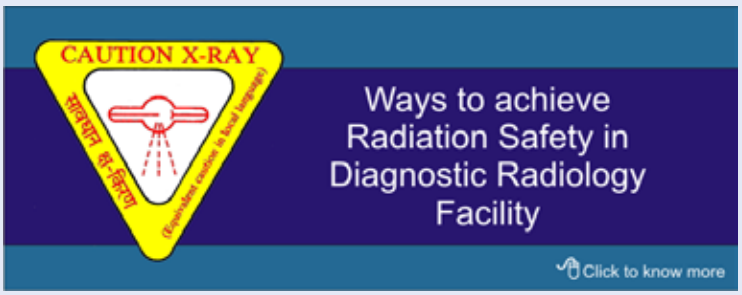
Obtain Licence to operate X-ray equipment

Guidelines And Request For Proposal For AERB Compliance For Public Health Facilities



Atomic Energy Regulatory Board

e-LORA (e - Licensing Of Radiation Applications)

Guidelines And Request For Proposal For AERB Compliance For Public Health Facilities

NATIONAL HEALTH MISSION

National Health Systems Resource Centre
Ministry of Health and Family Welfare
Government of India

"This document is ONLY suggestive in nature and is meant to serve as a broad guideline. States may contextualize this as may be necessary to be in accordance with financial rules and needs. "

सी.के.मिश्रा
सचिव
C.K.Mishra
Secretary

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

PREFACE

Radiology is essential for diagnosis and disease management. Furthermore it is a key component of Free Diagnostic Service Initiative. The widespread use of X-ray imaging with its ionising radiation has consequences on healthcare professionals and public. It is a statutory requirement to obtain licence of operation, for each public health facility providing X-Ray diagnosis and to comply with Atomic Energy Regulation Rule, 2004 laid down by Atomic Energy Regulation Board (AERB) to ensure adequate radiation safety in public health facilities. In this context Ministry of Health and Family Welfare in consultation with National Health Systems Resource Center has designed guidelines to ensure compliance.

AERB compliance could be achieved in health facilities by ensuring three parameters of compliance medical equipment type approval, site layout approval and adhering to quality assurance norms. Designating a Radiation Safety Officer (RSO) with adequate expertise as per AERB guideline is mandatory to accomplish this exercise.

I am certain that this guideline and model request for proposal document will serve as a valuable resource and I urge all States/UT's to rollout this initiative on a priority basis.

(C.K. Mishra)

Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@nic.in
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011

Manoj Jhalani
Additional Secretary & Mission Director, NHM
Telefax : 23063687, 23063693
E-mail : manoj.jhalani@nic.in

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

Dated the 13th October, 2017

FOREWORD

The National Health Mission has made much headway in improving access to health care services, through strengthening the public health system. One of the key components in strengthening is equipping public health facilities, with safe and adequate equipment for diagnosis and therapeutic purpose. Radio-diagnosis is an indispensable tool in healthcare delivery. Adequate precautions and compliance with Atomic Energy Regulatory Board (AERB) is, however, required during commission and operation to reduce associated health risks.

AERB's mandate is to ensure that the use of ionizing radiation and nuclear energy in India does not cause undue risk to the health of people and the environment. AERB's emphasis on hospital infrastructure specifications while delivering radio-diagnosis and therapy, use of radiation hazard warning illustrations, registration of facility and radiation safety officer in e-LORA, use of AERB type approved medical devices and annual quality assurance requires issue of license for operation.

In the year 2015, National Health Systems Resource Centre conducted survey on a sample basis in states to understand compliance of public health facilities with the AERB regulations and found significant gaps. To facilitate compliance with AERB regulations, modal RFP document has been prepared. This model tender document will support states in implementing AERB compliance in public health facilities. States could modify the RFP document, as deemed appropriate, but should share the edits along with their rationale with the Ministry. States could include AERB compliance activity in the NHM Program Implementation Plans.

We look forward to your feedback and learnings while implementing the AERB compliance project.

(Manoj Jhalani)

Dr. Manohar Agnani
Joint Secretary (Policy)
Telefax : 23061723
E-mail : agnanim@ias.nic.in

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

Foreword

The Government of India is supporting states under National Health Mission's Free Diagnostics Service Initiative to provide X-ray diagnosis free of cost. However, unsafe use of X-ray radiation has health risk associated with it and it is required that proper care is exercised during installation, commission and operation.

The Atomic Energy (Radiation Protection) rules – 2004, promulgated under the Atomic Energy Act, 1962, provides the legal framework for the safe handling of radiation generating equipment (in this context – X-Ray equipment (Mobile and stationary), Mammography and Computed Tomography Scan machines). As per the aforesaid rules it is mandatory for all users of radiation generating equipment, to obtain requisite 'license for operation' from Atomic Energy Regulatory Board for ensuring radiation safety of patients, occupational workers and general public.

To facilitate quick and easy roll out, the Ministry of Health and Family Welfare with the support of NHSRC, inputs of experts and state governments, has prepared this guidance document for compliance with these norms. The document includes the draft model tender document for guidance of the states/UTs. The service provider shall be responsible for gap analysis in X-Ray equipment facilities, facility up-gradation for compliance and facilitation of 'license for operation', with payment linked to each step separately. States/UT's should roll out the program under NHM on priority and adopt the tender document with suitable modifications, as appropriate to suit their context.

06/10/2017

(Dr. Manohar Agnani)

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CHAPTER 1

INTRODUCTION

1.1 Background

Medical use of x-rays for diagnosis and treatment has proven to be beneficial to society at large. Diagnostic Radiology includes various modalities of medical imaging by using X-rays. However, unsafe use of x-ray radiation has health risks associated with it and hence it is required that proper care is exercised throughout the life cycle of the equipment i.e. from manufacture, supply, installation, use, maintenance, servicing and ultimately decommissioning.

The Atomic Energy (Radiation Protection) Rules, 2004 [AE(RP)R-2004], promulgated under the Atomic Energy Act, 1962, provides the legal framework for the safe handling of radiation generating equipment (in this context - X-ray equipment). As per Rule 3 of AE(RP)R-2004 it is mandatory for all the manufacturers/ Suppliers/Users of x-ray equipment, to obtain requisite 'Licence' from AERB for carrying out any of the above activities.

The National Health Mission is India's flagship health sector program to revitalize rural and urban health sectors by providing flexible finances to State Governments. The Mission represents India's endeavour to expand the focus of health services beyond Reproductive and Child Health, so as to address the double burden of Communicable and Non-Communicable diseases as also improve the infrastructure facilities at District and Sub-District Levels.

During the period 2015-2017, NHSRC conducted a situational analysis of the level of compliance and gaps in compliance to AERB norms in selected states. This study was restricted only to public health facilities up to district hospital level and did not include private clinical establishments. Field visit was conducted in two states and desk review of public health facilities using data generated from the Biomedical Equipment Maintenance and Management Program (BMMP) in five states /UT's against data available on AERB e-governance website (eLORA) for licensed diagnostic radiology facilities in India. The analysis indicated non-compliance with AERB rules and highlighted the need for urgent action. Major observations were on non-compliance with AERB license of operation, lead shielding, type approval of medical equipments, warning lights, protective equipments like lead apron, thermo luminescent dosimeter (TLD) badges etc.

1.2 AERB facilitation of Radiation Safety Compliance as per Atomic Energy Act, 1962

To facilitate online submission of applications for various regulatory consents, AERB has launched e-governance application e-LORA (e-Licensing of Radiation Applications) System. All diagnostic and therapeutic institutions with X-ray or other radiations sources are required to obtain all the requisite consents from AERB through e-LORA.

Considering the large number of x-ray facilities spread across the country, AERB has formed Directorate of Radiation Safety (DRS) under Health and Family Welfare Department in few states, to carry out regulatory inspections of x-ray facilities (of the state) and support the utilities in obtaining licence/registration from

AERB. As of date, DRS are established and functioning in states of Kerala, Mizoram, Chhattisgarh, Tripura, Arunachal Pradesh and Punjab; in the remaining states the process is underway.

Besides decentralization of regulatory activities for effective implementation of regulations in the country, AERB has established its Regional Regulatory Centers (RRC) at Chennai, Kolkata and Delhi for Southern, Eastern and Northern regions respectively.

1.3 National Heath Mission (NHM) initiative to enhance X ray diagnostic facilities operational safety in public health facilities

Among several other interventions the Mission supports India's endeavour to improve safety and infrastructure facilities at district hospitals and below.

To rapidly strengthen public health facilities safety in terms of diagnostic radiology and equip public health facilities to address concerns related to radiation safety unaided, NHM has emphasized AERB safety guideline. In order to reinforce and support states in complying with AERB safety model Request For Proposal (RFP) has been developed. It's estimated that to meet all the safety regulations within AERB framework, an average Rs. 2.00 to 3.00 lakhs is required per facility. However in most facilities some level of infrastructure is available and therefore actual expenditure required would be less.

Based on the state's gap analysis budgetary provisions could be allowed in Program Implementation Plan (PIP) for augmentation of necessary infrastructure. The RFP document lays out the requirements for bidders to help facilities obtain "License for Operation" from AERB. Bidders are expected to complete this on turnkey basis through a process of Gap Analysis, Gap Filling and Obtaining the License.

CHAPTER 2

AERB GUIDELINE ON MEDICAL DIAGNOSTIC FACILITIES

2.1 Regulatory Requirements for Diagnostic Radiology facilities General Requirements

General Requirement:

The employer and licensee of the organisation as defined in atomic energy radiation protection rules, 2004, shall fulfil the responsibilities prescribed in the AERB safety code on radiation safety in manufacture, supply and use of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)].

Procurement of X-ray Equipment:

The employer shall procure NOC validated/ Type Approved X-ray equipment from authorized suppliers and after obtaining procurement permission from the Competent Authority.

Operation of X-ray Equipment:

No diagnostic X-ray equipment shall be operated for patient diagnosis unless Licence for operation is obtained from the Competent Authority.

Pre-requisites for obtaining Licence for Operation of X-ray Equipment:

X-ray Room Layout and Shielding Requirement

The room housing X-ray equipment shall have an appropriate area to facilitate easy movement of staff and proper patient positioning. Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray equipment so that radiation exposures received by workers and the members of the public are kept to the minimum and shall not exceed the respective limits for annual effective doses as per directives issued by the Competent Authority. Appropriate overlap of shielding materials shall be provided at the joints or discontinuities.

The control console of computed tomography equipment shall be installed in a separate room located outside but adjoining to computed tomography room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient. The gantry and couch shall be placed such that it enables the operator to have the complete view of the patient from the control room viewing window.

Interventional Radiology equipment room shall have an adjoining control room with appropriate facilities for shielding, direct viewing and oral communication. In case of room housing radiography equipment, chest stand shall be located in X-ray room such that no significant stray radiation reaches at control console/ entrance door/ areas of full time occupancy such that the dose limits to radiation worker and members of public are not exceeded.

Mobile X-ray equipment, when used as fixed X-ray equipment, shall comply with all the requirements of those of fixed X-ray installation. Movement of mobile X-ray equipment shall be restricted within the institution for which it is registered.

A permanent radiation warning symbol and instructions for pregnant/likely to be pregnant women shall be pasted on the entrance door of the X-ray installation, illustrating that the equipment emits x-radiation.

Vehicle Mounted X-ray Equipment:

X-ray equipment installed in a mobile van or vehicle, shall be provided with an appropriate shielding enclosure to ensure adequate built-in protection for persons likely to be present in and around the vehicle. Shielding shall be provided around the equipment from all the sides up to height of 2m from external ground surface. Radiation warning symbol shall be displayed on all sides of the vehicle.

Staffing Requirements:

X-ray installations shall have a radiologist/related medical practitioner/ X-ray technologist with adequate knowledge of radiation protection, to operate the X-ray equipment. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as prescribed in AERB safety code on radiation safety in manufacture, supply and use of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)]. The minimum qualification and training shall be as prescribed by the Competent Authority. All installations having X-ray equipment with fluoroscopy facility, computed tomography and all establishments performing special procedures, shall have the services of a qualified radiologist or related medical practitioner, with adequate knowledge of radiation protection for interpretation and reporting.

Radiological Safety Officer (RSO):

X-ray department shall have a RSO approved by the Competent Authority. The RSO may either be the employer himself/herself or an employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his X-ray installation. The minimum qualification and training shall be as prescribed by the Competent Authority.

Radiation Protection Devices:

Appropriate radiation protection devices such as barrier, apron, goggles, and thyroid shields shall be used during operation of X-ray equipment. These devices shall be verified periodically for their shielding adequacy. The requirements for radiation protection devices are as specified in Appendix-II of AERB guideline.

Personnel Monitoring Service:

Personnel monitoring services shall be provided to all the radiation workers.

Quality Assurance (QA) Requirements:

The end user shall ensure that periodic QA of the equipment is carried out by AERB authorized agencies. Periodic Quality Assurance shall be carried out at least once in two years and also after any repairs having radiation safety implications.

Servicing:

The end user shall ensure that servicing of the X-ray equipment is carried out by agencies authorized by the regulatory body.

Periodic Safety Reports:

The utility shall submit periodic safety reports in the format and frequency specified by the regulatory body.

Renewal of Licence:

The Licence accorded by the Competent Authority shall be renewed before its expiry.

Decommissioning of X-ray Equipment:

Decommissioning of the X-ray equipment shall be carried out by authorized agencies with prior intimation to the Competent Authority.

2.2 Tips to ensure radiation safety in public health facilities (till DH level)

General purpose X-Ray radiography

The general purpose radiography equipment are routinely used (nearly 70% of the times) for X-rays of chest and extremities. The other important examinations are abdomen, hip joints, lumbar spine etc.

Safety instruction for personnel (doctors, radiographers) who are operating the equipment:

1. Always operate the unit from the control room or standing behind the Mobile Protective Barrier (1.5 mm lead equivalent) or fixed protective barrier (such as a wall).
2. Always use the TLD at chest level while X-ray unit is being operated.
3. In the absence of Protective Barrier (such as operating Mobile X-ray equipment) always use Lead apron (0.25 mm lead equivalent) and wear TLD below the apron.
4. Always use collimator (diaphragm) to limit the field size to the area of interest in order to minimize the radiation exposure to other organs.
5. While operating mobile X-ray equipment, operate from a minimum distance of 2m from the equipment by stretching the connecting wire and don't allow anybody to be nearby.
6. In no case, except patient anybody shall come in the direction of the primary beam.
7. Ensure that Lead apron is worn by the person assisting an infirm patient during exposure.
8. Portable x-ray equipment shall always be positioned on a stand and not to be held in hand during exposure.
9. For mobile and portable X-ray equipments, cassette shall not be held in hand by any person.
10. Unless necessary use of bucky should be avoided.
11. During X-ray examinations of pregnant woman, abdomen must be covered with minimum 0.25 mm lead equivalent apron.
12. Avoid crowding of patients/relatives/ staff inside the X-ray room.
13. X-ray room door (lead lined with 1.7 mm lead equivalent) should be closed during exposure.

What the owner/ employer/ Radiation Safety Officer need to know:

1. Only AERB Type approved X-ray equipment shall be installed /used.
2. AERB registration certificate shall be displayed at prominent place near the X-ray room for public information.
3. Quality Assurance tests of the X-ray equipment is carried out periodically and after any maintenance and the records thereof are maintained.
4. Sufficient number of lead aprons (0.25 mm lead equivalent) is available for use with fixed and mobile X-ray equipment.
5. Lead aprons shall be stored either on a hanger or on a flat surface without crumpling.
6. Consistency of lead aprons shall be checked once in two years. Qualitative check can be done by taking radiograph of lead aprons.
7. The operators are instructed on all the requirements of radiation safety.
8. Charts of standard exposure parameters to achieve good image quality should be prepared for paediatric and adult patients separately and displayed at a prominent location such as control console.
9. TLD badges are provided to all the operators and workers involved during X-ray examination.
10. During non-working hours, TLD cards must be stored along with Control TLD card outside the X-ray room (in a radiation free area).
11. The owner shall ensure that the operator of the X-ray equipment is well conversant with clinical requirements of the examinations. Chest stand should always be provided with X-ray equipment for chest radiography.
12. Routine maintenance of the Radiography equipment is carried out. Particularly, it should be ensured that the field light (collimator bulb) is always functional.
13. Radiation symbol and warning placards in local languages are placed outside the X-ray room door
14. The chest stand and the control console should always be placed opposite to each other. If this is not possible, at least a partition wall with viewing window should be made between the control console and the chest stand.
15. Permanent occupancy of staff behind the chest stand wall (for e.g. Doctors, Receptionists or helpers) should be avoided.

CHAPTER 3

MODEL REQUEST FOR PROPOSAL

ATOMIC ENERGY REGULATORY BOARD (AERB) COMPLIANCE FOR PUBLIC HEALTH FACILITIES

DEPARTMENT OF HEALTH & FAMILY WELFARE
GOVERNMENT OF (Insert name of the State)……..

BID ENQUIRY DOCUMENT

For

Atomic Energy Regulatory Board Certification (AERB) Facilitation on turnkey basis : Gap Analysis, Gap filling and Issuance of License for operation by AERB

LIST OF CONTENTS

SECTION–I

INTRODUCTION

It is a statutory requirement to have radiation safety in all the diagnostic radiology facilities which have radiology/ radiation emitting equipment installed. These facilities should be in compliance with regulations specified under the Atomic Energy (Radiation Protection) Rules, 2004.

This document lays out the requirements for bidders to help facilities obtain "License for Operation" from AERB. Bidders are expected to complete this on turnkey basis through Gap Analysis, Gap Filling and obtaining the License.

Through this Request for Proposals, the Authority, <Insert the name of the Procuring Authority> invites Bids from Authorized Service Agencies approved by AERB for Medical Diagnostic X-Ray Equipment for such facilities as are mentioned in this document.

SECTION–II

NOTICE INVITING BID

<Insert the name of the Procuring Authority (Department/Directorate/Agency/Institution)>

Address: .....

.....

URL www: .....

Email: .....

Telephone Phone: .....

Bid Enquiry No. PHFW/ / / Dated: / /

NOTICE INVITING BIDS

1. <insert the designation and office of the bid inviting authority and the department/agency> invites sealed bids from eligible bidders for Atomic Energy Regulatory Board Certification (AERB) Facilitation on turnkey basis: Gap Analysis, Gap filling and Issuance of License for operation by AERB

2. Schedule of Events

Sl. No.	Description	Schedule
1	Date of sale of Bid Enquiry Documents	
2	Place of Sale/website download of Bid Enquiry Document	
3	Cost of the Bid Enquiry Document	
4	Pre-bid Meeting (Date & Time)	
5	Pre-Bid Meeting Venue	
6	Closing Date and Time of Receipt of Bid	
7	Earnest Money Deposit (EMD)	
8	Time, Date and Venue of Opening of Technical Bid/Bid	
9	Time, Date and Venue of Opening of Financial Bid/Bid	

3. Interested bidders may obtain further information from the above office. Bid Enquiry Documents may be purchased on payment of non-refundable fee of <insert bid cost in Rs.> per set in the form of account payee Demand Draft, drawn on a scheduled bank in India, in favor of "<insert the designation and office of the bid inviting authority>" payable at <insert the place>.

4. Bidder may also download the bid enquiry documents (a complete set of document is available on website) from the website www……...com or www……..nic.in and submit its bid by using the downloaded document, along with the required non-refundable fee as mentioned in Para 3 above.

The bid will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.

5. All prospective bidders may attend the Pre Bid meeting. The venue, date and time are indicated in Schedule of Events as in Para 2 above.

6. Bidders shall ensure that their bids, complete in all respects, are dropped in the bid box located at (place to be inserted) on or before the closing date and time indicated in the Para 2 above, failing which the bids will be treated as late bid and rejected. The bids send by post/courier must reach the above said address on or before the closing date and time indicated in para 2 above, failing which the bids will be treated as late bid and rejected.

7. In the event of any of the above mentioned dates being declared as a holiday / closed day for the authority, the bids will be sold/received/opened on the next working day at the appointed time.

8. The Bid Enquiry Documents are not transferable.

9. All bids must be accompanied by EMD as mentioned in para 2. Bids without EMD shall be rejected.

(Name and designation of bid inviting authority)

SECTION-III

INSTRUCTIONS TO BIDDER

1. General Instructions

a. The bidder should prepare and submit its offer as per instruction given in this section.

b. The bids shall be complete with all documents and signed appropriately on all pages. Those submitted by fax or through email with attachment shall not be considered.

c. The bids which are for only a portion of the components of the job /service shall not be accepted. (The bids should be for all three components of the job /service.)

d. The prices quoted shall be **firm** and shall include all taxes and duties. This shall be quoted in the format as per attached **Appendix 'D'** only.

e. The bids (technical and financial) shall be submitted (with a covering letter as per **Appendix 'C**) before the last date of submission. Late bids shall not be considered.

2. Inspection of Site and Equipment

The interested bidder may inspect the locations where the services are to be rendered during 10:00 AM to 5:00 PM on all working days till last date of sale of bid as given in the bid schedule. The <Insert designation of the bid inviting authority> shall not be liable for any expenditure incurred in such inspection or in the preparation of the bid(s).

3. Earnest Money Deposit (EMD)

a. The bid shall be accompanied by Earnest Money Deposit (EMD) as specified in the Notice Inviting Bid in the shape of Bank Draft / Bankers cheque in favour of <Insert designation of the bid inviting authority> payable at <insert place>.

b. No bidding entity is exempt from deposit of EMD. Bids submitted without EMD shall not be considered.

c. The EMD of unsuccessful bidder will be returned to them without any interest, within one month of conclusion of the contract. The EMD of the successful bidder will be returned without any interest, after receipt of performance security and letter of acceptance as per the terms of contract.

d. EMD of a bidder may be forfeited without prejudice to other rights of the Authority, if the bidder withdraws or amends its bid or impairs or derogates from the bid in any respect within the period of validity of its bid or if it comes to notice that the information /documents furnished in its bid is incorrect, false, misleading or forged. In addition to the aforesaid grounds, the successful bidders' EMD will also be forfeited without prejudice to other rights of Authority, if it fails to furnish the required performance security within the specified period.

4. Preparation of Bid

The bids shall be made in TWO SEPARATE SEALED ENVELOPES as follows:

I The **first envelopes** shall be marked in bold letter as "**TECHNOCOMMERCIAL BID"** which shall be sent forwarding letter **("Appendix-C")** and shall include the following:

1. Receipt regarding payment of Bid Cost if already paid.
2. Bank Draft /Bankers Cheque/ towards **E.M.D.** DD/ Banker's cheque towards the cost of bid document to be attached in case bid document has been downloaded from website.
3. Confirmation regarding furnishing **Performance Security** in case of award of contract.
4. Original bid document duly stamped and signed in each page along with the Forwarding Letter confirming the performing the assignment as per **"Appendix C".**
5. Particulars of the bidder as per "**Appendix-B".**
6. Copy of the Income Tax Returns acknowledgement for last three financial years.
7. Copy of audited accounts statement for the last three financial years.
8. Power of attorney in favour of signatory to bid documents.
9. Copy of the certificate of registration of CST, VAT, EPF, ESI and Service Tax with the appropriate authority valid as on date of submission of bid documents.
10. A duly notarized declaration from the bidder in the format given in the **"Appendix-F"** to the effect that the firm has neither been declared as defaulter or black-listed by any authority of Government of India OR Government of any State.

II. The second envelope shall contain the financial proposal and shall be marked in bold letters as "FINANCIAL BID". Prices shall be inclusive of all taxes & duties and quoted in the proforma enclosed at "**Appendix D**" as per scope of work / service to be rendered.

5. Bid Validity Period

The bids shall remain valid for 180 calendar days from the last date of submission of the bid.. The Authority may, however, request the bidders to extend the validity period and the bidders will within seven calendar days of issue of such a request, submit a response. If no response is submitted within the specified period, the Authority will treat the bid validity as having expired.

6. Bid Submission

The two envelopes containing both technical and the financial bid shall be put in a bigger envelope, which shall be sealed and superscripted with "BID NO <Insert Bid No.> due for opening on<Insert due date for Opening> by the government department collecting the bid.

The offer shall contain no interlineations or overwriting except as necessary to correct errors, in which cases such correction must be initialed by the person or persons signing the bid. In case of discrepancy in the quoted prices, the price written in words will be taken as valid.

7. Opening of Bids:

The technical and financial bid will be opened at the time & date specified in the schedule. The bidders may attend the bid opening if they so desire.

SECTION–IV

EVALUATION OF BIDS

1. Scrutiny of Bids

The bids will be scrutinized by a committee appointed by the authority for this purpose to determine whether they are complete and meet the essential and important requirements, conditions and whether the bidder is eligible and qualified as per criteria laid down in the Bid Enquiry Documents. The bids, which do not meet the aforesaid requirements, are to be treated as non-responsive and will be ignored. The decision of the authority as to whether the bidder is eligible and qualified or not and whether the bid is responsive or not shall be final and binding on the bidders. Financial bids of only those bidders, who qualify on technical bid, will be considered and opened.

2. Infirmity / Non-Conformity

The authority may waive minor infirmity and/or non-conformity in a bid, provided it does not constitute any material deviation. The decision of the authority as to whether the deviation is material or not, shall be final and binding on the bidders. Such relaxations shall be displayed on the website where bid was published. For the purpose of this clause the provisions of rule 7.3.4 minor infirmity/Irregularity/Non conformity of manual of procurement of goods-2017 of Ministry of Finance, Govt. of India will be applicable.

3. Bid Clarification

Wherever necessary, the authority may, at its discretion, seek clarification from the bidders seeking response by a specified date. If no response is received by this date, the authority shall evaluate the offer as per available information.

SECTION–V

SCOPE OF WORK

5.1 The obligations of the bidder under this service contract shall include services, activities and commitments as mentioned in Paragraphs 5.2.1 to 5.2.3 below. The details of locations are given in Appendix 'A'.

The bidder is required to provide entire set of services and will be responsible for safe execution of all the services required. The legal responsibility of entire project for complying to the statutory requirements like safety of the deployed staffs, compliance to the labour laws and any other compliance and clearances required for completing the assignments lies with bidder only.

5.2.1 Compliance Study

The bidder will conduct the safety regulations survey across all facilities and will identify gaps from the AERB Regulations [Atomic Energy (Radiation Protection) Rules, 2004]. This will include:

5.2.1.1 Data Collection in the prescribed format for all the facilities in scope of study.

5.2.1.2 Submission of Survey Report and Work plan for Infrastructure Development.

5.2.1.3 Enlist the infrastructure augmentation requirement.

5.2.1.4 Describe the implementation guidelines for infrastructure augmentation.

5.2.1.5 Submit a list of installed Radiology/Radiation emitting Equipment which are not type approved to the authority.

5.2.2 Infrastructure Development

Based on the gap analysis, the bidder shall upgrade the non-compliant facility as per AERB Regulations [Atomic Energy (Radiation Protection) Rules, 2004], and which shall include the following tasks to be performed.

5.2.2.1 Ensure Availability of patient (1 no.) and Healthcare worker (2 nos.) Lead Apron gown.

5.2.2.2 Installation of Warning Lights.

5.2.2.3 Lead Lining for Doors as per AERB Regulations.

5.2.2.4 Protective (Mobile) Barriers with Viewing Glass for Healthcare Workers.

5.2.2.5 Availability of Chest Stand (1 no.).

5.2.2.6 Civil Work like closure of Windows, Shifting of Entrance Door, Increase in wall thickness as per AERB Regulations.

5.2.2.7 Proper Display of Radiation Hazard Signage.

5.2.2.8 Conduct Quality Assurance and Calibration of all equipment.

5.2.2.9 Procurement/Purchase of all required items for Infrastructure upgrade, and their replacement or repair in case of defects after installation, shall be the responsibility of the bidder.

The bidder shall hand over of all the documents/ reports / findings /presentations/ collated data prepared as per the scope of this project to the Nodal Authority at the termination or end of the Contract.

5.2.3 Issuance of "License for Operation" by AERB

After ensuring compliance and upgradation of the facilities (as need be), the bidder shall facilitate issuance of "License for Operation" from AERB for the equipment and all the relevant facilities mentioned in Appendix A. For obtaining License of each facility, the bidder needs to enter facility details in e-LORA (e-Licensing of Radiation Applications).

The following are the steps for obtaining License through e-LORA for each facility:

5.2.3.1 Step 1- Registration of Facility with e-LORA.

5.2.3.2 Step 2- Declaration of X-ray Equipment details with e-LORA.

5.2.3.3 Step 3- "License for Operation" of Existing X-ray Equipment in e-LORA.

Step 3.1- Availability of Qualified Radiation Workers (TLD cards should be available).

Step 3.2- Availability of required Safety Tools.

Step 3.3- Layout and Shielding Details (as per AERB requirements).

Step 3.4- Quality Assurance Test Report.

Step 3.5- Approved RSO

5.3 It is understood that the successful bidder will be required to engage specialized agencies to carry out some of the tasks like construction activities. However, under no circumstances, the bidder will be allowed to sub contract either in full or in part, the services required to be performed by him.

5.4 Should a situation arise, wherein the Authority may require to conduct AERB compliance study and infrastructure upgradation work, alongside acquisition of License of Operation, for additional facilities, the bidder may be required to provide their expertise and services over for the same (within a Cluster/ clusters/state). However, in such a case, the bidder will be given a prior intimation and based upon a mutual agreement, the bidder will be paid additionally as per the payment terms of this RFP and its Contract.

SECTION–VI

ELIGIBILITY CRITERIA

1. The bidder shall be a legal entity and bidding in consortium is not permitted.
2. Only Agencies authorized by AERB as Service Agency (Medical Diagnostic X-ray Equipment) the list is available at http://www.aerb.gov.in/images/PDF/DiagnosticRadiology/3.4.30-List-of-Authorised-Service-Agencies-in-DR.pdf) are eligible to participate. As per AERB a service agency is defined as "The agencies associated with installation, commissioning, servicing, Quality Assurance, decommissioning and sale of pre-owned (used/refurbished) diagnostic x-ray equipment are termed as service agencies." http://www.aerb.gov.in/AERBPortal/pages/English/X-Ray/serviceguidelines.pdf
3. The Bidder is not presently blacklisted by the Authority or by any State Govt. or its organizations or by Govt. of India or its organizations.
4. The bidder shall have an average turnover of Rs < > per annum in last three financial years. In case of consortium bidding, aggregate financial turnover of all the members will be considered.
5. Experience of at least three years as AERB a service agency associated with installation, commissioning, servicing, Quality Assurance, decommissioning of pre-owned (used/refurbished) diagnostic x-ray equipment.

SECTION–VII

TERMS AND CONDITIONS

1. Signing of Contract

The authority shall issue the Notice for Award of Contract to the successful bidder within the bid validity period. And the successful bidder will be required to sign and submit the contract unconditionally within 15 days of receipt of such communication.

2. The authority shall issue the Notice for Award of Contract to the successful bidder within the bid validity period. And the successful bidder will be required to sign and submit the contract unconditionally within 15 days of receipt of such communication.

Modification to Contract

The contract when executed by the parties shall constitute the entire contract between the parties in connection with the jobs / services and shall be binding upon the parties. Modification, if any, to the contract shall be in writing and with the consent of the parties.

3. Performance Security

a. The successful bidder shall furnish a performance security in the shape of a Demand Draft/Bank Guarantee/FDR issued by a scheduled Bank in favour of Bid Inviting Authority for an amount equal to 10% of the total contract value. Contract value may be calculated as no. of facilities × financial bid per facility. The Bank guarantee shall be as per proforma at "Appendix E" and remain valid for a period, which is six months beyond the date of expiry of the contract. This shall be submitted within 15 days (minimum) of receiving of Notice for Award of Contract, failing which the EMD may be forfeited and the contract may be cancelled.

b. If the firm / contractor violate any of the terms and conditions of contract, the Performance Security shall be liable for forfeiture, wholly or partly, as decided by the Authority and the contract may also be cancelled.

c. The Authority will release the Performance Security without any interest to the firm / contractor on successful completion of contractual obligations.

4. Compliance of Minimum Wages Act and other statutory requirements

The bidder shall comply with all the provisions of Minimum Wages Act and other applicable labour laws. The bidder shall also comply with all other statutory provision eligibility criteria of human resources used by the bidder for providing the services.

5. Income Tax Deduction at Source

Income tax deduction at source shall be made at the prescribed rates from the bidder's bills. The deducted amount will be reflected in the requisite Form, which will be issued at the end of the financial year.

6. Payment Terms

The Payment will be linked to the following delivery milestones for a Cluster/State:

S. No.	Description of Mile stone	% of contract value
1	Signing of contract and submission of bank guarantee/FDR	10 % Mobilization advance
2	Submission and Verification of Compliance Study	10 %
3	Completion of Infrastructure Development	40%
3.1	Completion of Registration of each Facility &	10%
3.2	Provision of safety tools and completion of civil works in all facilities	10%
3.3	Quality Assurance and Calibration of all equipment	10 %
3.4	Provision of TLD badges for all radiation health workers	10%
4	Obtaining "License for Operation" from AERB for each facility	40%
4.1	Obtaining "License for Operation" from AERB for	20%
4.2	Obtaining "License for Operation" from AERB for	20%

The Authority may/shall form an Inspection Committee which will perform the Final Inspection of the work done by the bidder as part of Scope of Work mentioned in the RFP.

6.2 The bidder shall submit a Self-Declaration to the Paying Authority, comprising of relevant proofs (where applicable) of work done for AERB compliance at that facility, for completion of each milestone, which shall form the basis for the payment.

6.3 The bidder will submit the invoice/Self-Declaration Form on monthly basis to the Paying Authority.

6.4 After verification of invoices/Self-Declaration Form, the Paying Authority will make the payment within 30 days of all invoices/Self-Declaration Form raised.

6.5 The payment will be subject to all Statutory Taxes, Tax Deducted at Source (TDS), as per Applicable taxes and laws.

6.6 The bidder hereby acknowledges and agrees that it is not entitled to any revision of the Payment Terms or other relief from the Paying Authority except in accordance with the express provisions of this Agreement.

Penalties would apply on payments, as defined in this RFP document, due to non-conformance to the Service and Operations Requirements

7. Damages for Mishap/Injury

The authority shall not be responsible for damages of any kind or for any mishap/injury/accident caused to any personal /property of the bidder while performing duty in the authority's / consignee's premises. All liabilities, legal or monetary, arising in that eventuality shall be borne by firm/ contractor. The successful bidder will indemnify the Authority, the State Government and the Facilities in respect of such events.

8. Termination of Contract:

The Authority may terminate the contract, if the successful bidder withdraws its bid after its acceptance or fails to submit the required Performance Securities for the initial contract and or fails to fulfill any other contractual obligations. In that event, the authority will have the right to procure the same services from

next eligible bidder and the extra expenditure on this account shall be recoverable from the defaulter. In case of termination of contract security deposit and EMD may be forfeited.

9. Arbitration

a. If dispute or difference of any kind shall arise between the authority and the bidder/contractor in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

b. If the parties fail to resolve their dispute or difference by such mutual consultations within thirty days of commencement of consultations, then either the authority or the bidder/contractor may give notice to the other party of its intention to commence arbitration, as hereinafter provided. The applicable arbitration procedure will be as per the Arbitration and Conciliation Act, 1996 of India. In that event, the dispute or difference shall be referred to the sole arbitration of an officer to be selected by the <insert bid issuing authority> as the arbitrator. If the arbitrator to whom the matter is initially referred is transferred or vacates his office or is unable to act for any reason, he / she shall be replaced by another person selected by <insert bid issuing authority> to act as Arbitrator. Such person shall be entitled to proceed with the matter from the stage at which it was left by his predecessor. The award of the provision that the Arbitrator shall give reasoned award in case the amount of claim in reference exceeds Rupees One Lac (Rs.1,00,000/-)

c. Work under the contract shall, notwithstanding the existence of any such dispute or difference, continue during arbitration proceedings and no payment due or payable by the Authority to the bidder shall be withheld on account of such proceedings unless such payments are the direct subject of the arbitration.

d. Reference to arbitration shall be a condition precedent to any other action at law.

e. Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

10. Applicable Law and Jurisdiction of Court:

The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force. The Court located at the place of issue of contract shall have jurisdiction to decide any dispute arising out of in respect of the contract. It is specifically agreed that no other Court shall have jurisdiction in the matter.

11. Time Frame for Completion of Services

The overall duration for completion of services for each cluster can be categorized across three phases which would be considered from the day of signing of the Contract by the Authority and the Selected Bidder.

Phase 1: Completion of Compliance Study of all the facilities in a Cluster within 60 days from the day of signing of the contract by both parties.

Phase 2: Completion of Infrastructure Development of those Radiology/Radiation Emitting Equipment at the Facilities which are Non-Compliant to meet all statutory Safety Regulations of AERB within 180 days from the day of signing of the contract by both parties.

Phase 3: Issuance of License of Operation from AERB for all the Radiology/Radiation Emitting Equipment at facilities in a Cluster/State within 365 days from the day of signing of contract.

12. Penal Charges

12.1 For delay up to 15 days in completion of services in each phase, a penalty of 0.5 % of Contract Value of a Cluster/state shall be levied.

12.2 For delay between 16-30 days in completion of services in each Phase, a penalty of 1 % of Contract Value of a Cluster/state will be levied.

12.3 For delay between 30-45 days in completion of services in each Phase, a penalty of 5 %(of Contract Value of a Cluster/state will be levied. The maximum penalty for delay is 5% of the contract value.

12.4 For delay beyond 45 days contract may be terminated along with forfeiture of performance security and deduction of payment for the work completed. The said deductions may be used for payment to next eligible vendor.

APPENDIX-A

Facility details for the Project

S.No.	Name of the Institute	Institute Address
Total		

APPENDIX-B

PARTICULARS OF THE BIDDER'S COMPANY

(To be submitted by all bidders)

1. Name :
2. Registered Address
3. Phone/Fax/Mail id
4. Type of Organization : Prop./Partnership/Company/Consortium/Trust/ Not for Profit Organization etc.
5. Registration. Nos.
   a. EPF
   b. ESI
   c. Sales Tax
   d. VAT
   e. Service Tax
   f. PAN No.
   g. Audited Accounts Statement for past three financial years
   h. Copy of Income Tax Return for past three financial years(whichever is applicable)
6. Brief write-up about the firm / company. (use extra sheet if necessary)

Signature of Bidders
Date: Name
Place: Office Seal

APPENDIX-C

Forwarding Letter for Technical Bid

(To be submitted by all bidders on their letterhead)

Date…….

To

<Name, Designation and Address of Bid Inviting Authority>

Sub: Bid for supply of services under Bid No….

Sir,

We are submitting, herewith our bid for Atomic Energy Regulatory Board Certification (AERB) Facilitation on turnkey basis :Gap Analysis, Gap filling and Issuance of License for operation by AERB for the state/ cluster<insert number>

We are enclosing Receipt No…….. or Bank Draft/Bankers Cheque No……., Dated……(amount……) towards bid cost/fee (if documents have been downloaded from website) and Bank Draft / Bankers Cheque/ bank guarantee / Fixed Deposit Receipt (FDR) No…….. Dated…… (Amount……) towards Earnest Money Deposit (EMD), drawn on…… Bank in favor of <Bid Inviting Authority>.

We agree to accept all the terms and condition stipulated in your bid enquiry. We also agree to submit Performance Security as per terms of Bid Enquiry document.

We agree to keep our offer valid for the period stipulated in your bid enquiry.

Enclosures:

1.

2.

3.

4.

5.

Signature of the Bidder……

APPENDIX-D

FINANCIAL BID

Name of the Bidder……..

1. The Quote is for per facility Cost for Atomic Energy Regulatory Board Certification (AERB) Facilitation on turnkey basis: Gap Analysis, Gap filling and Issuance of License for operation by AERB, as described below:

S.No.	Description of Cost heads	Cost (INR)	Applicable taxes/duties	Total
1	Cost of Compliance Study per Facility	A1	B1	C1
2	Cost for Total Infrastructure development per facility, inclusive of civil work	A2	B2	C2
3	Cost associated with obtaining of "License for operation" from AERB per facility	A3	B3	C3
Total Price per Installation (D) (in Rs.)		D= C1+C2+C3		

For amount A2 = "Cost for Total Infrastructure Development per Installation/ Facility, inclusive of Civil work", the Bidder MUST provide a price quote of the following items as per table below.

The arithmetic sum of the prices of the items under the below table MUST equal the value of "Cost for Total Infrastructure Development per Installation/ Facility" = A2.

S.No.	Items	Unit Price Exclusive of Taxes
1	Cost of Lead Apron gown	
2	Cost Warning Lights	
3	Cost of Lead Lining for Doors as per AERB Regulations	
4	Cost of installation of Lead Glass as per AERB Regulations	
5	Cost Protective (Mobile) Barriers with Viewing glass	
6	Cost of Chest Stand	
7	Cost of Signage for Display of Radiation Hazard	
8	Cost of conducting Quality Assurance Test /Calibration (X-Ray)	
9	Cost of conducting Quality Assurance Test /Calibration (mammography)	
10	Cost of conducting Quality Assurance Test /Calibration (CT Scanner)	
11	Avg. cost of labor / manpower to perform upgradation work with respect to all the above listed items, at a facility / installation including civil work	
Gross Total		

2. The bidder has to deposit 10% of the contract value as performance security in form of Irrevocable Bank Guarantee/Fixed Deposit Receipt (FDR) with validity 6 months beyond the duration of the contract.

3. Total price per installation (D) is a lump sum figure and no additional amount will be paid. The unit price A2 break up is only for price justification purposes.

Signature……

Name……..

APPENDIX-E

PROFORMA FOR BANK GUARANTEE

To

< Name, Designation and Office Address of Bid Inviting Authority>

WHEREAS……..(Name and address of the Bidder) (Hereinafter called " the Bidder" has undertaken, in pursuance of contract No…….. dated …….. (Herein after "the contract") to provide Atomic Energy Regulatory Board Certification (AERB) Facilitation on turnkey basis :Gap Analysis, Gap filling and Issuance of License for operation by AERB AND WHEREAS it has been stipulated by you in the said contract that the bidder shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give such a bank guarantee on behalf of the bidder;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the bidder, up to a total of…….. (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the bidder to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforeside, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the bidder before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the bidder shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to 6 months after the contract termination date …….. (Indicate date)

……...
(Signature with date of the authorized officer of the Bank)

…….
Name and designation of the officer

……..
Seal, name & address of the Bank and address of the Branch

APPENDIX-F

DECLARATION BY BIDDER

I / We do hereby declare I / We have not been de- recognized / black listed by any State Govt. / Union Territory / Govt. of India / Govt. Organisation / Govt. Health Institutions.

Signature of the bidder:
Date:
Name & Address of the Firm:

Affidavit before Executive Magistrate / Notary Public in Rs.100.00 stamp paper.

Mapping of Radiation Safety compliances in Public Health Facilities

State				District											Date					
					AERB Approval			Infrastructure			Process				Outcome – Safety					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
S.N	Type of Facility	Facility Name	Type of Machine	Model No.	Type Approval	Layout Approval	AERB Registration/ License	Room Size	Machine Orientation	Lead Line	X-Ray		HR		Lead Gown		TLD	Warning Light	Chest Stand	Mobile Protective Barrier
											Analog	Digital	Radio -grapher	Radio logist	Patient	Health Worker	Health Worker			

CONTRACT FORMAT

CONTRACT FORM FOR PROVIDING AERB Certification Facilitation on turnkey basis: Gap Analysis, Gap filling by Infrastructure Development and Issuance of License for operation by AERB

……..……..

……..……..

(Address of the Bid Inviting Authority/Office issuing the contract)

CM Contract No._____ dated_____

This is in continuation to this office's Notification for Award of contract No …….. dated

Name & address of the Bidder: …….....

Reference: (i) Bid Enquiry Document No ……. Dated …….and subsequent Amendment No ……., dated …….. (if any), issued by the Bid Inviting Authority (ii) Bidder's Bid No ……. Dated ……and subsequent communication(s) No ……..

Dated ……. (if any), exchanged between the supplier and the authority in connection with this bid.

THIS AGREEMENT made the ……. Day of …….. 20… between (name of bid inviting authority) (hereinafter called the **Procurer**) of one part and ……. (name of bidder) (Hereinafter called the **Service provider**) of the other part:

WHEREAS the Procurer is desirous that certain services should be provided by the Bidder, viz, (brief description of services) and the Procurer has accepted a bid submitted by the Bidder for the Services for the sum of …… (Contract price in words and figures) (Hereinafter called the Contract Price),

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. The following documents shall be deemed to form part of and be read and constructed as integral part of this Agreement, viz.:
   (i) Terms and Conditions;
   (ii) Location and Description of Equipment;
   (iii) Job Description;
   (iv) Manufacturer's Authorization Form (if applicable to this bid);
   (v) Authority's Notification of Award.
2. In consideration of the payments to be made by the Procurer the Bidder hereby covenants to provide the Comprehensive Maintenance Services for the specified equipments in conformity in all respects with the provisions of the Contract.
3. The Procurer hereby covenants to pay the Bidder in consideration of the services , the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed in the Contract.

4. The bank guarantee valid till _____ [(fill the date)] for an amount of Rs. _____ [(fill amount) equivalent to 10% (minimum) of the cost of the contract value] shall be furnished in the prescribed format given in the TE document, within a period of 15 (fifteen) days of issue of Notice for Award of Contract failing which the EMD shall be forfeited.

5. Payment terms: The payment will be made against the bills raised to the Procurer by the Provider on weekly basis after satisfactory completion of said period, duly certified by the designated official. The payment will be made in Indian Rupees.

6. Paying authority: _____ (name of the Procurer i.e. Office, Authority)

_____

(Signature, name and address of authorized official)
For and on behalf of_____

Received and accepted this contract
(Signature, name and address of the supplier's executive duly authorized to sign on behalf of the Provider)

For and on behalf of _____
(Name and address of the Provider)
(Seal of the provider)

Date: _____

Place:_____

CONTRIBUTIONS FROM FOLLOWING EXPERTS ARE GRATEFULLY ACKNOWLEDGED

1	Mr. C K Mishra, Secretary, MoHFW
2	Mr. Manoj Jhalani, AS & MD, MoHFW
3	Mr. Gautam Guha, Ex. AS & FA, MoHFW
4	Dr. Manohar Agnani, JS, MoHFW
5	Ms. Limatulla Yaden, Director (NHM-I), MoHFW
6	Ms. Sunita Sharma, Director (NHM-IV), MoHFW
7	Dr. Sanjiv Kumar, Ex. Executive Director, NHSRC
8	Dr. Avinash Sonawane Uddhav, Scientist H, AERB
9	Dr. S B Sinha, Advisor, NHSRC
10	Dr. Uddipan Dutta, Principal Administrative Officer, NHSRC
11	Dr. Jitendar Sharma, Ex. Sr. Consultant, NHSRC
12	Er. Mohammad Ameel, Sr. Consultant, NHSRC
13	Er. Prabhat Arora, Ex. Consultant, NHSRC
14	Er. Anjaney, Consultant, NHSRC
15	Er. Ajai Basil, Consultant, NHSRC
16	Er. P S Vigneshwaran, Consultant, NHSRC
17	Ms. Akriti Chahar, Consultant, NHSRC
18	Mr. Sahil Agarwal, Consultant, NHSRC
19	Dr. Krushana Sirmawnar, Consultant, MoHFW
20	Dr. Nisarg, Consultant, MoHFW
21	Ms. Kainat Ishteyaque, Research Associate, IPC-NHSRC
22	Mr. Mohammad Zoheb, Fellow, NHSRC
23	Ms. Kesari, Fellow, NHSRC

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