

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE ATOMIC ENERGY REGULATORY BOARD (AERB)

Government of India, Mumbai 400 094

AND

DEPARTMENT OF HEALTH & FAMILY WELFARE

Government of

....., State

....., 2014

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**DEPARTMENT OF HEALTH & FAMILY WELFARE
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....., State

1.0 This Memorandum of Understanding (hereinafter called M.O.U.) covers the terms and conditions under which the Atomic Energy Regulatory Board (hereinafter called AERB) and the Department of Health & Family Welfare (hereinafter called Department) have agreed to participate in the regulatory inspections of medical diagnostic x-ray equipment/installations in -----(hereinafter called as x-ray installations) and other regulatory functions as directed by AERB

1.1 This MOU made and entered into on this day ofTwo Thousand Fifteen (2015) between the Atomic Energy Regulatory Board (AERB), a Government of India body, having its registered office at Niyamak Bhavan, Anushaktinagar, Mumbai 400 094 (hereinafter called AERB which expression shall where the context so admits include its successors and permitted assigns) on the first part

AND

the Department of Health & Family Welfare, Government of, having its offices in (hereinafter called Department which expression shall where the context so admits include its successors and permitted assigns) of the other part.

2.0 PREAMBLE

2.1 WHEREAS AERB is engaged in exercising regulatory functions for all activities related to the use and handling of ionizing radiation sources in the country, on behalf of the Government of India, and is desirous of authorising the Department of Health & Family Welfare, Government of for conducting regulatory inspections of x-ray installations and other regulatory functions as directed by AERB as per Rule 30 (1, 2, 3, 4, 5, 6a, 6b, 6c, 6d) of the Atomic Energy (Radiation Protection) Rules 2004 promulgated under the Atomic Energy Act, 1962.

2.2 WHEREAS Department is willing to set up a Radiation Safety Agency (RSA) such as Directorate of Radiation Safety (DRS) , Radiation Safety Cell (RSC), etc., having qualified manpower (as indicated in Annexure-1) to undertake the inspection activity. Now, therefore, in consideration of the premises and mutual covenants hereinafter contained, the parties hereto agree as follows :

3.0 SCOPE OF THE MOU

3.1 The MOU details the terms and conditions relating to the respective responsibilities and obligations of the parties, and confidentiality pertaining to the specified regulatory functions.

4.0 RESPONSIBILITIES OF THE DEPARTMENT

4.1 The Department shall set up a RSA with the staff with designations, academic and professional qualifications as indicated in Annexure-I. The Department would also designate the Head of RSA, as the Officer co-ordinating with AERB and the Department. The Head shall be directed to provide the list of radiation safety

inspectors appointed by RSA involved in the specified regulatory functions with their detailed profile.

4.2 The Department shall assign in writing the following functions and responsibilities to RSA.

RSA shall

- I be the agency under the Government of entrusted with the responsibility of implementing Rule 30 (1, 2, 3, 4, 5, 6a, 6b, 6c, 6d) of the Atomic Energy (Radiation Protection) Rules 2004 and the guidelines promulgated by the AERB from time to time regarding radiation safety in radiation facilities in The installations of the Department of Atomic Energy, Government of India, shall be excluded from the purview of RSA.
- II Undertake regulatory inspections of x-ray installations as per the Guidelines of AERB Safety Manual for ‘Regulatory Inspection and Enforcement in Radiation Facilities (AERB/RF/SM/G-3)’.
- III Verify the compliance with requirements stipulated in the Atomic Energy (Radiation Protection) Rules, 2004 and in the relevant Notifications, Safety Standards, Codes and Guides of AERB during the regulatory inspection of x-ray installations and suggest corrective measures to the x-ray installations if any, as appropriate.
- IV Use recommended and applicable inspection checklist of AERB for carrying out regulatory inspections.
- V Organize awareness programs on Radiation Safety for x-ray facilities and provide training /assist them for obtaining AERB Licence through e-LORA (e - Licensing Of Radiation Applications which is web-based online system of AERB)

- VI Organize training programmes/ workshops/seminars on radiation safety from time to time in co-operation with appropriate agencies and under the guidance of AERB to update the knowledge of radiation safety among the technical people involved.
- VII Send the periodic report to AERB about all the activities of RSA including inspection reports/inspection recommendations/observations and investigation reports of excessive exposures if any. Reports to be submitted in hard copy and in future to be uploaded/ submitted through e-LORA as applicable.

5.0 RESPONSIBILITIES OF AERB

- 5.1 AERB shall arrange training programme at least once in three years to the staff of the RSA to prepare them for carrying out the regulatory inspections and other specified regulatory functions assigned by AERB. The TA/DA expenses of the team from the RSA for this programme shall be borne by the Department. There shall be no charge levied for the training services provided by AERB.
- 5.2 AERB shall issue an appropriate authorization for each employee of the RSA entrusted with the inspection work and specified regulatory functions on behalf of AERB. Such an authorization shall be returned to AERB immediately upon retirement or the disengagement of the particular employee from the inspection activity.
- 5.3 AERB shall provide to RSA the information available with it regarding the list of x-ray installations and other relevant data. AERB will also provide the details of the institutions, who have obtained Licence from AERB through e-LORA for undertaking regulatory inspections.

6.0 JOINT REVIEW

6.1 Chairman, AERB and Secretary, Department of Health & Family Welfare, Government of shall jointly review the overall progress of work along with the Head, RSA at least once annually. Such reviews shall be held in and Mumbai, alternately. First such review shall be held in within six months of the formation of the RSA. The Head, RSA should submit to AERB a detailed status report on the regulatory inspections and other assigned functions periodically and hold a review meeting with AERB at Mumbai once in 12 months. TA/DA for the review meeting shall be met by RSA.

7.0 EFFECTIVE DATE, DURATION AND TERMINATION OF MOU

7.1 The MOU shall be effective from the date of signing and shall remain in force for a period of five (5) years from the effective date. MOU shall be extended on mutual discussion and consent between Chairman, AERB and Secretary, Department of Health & Family Welfare,

7.2 During the tenure of the MOU, parties hereto can terminate the MOU either for violation of any of the clauses of the MOU or for other valid reasons, by giving six (6) month's notice in writing to the defaulting party. Failure of either party to terminate the MOU on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this MOU.

8.0 SETTLEMENT

8.1 In the event of termination of the MOU vide clause 7.2, the rights and obligations of the parties hereto shall be settled by mutual decisions.

9.0 CONFIDENTIALITY

9.1 RSA shall not divulge the information collected during the regulatory inspection or while carrying out any assigned regulatory functions to any other outside

agency or persons without obtaining the prior permission from AERB. No publications shall arise from RSA on the analysis of inspection work and data without the explicit concurrence of AERB.

10.0 RELATIONSHIP BETWEEN RSA AND AERB

10.1 The RSA shall carry out the functions envisaged under the Rule 30 (1, 2, 3, 4, 5, 6a, 6b, 6c, 6d) of the Atomic Energy (Radiation Protection) Rules 2004. AERB shall have the right to inspect any radiation facility on its own or to re-inspect a representative number of radiation facilities already inspected by RSA to verify the correctness of its observations.

10.2 AERB shall have the authority to withdraw the authorisation extended to the Head, RSA or any of its inspectors to carry out various functions under the Rule 30 (1, 2, 3, 4, 5, 6a, 6b, 6c, 6d) of the Atomic Energy (Radiation Protection) Rules 2004 after conveying in writing the reasons for the withdrawal. AERB decision in this matter shall be final and binding on the RSA and the..... State Government.

10.3 If RSA finds that any institution has violated the rules and guidelines of radiation safety, it will inform AERB about the violation in detail, along with recommendation on action to be taken. Necessary action will be taken by AERB and intimated to RSA.

11.0 APPEAL AGAINST DECISIONS OF RSA

11.1 Appeals, if any, against the decisions of the RSA will lie with the Atomic Energy Regulatory Board.

12.0 LEGAL MATTERS

12.1 All legal matters, including court cases, complaints, RTIs etc., arising out of the functioning and enforcement of actions of RSA shall be handled by appropriate lawyers/ legal representatives to be appointed by the State Government/Union Territory. AERB also reserves the right to be represented through the same State Government/ Union Territory lawyers appointed by the RSA, in case AERB is made a co-respondent in any case. The legal fees etc. for such defending RSA action shall be borne by the RSA, except for the fees of lawyers appointed by AERB.

13.0 FORCE MAJEURE

13.1 Neither party shall be held responsible for non-fulfillment of their respective obligations under this MOU due to the exigency of one or more of the force majeure events such as but not limited to acts of God, war, flood, earthquakes, strike, lockouts, epidemics, riots, civil commotion, etc. provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within two weeks of such occurrence or cessation. If the force-majeure conditions continue beyond six months, the parties shall then mutually decide about the future course of action.

14.0 NOTICES

14.1 All notices and communications to be served on the Department shall be considered as duly served if the same shall have been delivered to, left with or posted by registered mail to the RSA at its registered headquarters address in..... Similarly, all notices and other communications required to

be served on AERB under the terms of this MOU shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to AERB at its headquarters address in Mumbai.

15.0 ARBITRATION

15.1 Except where otherwise provided, any dispute arising out of this MOU shall be referred to the sole arbitration of a person mutually agreed by Chairman, AERB and Secretary, Department of Health & Family Welfare, Government of whose decision shall be final and binding. The Arbitrator may, from time to time, with the consent of the parties, enlarge the time for making and publishing the award.

16. SERVICE CHARGES

AERB is not charging currently for services toward the consenting processes such as registration, License etc.,) for x-ray installations. However, in order to maintain the sustainability of RSA, the State Government may charge the radiation facilities for the radiological and other associated services rendered towards effective implementation of radiation safety in the interest of public and patient safety in the respective States.

SEAL OF PARTIES

In witness whereof the parties hereto have signed this Memorandum of Understanding on the day, month and year mentioned hereinbefore.

Parties

For and on behalf of
the Department of Health &
Family Welfare

For and on behalf of AERB

Signature : _____

Name :

Designation : Secretary, Department
of Health & Family Welfare
Government of

Seal : _____

Witness : (Name & Address)

1. _____

2. _____

Date : _____

Signature : _____

Name : (Shri R.Bhattacharya)

Designation : Secretary, AERB

Seal : _____

Witness : (Name & Address)

1. _____

2. _____

Date : _____

Annexure-I

**MINIMUM QUALIFICATIONS AND PROFESSIONAL EXPERIENCE OF THE STAFF
OF RADIATION SAFETY AGENCY (RSA)**

Name of the Post	Academic Qualification(s)	Professional Experience
Head, RSA	(a) a post graduate degree in physics from a recognized university and, (b) a Post M.Sc. diploma in radiological physics or equivalent from a recognized university. OR (a) a basic degree in science from a recognized university, with physics as one of the main subjects and; a post graduate degree in radiological physics or equivalent from a recognised university.	Qualified physicist with at least five years of working experience in radiation safety/at least five years of safety related working experience in radio-diagnosis/radiotherapy in a premier academic/research institution.
Radiation Safety Inspector	(a) a post graduate degree in physics from a recognized university and, (b) a Post M.Sc. diploma in radiological/medical physics or equivalent from a recognized university. OR (b) a basic degree in science from a recognized university, with physics as one of the main subjects and; (c) a post graduate degree in radiological physics or equivalent from a recognised university.	Qualified physicist with at least two years of working experience in radiation safety/at least two years of safety related working experience in radiation facility in a premier academic/research institution.