CODE NO. AERB/RF-MED/SC-2 (Rev. 2)

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GOVERNMENT OF INDIA

AERB SAFETY CODE

NUCLEAR MEDICINE FACILITIES

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY CODE NO. AERB/RF-MED/SC-2 (Rev. 2)

NUCLEAR MEDICINE FACILITIES

Approved by the Board on November 4, 2010

Atomic Energy Regulatory Board
Mumbai-400 094
India

March 2011

Price

Order for this code should be addressed to:

The Administrative Officer
Atomic Energy Regulatory Board
Niyamak Bhavan
Anushaktinagar
Mumbai-400 094
India

FOREWORD

Activities concerning establishment and utilization of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act, 1962. In pursuance of the objective of ensuring safety of members of the public and occupational workers as well as protection of environment, the Atomic Energy Regulatory Board (AERB) has been entrusted with the responsibility of laying down safety standards and framing rules and regulations for such activities. The Board has, therefore, undertaken a programme of developing safety codes, safety standards, and related guides and manuals for the purpose. While some of these documents cover aspects such as siting, design, construction, operation, quality assurance and decommissioning of nuclear and radiation facilities, other documents cover regulatory aspects of these facilities.

Safety codes and safety standards are formulated on the basis of nationally and internationally accepted safety criteria for design, construction and operation of specific equipment, structures, systems, and components of nuclear and radiation facilities. Safety codes establish the objectives and set requirements that shall be fulfilled to provide adequate assurance for safety. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. The documents are revised when necessary, in the light of experience and feedback from users as well as new developments in the field.

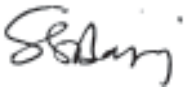
The first safety code on 'Nuclear Medicine Laboratories', AERB/SC/MED-4 was issued by AERB in 1989. It specified mandatory requirements for a nuclear medicine facility, covering the entire spectrum of operations ranging from setting up of a facility to its ultimate decommissioning, including procedures to be followed during an emergency situation. The code also stipulated requirements of personnel and their responsibilities. The code had been revised and published in October 05, 2001 as AERB/SC/MED-4 Rev.1(2001). Based on the feedback obtained on this version, changes are incorporated in the current version which include recognition of additional degree/diploma courses by AERB for nuclear medicine technology, new diagnostic modalities such as positron emission tomography (PET) and treatment modalities with new radiopharmaceuticals, revision on the regulatory code with respect to criteria for release of I-131 administered patients from hospitals and to include other radionuclides, eligibility criteria for RSO for high dose therapy centres and requirement of staff for nuclear medicine facility.

The revised code is effective from the date of issue and supersedes the all earlier codes including AERB/SC/MED-4 Rev. 1 (2001).

Appendices are an integral part of the document, whereas footnotes and bibliography are included to provide further information on the subject that might be helpful to the user.

Specialists in the field drawn from the Atomic Energy Regulatory Board, the Bhabha Atomic Research Centre and other consultants have prepared this Code. It has been reviewed by experts and the Standing Committee on Radiation Safety Documents (SCRSD) and Advisory Committee on Radiological Safety (ACRS).

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft and helped in its finalisation. The list of experts, who have participated in this task, along with their affiliations, is included for information.



(S.S. Bajaj)
Chairman, AERB

DEFINITIONS

Activity

The quantity 'A' for an amount of radionuclide in a given energy state at a given time is defined as:

$A = dN/dt$

where, 'dN' is the expectation value of the number of spontaneous nuclear transformations from the given energy state in a time interval 'dt'. The SI unit of activity is the reciprocal of seconds(s^{-1}), termed the Becquerel (Bq).

Annual Limit on Intake (ALI)

The intake by inhalation, ingestion or through the skin of a given radionuclide in a year by the reference man, which would result in a committed dose equal to the relevant dose limit. The ALI is expressed in units of activity.

Committed Absorbed Dose, D (τ)

The quantity 'D (τ)' is defined as

$$D(\tau) = \int_{t_0}^{t_0+\tau} D(t)\, dt$$

where 't_0' is the time of intake, 'D (t) dt' is the absorbed dose rate at time 't' and 'τ' is the time elapsed after an intake of radioactive substance. When 'τ' is not specified, it will be taken to be 50 years for adults and age 70 years for intake by children.

Competent Authority

Any official or authority appointed, approved or recognised by the Government of India for the purpose of the rules promulgated under the Atomic Energy Act, 1962.

Contamination

The presence of radioactive substances in or on a material/the human body or other places in excess of quantities specified by the competent authority.

Controlled Area

A delineated area to which access is controlled and in which specific protection measures and safety provisions are, or could be, required for

(a) Controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(b) Preventing potential exposures or limiting their extent should they occur.

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation in a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Decontamination

The removal or reduction of contamination by physical or chemical means.

Disposal (Radioactive Waste)

The emplacement of waste in a repository without the intention of retrieval or the approved direct discharge of waste into the environment with subsequent dispersion.

Dose

A measure of the radiation received or absorbed by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose, or committed effective dose are used, depending on the context. The modifying terms are used when they are necessary for defining the quantity of interest.

Effective Dose

The quantity 'E', defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_{T} W_T . H_T$$

where H_T is the equivalent dose in tissue 'T' and 'W_T' is the tissue weighting factor for tissue 'T'. The unit of effective dose is $J.kg^{-1}$, termed the sievert (Sv).

Equivalent Dose

The quantity $H_{T,R}$ defined as

$$H_{T,R} = D_{T,R} . W_R$$

where $D_{T,R}$ is the absorbed dose delivered by radiation type 'R' averaged over a tissue or organ T and W_R is the radiation weighting factor for radiation type 'R'. When the radiation field is composed of different radiation types with different values of W_R, the equivalent dose is:

$$H_T = \sum_{R} W_R . D_{T,R}$$

Internal Exposure

Exposure due to a source within the body.

Licence

A type of regulatory consent, granted by the regulatory body for all sources, practices and uses for nuclear facilities involving the nuclear fuel cycle and also certain categories of radiation facilities. It also means authority given by the regulatory body to a person to operate the above said facilities.

Nuclear Medicine

The speciality that utilises radio-pharmaceuticals to investigate disorders of anatomy, physiology and patho-physiology, for diagnosis and/or treatment of diseases.

Quality Assurance (QA)

Planned and systematic actions necessary to provide the confidence that an item or service will satisfy given requirements for quality.

Radiological Safety Officer (RSO)

Any person who is so designated by the employer and who, in the opinion of the competent authority, is qualified to discharge the functions outlined in the Radiation Protection Rules, 2004.

Radioactive Waste

Material, whatever be its physical form, remaining from practices or interventions for which no further use is foreseen. It can be (a) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (b) exposure to which is not excluded from regulatory control.

Worker

Any person who works, whether full-time, part-time or temporarily, for an employer and who has recognised rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker).

SPECIAL DEFINITIONS

Administration

Process of administering of radiopharmaceuticals into the body of a patient by oral route, by inhalation, or by injection.

Comforter

Individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment.

Dosage

The activity of a radiopharmaceutical administered for diagnosis or therapeutic purpose.

Employer

Any person with recognised responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both a worker and employer).

Licensee

A person to whom license is granted by the competent authority under the relevant Rules.

Misadministration

The administration of:

(a) a radiopharmaceutical other than the one intended;

(b) a radiopharmaceutical to the wrong patient;

(c) a radiopharmaceutical by a route of administration other than that intended by the prescribing physician;

(d) a diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 per cent; or

(e) a therapeutic dosage of radiopharmaceutical differing from the prescribed dosage by more than 10 per cent.

Rules

Atomic Energy (Radiation Protection) Rules, G.S.R. 303, 2004.

Note**:** Words and expression not defined in this code, but defined in the act and rules shall have meanings respectively assigned to them in the act and rules.

CONTENTS

1. INTRODUCTION

1.1 General

Radioisotopes in unsealed form are used to carry out diagnostic and therapeutic operations in nuclear medicine practices and such radioisotopes have a potential for contamination and exposure. The Atomic Energy Regulatory Board (AERB) published a safety code on Nuclear Medicine Facilities in 1989, which was subsequently revised in 2001. This present code is being issued under the Atomic Energy (Radiation Protection) Rules, 2004.

1.2 Objective

This code stipulates radiation safety requirements in handling radioactive materials for nuclear medicine applications in order to:

(a) ensure that workers and members of the public are not exposed to radiation in excess of limits specified by the competent authority under the Atomic Energy (Radiation Protection) Rules, G.S.R. 303, 2004, and safety directives issued by the competent authority from time to time;

(b) reduce such radiation exposures to levels as low as reasonably achievable (ALARA);

(c) ensure safe handling, physical security of radioactive materials, patient protection and management of radioactive waste; and

(d) detect hazardous situations and initiation of prompt remedial measures to mitigate consequences.

1.3 Scope

Radiation safety in handling radiation sources is governed by sections 14, 16 and 17 of the Atomic Energy Act, 1962 and Atomic Energy (Radiation Protection) Rules, 2004, issued under the Act. The radiation surveillance procedures for medical applications of radiation, G.S.R. 388, 1989 specify the general requirements for radiation safety of:

(a) persons handling radiation sources for medical applications;

(b) patients who undergo medical treatment voluntarily for their health benefit;

(c) persons connected with the patient either by living with him or assisting him during the medical treatment; and

(d) members of the public unrelated to medical use of radiation.

This Code elaborates safety provisions applicable to this branch of medicine. In addition, regulations relevant to use of radioactivity for medical purposes are contained in radiation surveillance procedures for transport of radioactive material, Atomic Energy (Safe Disposal of Radioactive Waste) Rules, G.S.R. 125, 1987 and AERB safety code on 'Transport of Radioactive Material', AERB/SC/TR-1 (1986) currently in force.

2. REGULATORY CONTROLS

The licence for any practice involving radiation exposure is based on a system of licence, authorisation, registration and consent as established by the competent authority.

The licence is issued on the basis of a written application (Appendix - I). The licensee shall ensure that persons handling radioactive materials for nuclear medicine purposes are familiar with the mandatory provisions of the Atomic Energy (Radiation Protection) Rules, G.S.R. 303, 2004, the Atomic Energy (Safe Disposal of Radioactive Waste) Rules, G.S.R. 125, 1987, the safety directives issued by the competent authority from time to time, and other instructions of the competent authority in specific cases. The licensee shall ensure compliance with the mandatory requirements specified in the above documents in addition to the specific requirements contained in this code.

The licensee shall be a fulltime employee of the institution.

The employer shall designate with the approval of the competent authority a person having qualifications prescribed in subsection 3.5 of this code to function as a radiological safety officer (RSO). RSO shall be a full time employee of the institution.

Nuclear medicine facilities shall have RSO-II as per qualifications specified in Section 3. Facilities with radioisotope producing accelerators such as medical cyclotron shall have RSO-III as per qualifications specified in Section 3. The format of application for nomination for approval for RSO is given in Appendix-II.

Licence in the form of authorisation from competent authority is required to procure radioactive material. The licensee shall be responsible for the safety and security of the radioactive material, its proper use, and the safe disposal of waste.

The nuclear medicine facility shall not be commissioned until the competent authority approves the facility. Any change or modification to an already approved facility shall be carried out only with the prior approval of the competent authority.

Transport of radioactive material in public domain shall be in accordance with provisions of AERB safety code on 'Transport of Radioactive Material', AERB/SC/TR-1 (1986) currently in force.

The licensee shall not take radioactive material out of the approved premises. The licensee shall not lend, gift, transfer, sell or receive any radioactive material other than those specified in the authorisation without the prior approval of the competent authority.

Radioactive material shall not be disposed off without prior approval of the competent authority. The licensee shall obtain authorisation, as per Rule 4 of the Atomic Energy (Safe Disposal of Radioactive Waste) Rules, G.S.R. 125, 1987, from the competent authority.

Any person duly authorised by the competent authority shall inspect the nuclear medicine facility, the radioactive sources available in-house, the radioisotope inventory, logbooks, records of area monitoring and contamination monitoring, instruments and devices used for the above and/or quality assurance programme, records of unusual occurrences during handling of the sources and transport of radioactive materials, records of radioactive waste generated and disposed off and emergency response plans.

The nuclear medicine facility shall be decommissioned only after prior approval of the competent authority and after removing all radioactive and contaminated materials from the facility. Prior approval of the competent authority is necessary for re-use of the facility.

3. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

3.1 Employer

The employer shall:

(a) be the custodian of radiation sources in his possession and shall ensure physical security of the sources at all times;

(b) employ adequate number of nuclear medicine physician(s), nuclear medicine technologist(s) and RSO on a continual basis;

(c) report to the competent authority in the event of above qualified staff leaving the institution and alternate arrangements made;

(d) provide appropriate equipment and tools to concerned persons for safe handling of radioactive material;

(e) assign responsibilities to individuals in accordance with this code and establish lines of communication and authority;

(f) provide personnel monitoring devices to radiation workers;

(g) provide any special personnel monitoring device, including those for internal monitoring, that may be required; and

(h) ensure that provisions of this code are implemented by the licensee, RSO and other workers.

3.2 Licensee

The licensee shall

(a) constitute a local safety committee to review the safety of the facility in terms of operational safety, quality assurance and regulatory compliance. RSO shall be a member of the committee, which shall include persons familiar with operations of the facility. Competent authority shall be informed about the committee and its work;

(b) constitute a radiation protection programme depending on the type of nuclear medicine facility. The programme shall be submitted to the competent authority prior to obtaining license;

(c) submit periodic safety status report to the competent authority;

(d) report to the competent authority on any change in safety organisation of the facility; and

(e) report any unusual occurrence, pertinent to radiological health and safety, to the competent authority within 24 hours of the event and follow it up with detailed report as given in subsection 5.6 of this code.

3.3 Nuclear Medicine Physician

3.3.1 Qualifications

(a) A MBBS degree recognised by the Medical Council of India; and

(b) A post graduate degree/diploma in nuclear medicine recognised by the Medical Council of India or National Board of Examination, Ministry of Health and Family Welfare.

3.3.2 Responsibilities

The nuclear medicine physician shall

(a) have the responsibility of dosage administration and maintenance of records providing name of the patient, nature of procedure, radiopharmaceutical prescribed, quantity prescribed, name of the nuclear medicine physician with signature and date, and name of the person administering the radiopharmaceutical with signature and date;

(b) prevent any possibility of misadministration and promptly report to the licensee and the competent authority in the event of any misadministration, adverse reaction or death of a patient administered with radioactivity;

(c) consider factors such as proper choice of radiopharmaceuticals, monitoring of procedure and immobilisation of the patient in order to minimise absorbed dose to the patient;

(d) consider justification of diagnosis/therapy on pregnant patients/ lactating mothers in order to limit the exposure to the foetus/infant not exceeding an absorbed dose of 1 mGy;

(e) consider appropriate measures for dose fractionisation, in order to minimise non-stochastic effects following radionuclide therapy;

(f) adopt specific dosimetric consideration in pediatric patients to ascertain the risk-benefit ratio;

(g) inform patient on safety measures to be observed to avoid radiation exposure to the family members and others;

(h) ensure that where the quantity of radioactivity administered to a patient is in excess of the limits specified in subsection 3.5.5 (iv) for radiopharmaceuticals emitting gamma radiation or for radiopharmaceuticals emitting beta radiation as given in Table-1, (i) patient is hospitalised and kept isolated, (ii) spread of contamination prevented and (iii) exposure of staff, other patients and public minimised;

(i) instruct nursing and ancillary staff on radiation safety and precautions in nursing/management of therapy patients;

(j) obtain an informed consent from the relatives of the patient, prior to administration of therapeutic dose; and

(k) instruct on the time duration for avoidance of pregnancy following radionuclide therapy such that the absorbed dose to the conceptus shall not exceed 1 mGy.

3.4 Nuclear Medicine Technologist

3.4.1 Qualifications

(a) A bachelor's degree in nuclear medicine technology from a university; or

(b) A bachelor's degree in science from a university; and post graduate degree/diploma in nuclear medicine technology from a university

3.4.2 Responsibilities

The nuclear medicine technologist shall

(a) ensure proper functioning of all nuclear medicine equipment, carry out periodic calibrations, quality assurance checks and maintenance;

(b) ensure the radiopharmaceutical quality requirements, the route of administration and the accuracy of dosage before giving it to a patient and take precautions to avoid misadministration;

(c) avoid spillage of radioactivity or contamination of the patient, premises, persons and material by exercising care during dispensing/ administration of radioactivity;

(d) report to RSO and the nuclear medicine physician of any mishap in dispensing/administration of dosage to the patient or any unusual incident; and

(e) assist the RSO in maintaining records of sources and radioactive waste as specified in subsection 3.5.5 (f).

3.5 Radiological Safety Officer

3.5.1 Qualifications for RSO Level-II

A post-graduate degree/diploma in Nuclear Medicine recognised by Medical Council of India or National Board of Examination, Ministry of Health and Family Welfare;

or

A degree/post graduate diploma/post graduate degree in Nuclear Medicine Technology from an institution/university.

3.5.2 Approval of RSO-II

Approval by the competent authority.

3.5.3 Qualifications for RSO Level-III

Post M.Sc. diploma/post graduate degree in radiological physics/medical physics or equivalent from a university.

3.5.4 Approval of RSO-III

Approval by the competent authority.

3.5.5 Responsibilities

RSO shall

(a) advise and assist the licensee to organise a radiation protection programme appropriate for the facility and ensure that staff observe safe work practices;

(b) ensure safety, security and containment of radioactive sources, carry out radiation and contamination monitoring of work areas, patient waiting areas, radioactive waste disposal sites and public areas, and maintain record;

(c) ensure that radiation monitoring instruments are kept in proper working condition and are calibrated at regular intervals;

(d) establish procedures for management of emergency situations and conduct periodic drills to ensure their effectiveness;

(e) report any unusual incident in writing to the licensee, with a copy endorsed to the competent authority and take remedial measures to mitigate consequences of the incident and to prevent recurrence;

(f) maintain records of the doses of workers, the inventory of sources received, used and disposed off, any unusual incident, cause of such incident and remedial measures taken;

(g) ensure segregation and monitoring of the waste prior to interim storage or final disposal;

(h) advise and assist the licensee in ensuring regulatory compliance for obtaining authorisation from the competent authority for procurement, use, transport or disposal of radioactive material;

(i) inform the competent authority of his/her leaving the institution;

(j) advise and assist the licensee in transport of radioactive material/ radioactive waste in the public domain;

(k) ensure urgent processing of personnel dosimeters in cases of suspected overexposure; and

(l) display advisory notices in the nuclear medicine departments to avoid unintentional exposures to pregnant women/lactating mothers.

RSO attached to therapy centers shall, in addition to the above shall

(i) ensure that patients administered with radioisotopes for in-patient therapy are hospitalised in the approved isolation wards;

(ii) carry out regular monitoring of therapy patients, patient areas and nurse's station areas;

(iii) ensure that effective dose to the patient's comforter shall not normally exceed 5 mSv during the period of a patient's treatment;

(iv) ensure that dose to any family member other than comforter does not exceed 1 mSv/year, prospectively estimated prior to discharge of the patient;

(v) ensure that radiation level at 1 m from patient being discharged does not exceed 50 μSv/h at the time of discharge. Provide detailed instructions in English and local language on the safety precautions to be followed by the comforter and other family members so as to keep the doses below the levels specified in (iii) and (iv) respectively;

(vi) ensure that activity limit for discharge of patients administered with beta emitting radionuclides is as given in Table-1;

(vii) ensure sampling and monitoring of effluents from therapy wards prior to their release to public sewers;

(viii) ensure liquid effluents released to public sewer does not exceed authorised discharge limits;

(ix) maintain a separate logbook for data on monitoring of therapy patients from the time of hospitalisation until discharge from the ward;

(x) segregate and monitor patient linen prior to interim storage or reuse;

(xi) provide personnel monitoring to patient's comforter(s), if required, and maintain appropriate records;

(xii) give appropriate instructions for radiation safety and precautions to patient comforters in management of therapy patients;

(xiii) restrict entry of visitors to isolation wards;

(xiv) issue necessary written instructions at the time of discharge of therapy patients to minimise radiation exposure of family members especially to children and pregnant women; and

(xv) decide, in consultation with the physician-in-charge, the safety precautions to be followed, regarding disposal of cadavers containing radionuclides in accordance with the procedures approved by the competent authority.

TABLE-1 : ACTIVITY LIMIT FOR DISCHARGE OF PATIENTS ADMINISTERED WITH BETA EMITTING RADIONUCLIDES (THERA PEUTIC USE) FROM HOSPITAL

S. No.	Radioisotope	Activity (MBq)
1.	Y-90	4000
2.	Sm-153	4000
3.	In-111	400
4.	Sr-89	300
5.	P-32	1200
6.	Re-188	4000

4. RADIOLOGICAL SAFETY REQUIREMENTS FOR NUCLEAR MEDICINE FACILITIES

Nuclear medicine facilities shall be located away from general patient wards and public occupancy areas. The nuclear medicine facilities shall not be located in residential buildings. Design and construction of a nuclear medicine laboratory and an isolation ward shall be as per plan approved by the competent authority.

Active rooms, wards and areas of source storage and handling shall be marked with radiation symbol and legend denoting the identification of active area and presence of radiation hazard. Isolation wards shall be provided for patients undergoing nuclear medicine therapy requiring hospitalisation. Areas of high activity and contamination shall be demarcated by physical barriers. Active areas shall be arranged in increasing order of the activity with entrance provided at the lowest active area.

Walls, floor and doors of the active areas shall have hard, washable, non-porous and leak-proof covering. Work surfaces shall be covered with non-porous and non-reactive material.

Plumbing shall provide direct flow of liquid effluents from active areas directly to the delay tank. Effluent lines and delay tank (for interim storage of high level radioactive waste[1]) shall be leak-proof and corrosion-resistant.

Ventilation system shall be of once-through type with unidirectional airflow from areas of low activity to high activity. The exhaust from fume hoods shall be let out directly into the open after passing through charcoal and high efficiency particulate activity filters (HEPA).

Radiation level at 5 cm from the surface of the in-house transport container shall not exceed 10 μSv/h. Radiation symbol shall be permanently marked on its outer surface. Means shall be provided for securely locking the container.

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[1] The management of radioactive waste generated while handling radioactive material for nuclear medicine applications shall be done in accordance with the AERB safety guide titled 'Management of Spent Radioactive Sources and Radioactive Waste Arising from the Use of Radionuclides in Medicine, Industry and Research including Decommissioning of Such Facilities' (AERB/RF/SG/RW-6).

The following radiation measuring equipment shall be available in working condition:

(a) portable beta-gamma area monitor(s),

(b) contamination monitor(s) for personnel/area/surface/ clothing, and

(c) radioisotope calibrator.

Radiation monitoring equipment shall be calibrated at intervals specified by the competent authority and records maintained.

Radioactivity concentration in liquid effluents shall be within the limits such that the effective dose to the members of public does not exceed 100 μSv/ year.

Personnel monitoring device(s) shall be provided to all radiation workers.

Necessary safe handling and radiation protection accessories shall be provided.

5. MANAGEMENT OF RADIATION EMERGENCY

Licensee shall prepare emergency preparedness plans.

Personnel who are identified for emergency response actions shall be trained in handling emergencies.

Intervention shall aim at limiting external exposure, intake of radioactive materials and spread of contamination. The initiation and termination of intervention shall be to maximise the averted dose.

In case of spillage of radioactivity, the residual fixed contamination (beta-gamma) after decontamination shall not exceed the levels specified by the competent authority.

Licensee shall report to the competent authority within 24 hours of the event of the following unusual occurrences, which have hazardous consequences or potential to cause hazardous consequences:

(a) Spillage of radioactive material

(b) Loss/theft of radioactive material

(c) Death of a patient administered with therapeutic quantity of radioactivity

(d) Misadministration of radiopharmaceutical

(e) Any other event that may lead to situations of radiological consequence.

Detailed follow-up report including the following shall be submitted to the competent authority:

(a) Date and time of occurrence :

(b) Radionuclide, its activity and radiopharmaceutical composition :

(c) Brief description of the incident :

(d) Action taken :

(e) Probable causes of the incident :

(f) Steps taken for avoiding recurrence of the incident :

APPENDIX-I

Form No: AERB/RSD/NMF/ACO

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai - 400 094

APPLICATION FOR AUTHORISATION FOR COMMISSIONING AND OPERATION OF NUCLEAR MEDICINE FACILITY

(a) *This application would be considered by the competent authority for issuance of authorisation for the commissioning and operation of the facility, under the Atomic Energy (Radiation Protection) Rules, 2004.*

(b) *This form is intended to enable AERB to assess the suitability of the institution for procurement and use of radiation sources, which includes radiation generating equipment (hereinafter referred to as 'source')*

(c) *The duly filled in form should be sent to Director/Head, Radiological Safety Division (RSD), AERB, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with the necessary documents.*

(d) *Incomplete applications and those without all relevant documents are liable to be rejected*

(e) *All the forms pertaining to nuclear medicine can be downloaded from the website (www.aerb.gov.in)*

(f) *Attach extra sheets wherever required.*

PART A

GENERAL PARTICULARS

A.1 Name and address of the institution:

Telephone No: (O): (R)
Fax No.
E mail

A.2 Name and address of the Head of the institution[$] :

Telephone No. (O): (R)
Fax No.
Mobile No.
E mail

A.3 Name and designation of the applicant[#] :

Telephone No. (O): (R)
Fax No.
Mobile No.
Email

A.4 Name and designation of the Radiological Safety Officer (RSO)*:

Telephone No. (O): (R)
Fax No.
Mobile No.
E mail

RSO Approval reference No. :
Valid up to :

A.5 Address for correspondence with PIN code:

A.6 This application is for

First Regulatory Licence			
Additional**	Ref No.	Date:	Valid till:
Renewal	Ref No.	Date:	Valid till:

[#] *Applicant is the person in whose name the authorisation (licence) to handle the source may be issued, under AE RPR-2004, would have the responsibilities of '**licencee'** prescribed in AE-RPR,2004 and should be a full time employee of the institution.*

[$] *The head of the institution is the person who would have the responsibilities of '**employer'** prescribed in AE-RPR-2004.*

* *RSO is the person who is so designated by employer, approved by competent authority and has the responsibilities of '**Radiological Safety Officer'** prescribed in AE-RPR, 2004*

** *In case of approved site and layout plan.*

PART B

PARTICULARS OF THE FACILITY

B.1 Details of proposed radioactive sources to be used

B.1.1 In-vivo diagnosis

S. No.	Radioisotope	Radiopharma-ceutical	Maximum proposed activity to be Procured from BRIT per week	Maximum proposed activity to be Imported per week

B.1.2 Radionuclide Therapy (Low and high dose)

S. No.	Radioisotope	Radiopharma-ceutical	Maximum proposed activity to be Procured from BRIT per week	Maximum proposed activity to be Imported per week

B.1.3 List of sealed source(s) if any (to be used for calibration/quality assurance) used in the facility with the radionuclide, activity, date of procurement, purpose, supplier/manufacturer details

B.2 Equipment details

B.2.1 Imaging equipment

Name of the equipment	Make and model	Date of installation	Working (Yes/No)

B.2.2 Non-imaging equipment

Name of the equipment	Make and model	Date of installation	Working status

B.3 Isolation wards for therapy patients (undergoing treatment with high doses)

No. of isolation wards	Total No. of beds	Average No. of patients planned to be treated/ month	Delay tank capacity and dimensions

B.4 Monitoring & measuring instruments (survey instruments and dose calibrator)

Name of the instrument	Make, model and serial No.	Measurement range	Working status	Date of last calibration

B.5 Handling and general facilities

Fume Hoods (F.H.)	No. of functioning F.H. available:	Used for:
L-benches	No. of L-benches:	Used for:
Lead bricks/lead pots for shielding		
Drainage system		
Radioactive waste storage facility	Solid waste: Liquid waste:	

B.6 Name, qualification and experience of personnel

S. No.	Category of personnel	Name	Academic qualification	Type of training/ experience	When and where trained	Duration of training	Personnel monitoring service No.	Authorisation reference No. (If any)
1.	Nuclear medicine physicians							
2.	Nuclear medicine technologists							

S. No.	Category of personnel	Name	Academic qualification	Type of training/ experience	When and where trained	Duration of training	Personnel monitoring service No.	Authorisation reference No. (If any)
3.	Radiological Safety Officer (RSO)							
4.	Other auxiliary staff, in nuclear medicine facility							

B.7 Details of local safety committee constitution.

B.8 Procedures for disposal of radioactive waste

Radioisotope	Nature of waste generated		Method of disposal		Activity disposed MBq/week	
	Solid	Liquid	Solid	Liquid	Solid	Liquid

B.9 Documents to be attached with the application:

(i) Copy of approval of layout plan of the nuclear medicine laboratory issued by BARC/AERB

(ii) Copy of RSO approval letter or a duly filled in Application for approval of nomination of RSO in medical institution.

(iii) Personnel monitoring services details

(iv) Copy of the appointment and acceptance for the radiation workers

(v) Security plan for the facility[2]

[2] AERB safety guide on 'Security of Radioactive Sources in Radiation Facilities', AERB/RF-RS/SG-1 (under preparation)

PART C

UNDERTAKING

I/we hereby certify that

(a) all the statements made above are correct to the best of my/our knowledge and belief.

(b) no activity will be carried out for purposes other than those specified in this form.

(c) the facility shall not be commissioned/operated until the authorisation is obtained from the competent authority.

(d) all provisions of the Atomic Energy (Radiation Protection) Rules, 2004 shall be strictly complied with.

(e) the facility shall not be transferred/sold/ rented by me/us to another user without prior permission of the competent authority.

(f) full facilities will be accorded by me/us to any authorised representatives of the competent authority to inspect this installations at any time.

(g) radiation surveillance and medical surveillance of all persons engaged in radiation work as required by the competent authority will be duly carried out at my/our expense.

(h) all recommendations that may be made from time to time by the competent authority in respect of radiation safety and physical security measures will be duly implemented.

(i) duly qualified/experienced radiological safety officers/operators, will be appointed before the commencement of operation of the facility.

(j) the procedures approved by AERB regarding decommissioning/dismantling and reuse of the site of the decommissioned facility will be strictly complied with.

(k) AERB will be kept informed about absence of the qualified manpower. (as given in Table B.6)

(l) AERB will be kept informed about any changes in the information furnished above.

In case, it is found, at any stage, that the information provided by me/us is false and/or

not authentic, then I/we hereby accept that appropriate regulatory actions may be initiated against me/us and our institution, in accordance with the applicable Rules.

Place:
Date:

Signature:
Name of the Applicant:
Designation:

Signature:
Name of Head of the Institution:
Designation:

(Seal of the institution)

APPENDIX-II

Government of India
Atomic Energy Regulatory Board

Niyamak Bhavan
Anushaktinagar,
Mumbai - 400094

FORMAT FOR THE 'APPLICATION FOR APPROVAL OF NOMINATION OF RADIOLOGICAL SAFETY OFFICER IN MEDICAL INSTITUTIONS'

To be submitted by the applicant to the Chairman, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400094.

PART-1 : PARTICULARS OF THE INSTITUTION

1. Name and address of the institution with PIN code

2. Name, designation and address of the head of the institution with PIN code (the applicant) in block letters

3. Mode of communication:

Telephone with STD code: During office hours								
Telephone with STD code: After office hours								
Fax								
Telex								
Telegram								
Email								

4. This application is for

First time RSO approval				
Renewal of RSO approval level-II/III		Ref No.:	Date:	Valid till:

5. Type of nuclear medicine facility: Diagnosis/therapy/both

6. Nuclear Medicine

S. No.	Radionuclide	Chemical/ Physical form	Maximum activity in stock (GBq)	Maximum activity used at a time (GBq)
1				
2				

7. Details of radiation measuring/monitoring instruments

S. No.	Name of the manufacturer	Make and type	Radiation types detected	Scale ranges	Date of purchase	Date of most recent calibration

8. Details of unusual occurrences that have taken place in the past. Include any radiation emergencies, loss or misplacement of sources and transport incidents

S. No.	Date of incident	Radiation equipment or source involved	Nature of incident	Details of action taken	Number of persons involved	Maximum dose received by an individual as a result of the incident

9. Details of radiation workers in the institution

S. No.	Name of employee and date of birth	Designation	Responsi-bilities and functions	Date of commencement of radiation work	Personnel monitoring service number
1					
2					
3					

PART-2 : PARTICULARS OF RSO - DESIGNATE

1. Name (with initials expanded) of the person to be designated as RSO (in block letters)

Please affix a recent passport size photograph

2. Present designation of the nominee

3. Address with PIN code (in block letters)

Office address

Telphone No. with STD code

Residential address

Telphone No. with STD code

Permanent home address

Telphone No. with STD code																			

4. Academic qualifications and training courses attended on radiation safety

Qualifications	**S. No.**	**University/ Examining body**	**Degree/ Diploma**	**Year of passing**	**Subject(s) of study**
Academic	1 2				
Training courses in radiation safety	1 2				

5. Experience in radiation work

S. No.	**Year(s) of work**	**Name of institution and address**	**Radiation equipment, sources handled**	**Maximum activity handled**	**PMS number**
1					
2					
3					

6. Radiation equipment/radioactive materials for which the RSO will be responsible

Radiation equipment	
Radioactive material	

7. Additional responsibilities proposed to be assigned to RSO

8. (a) I hereby certify that the information furnished above is correct to the best of my knowledge and belief.

(b) I undertake to abide by the conditions stipulated by the competent authority from time to time and follow guidelines in discharging the duties and responsibilities as RSO.

(c) I further undertake to inform the Atomic Energy Regulatory Board immediately in case I am relieved of my services as RSO.

Date: Signature of RSO-designate

9. (a) I hereby certify that all statements made in the application are correct to the best of my knowledge and belief.

(b) I hereby undertake to provide all necessary facilities to RSO to discharge his/her duties and functions effectively.

(c) I further undertake to inform the Atomic Energy Regulatory Board immediately in case the RSO is relieved of his/her duties.

Place: Signature of the head of the institution (the applicant).

Date: Name:

(Seal of the institution)

BIBLIOGRAPHY

1. Atomic Energy Act, 1962 (33 of 1962).
2. Atomic Energy (Radiation Protection) Rules, G.S.R. 303, 2004.
3. Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, G.S.R. 125, 1987.

LIST OF PARTICIPANTS

COMMITTEE FOR REVIEW OF SAFETY CODE FOR NUCLEAR MEDICINE FACILITIES

Dates of meeting	:	May 29,2002 June 11,2002 July 11,2004

Members of the Committee: (Revision-2)

Dr. K. Thirumurthi (Chairman)	:	Sai Nuclear Medicine Services, Chennai.
Dr. G.S. Pant	:	AIIMS, New Delhi
Shri A.R. Sundararajan	:	AERB (Former)
Shri P.K. Gaur	:	BARC (Former)
Shri G. Janakiraman	:	AERB (Former)
Smt. B. Nagalakshmi	:	AERB

STANDING COMMITTEE FOR REVIEW AND REVISION OF RADIATION SAFETY DOCUMENTS (SCRSD)

Dates of meeting	:	December 4, 2006 December 5, 2006 December 12, 2006 March 21, 2007 March 22, 2007

Members of Committee:

Dr. A.R. Reddy (Chairman)	:	DRDO (Former)
Dr. P.S. Iyer	:	BARC (Former)
Shri R.J. Pardikar	:	BHEL, Thiruchirappalli
Dr. B.C. Bhatt	:	BARC (Former)
Dr. D.N. Sharma	:	BARC
Shri P.K. Nema	:	BARC
Dr. U.N. Nayak	:	BARC
Shri V.G.R. Subramaniam	:	BRIT (Former0
Dr. A.N. Nandakumar	:	AERB (Former)
Shri K.D. Pushpangadan (Member-Secretary)	:	AERB

ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY (ACRS)

Date of meeting	:	March 21 and 22, 2007

Members of Committee:

Dr. U.C. Mishra (Chairman)	:	BARC (Former)
Dr. A.R. Reddy	:	DRDO (Former)
Dr. Gursharan Singh	:	BARC
Dr. B.C. Bhatt	:	BARC (Former)
Dr. S.K. Shrivastava	:	TMH, Mumbai
Dr. (Smt.) Meera Venkatesh	:	BARC
Shri S.P. Agarwal (Member-Secretary)	:	AERB

PROVISIONAL LIST OF REGULATORY DOCUMENTS ON MEDICAL FACILITIES INVOLVING RADIATION

S. No.	Safety Code No.	Titles
1.	AERB/RF-MED/ SC-1 (Rev. 1)	Radiation Therapy Sources, Equipment and Installations, Mumbai, India, 2011.
2.	AERB/RF-MED/ SC-2 (Rev. 2)	Nuclear Medicine Facilities, Mumbai, India, 2011.
3	AERB/SC/MED-2 (Rev. 1)	Medical Diagnostic X-ray Equipment and Installations, Mumbai, India, 2001.
4.	AERB/SS-5	Design and Manufacture of X-ray Analysis Equipment, Mumbai, India, 1992.
5.	AERB/SG/MED-1	Medical Management of Persons Exposed in Radiation Accidents, Mumbai, India, 1990.
6.	AERB/SM/MED-1	Atlas of Reference Plans for Medical Diagnostic X-ray Installations, Mumbai, India, 1988.
7.	AERB/SM/MED-2	Handbook for Medical Management of Persons Exposed in Radiation Accidents, Mumbai, India, 1989.

AERB SAFETY CODE NO. AERB/RF-MED/SC-2 (Rev. 2)

Published by **:** Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar
Mumbai - 400 094
INDIA.

BCS