggestions for bringing out a greater degree of compliance with the IAEA Safety Standards and Guidance documents.

Additionally, AERB officials have also participated in the IAEA-IRRS missions to a few countries as team-members and have contributed towards strengthening the regulatory safety regime in the respective countries. All such processes of global

safety cooperation intrinsically benefit the experts involved by sharing of good practices and learning from others' strengths. The actions taken by AERB with regard to the recommendations made by the peer review committee are as follows:—

- Graded approach guidance document has been prepared and is in trial use,
- Maintenance of independence in decision making with continued interfaces with licensees to obtain frank and open information from the licensees,
- Competency mapping exercises have been completed for all the officers and training programmes based on identified gaps are being conducted,
- Public outreach programmes are being implemented using broadcast, print and digital media and AERB website along with consideration of public comments for improvement of draft safety codes,
- Implementation of QMS and independent external audit by BIS. The system is being enhanced to meet the requirements of IAEA GSR-3 which was revised later on as IAEA GSR Part-2.
- Managing and monitoring organisation changes w.r.t. safety at utility end
- Strengthening of inspection of nuclear power plants through increase in unannounced inspection and duration of particular inspection,
- AERB Safety Guidelines 'Preparation of off-site Emergency Response Plans for Nuclear Installations' (AERB/SG/EP-2) was revised to bring in line with IAEA safety requirements (GSR Part 7) and AERB Safety Guidelines titled 'Criteria for Planning, Preparedness and Response for Nuclear or Radiological Emergency (AERB/SG/EP-5)'

With regard to the completion of the legislative process of the NSRA Bill, it is submitted that on receipt of the necessary administrative clearances, the Bill will be placed before the Parliament.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted a Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. On receipt of recommendations of internal Committee, a new NSRA Bill, will be considered for introduction in the Parliament after observing all necessary formalities.

The NSRA Bill, 2011 along with official amendments had been submitted to the Cabinet Secretariat for cabinet approval after fresh inter-ministerial consultations. However, the Committee of Secretaries advised the Department to re-examine the Bill. The Department, thus, constituted the Committee and withdrew the Bill. Thus the NSRA Bill, 2015 will not be pursued further for the present. The internal Committee constituted under the chairmanship of Dr. R.B. Grover, former DAE Homi Bhabha Chair Professor and Member, Atomic Energy Commission (AEC) to re-examine the draft Bill, submitted its report and is being examined."

29. The Committee are constrained to find that eight years have elapsed without any fruitful development for empowering AERB as an independent regulatory authority which has proved to be a roadblock in the effective and prudent regularisation of nuclear energy in the country. Taking into consideration the Ministry's submission that once the NSRA Bill is tabled in Parliament and enacted into a law, all the deficiencies would be corrected, the Committee exhort the Ministry

to take urgent requisite steps in that direction so that AERB is recognised as an independent regulator commensurate with the internationally accepted norms and stronger nuclear energy regulations are put in place at the earliest.

NEW DELHI;
30 January, 2020
10 Magha, 1941 (*Saka*)

ADHIR RANJAN CHOWDHURY
Chairperson,
Public Accounts Committee

APPENDIX-II

(Vide Paragraph 5 of Introduction)

ANALYSIS OF THE ACTION TAKEN BY THE GOVERNMENT ON THE
OBSERVATIONS/RECOMMENDATIONS OF THE PUBLIC ACCOUNTS COMMITTEE
CONTAINED IN THEIR 90th REPORT (FIFTEENTH LOK SABHA)

- | | | |
|-------|---|-----------------------------------|
| (i) | Total number of Observations/Recommendations | 18 |
| (ii) | Observations/Recommendations of the Committee which have been accepted by the Government:
Para Nos. 1, 6, 7, 8, 9, 12, 13, 16 & 18 | Total : 08
Percentage: 50% |
| (iii) | Observations/Recommendations which the Committee do not desire to pursue in view of the reply of the Government:

Para Nos. - Nil | Total : Nil
Percentage: 0 |
| (iv) | Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration:

Para Nos. 2,4,5,10,14,15 &17 | Total : 07
Percentage: 38.88 % |
| (v) | Observations/Recommendations in respect of which the Government have furnished interim replies:
Para Nos. 3 &11 | Total : 02
Percentage: 11.12 % |