

**THE SUSTAINABLE HARNESSING AND ADVANCEMENT OF
NUCLEAR ENERGY FOR TRANSFORMING INDIA
REGULATIONS, 2026.**

G.S.R. XXX.--- In exercise of the powers conferred under sub-section(1) of Section 85 and other enabling provisions of the Sustainable Harnessing and Advancement of Nuclear Energy For Transforming India Act, 2025, Atomic Energy Regulatory Board hereby makes the following regulations, namely:-

CHAPTER-I

PRELIMINARY

- 1. Short title and commencement:** (1) These regulations may be called the Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India (SHANTI) Regulations, 2026.
(2) They shall come into force on the date of their publication in the Official Gazette.
- 2. Definitions:** In these regulations, unless the context otherwise requires:-
 - (1) ‘absorbed dose’ means the energy imparted by ionising radiation per unit mass of matter;
 - (2) "accident" means any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;
 - (3) “Act” means the Sustainable Harnessing and Advancement of Nuclear Energy For Transforming India Act, 2025 (No. 39 of 2025);
 - (4) “activation” means production of induced radioactivity by nuclear reactions;
 - (5) ‘adequate protection’ in context of radiation protection means protection against radiation so provided that the regulatory constraints specified by the Board are not exceeded;
 - (6) “appropriate” means appropriate in the opinion of the Board to ensure adequate protection;
 - (7) “approval” means written approval granted by the Board; and depending on the context refers to design approval, type approval, package design approval, shipment approval, procurement approval and approval for transfer of decayed or disused sources;
 - (8) “conditioning” means those operations, chemical or physical, that transform the radioactive waste into a form suitable for transport, storage or final disposal and may include converting the waste to another form, enclosing the waste in containers and providing additional packaging;

- (9) “consignment” means any package or packages, or load of nuclear material or radioactive material or prescribed substance presented by a consignor for transport;
- (10) "contamination" means presence of a radioactive substance in or on a material or in the human body or other place in excess of quantities specified in the relevant regulatory documents issued by the Board;
- (11) “controlled area” means any area in which specific protection measures and safety provisions are or could be required for:
 - (i) controlling exposures or preventing the spread of contamination during normal working conditions; and
 - (ii) preventing or limiting the extent of potential exposures;

[Note: For removal of doubts, the concept of controlled area is different from the concept of areas classified from consideration of security.]
- (12) “disposal”, in the context of radioactive waste management, means controlled discharge of effluent to the environment or emplacement of radioactive waste in an appropriate facility without the intention of retrieval;
- (13) "dose" is a measure of the energy deposited by radiation per unit mass of matter and the terms absorbed dose, or committed effective dose, or committed equivalent dose, or effective dose, or equivalent dose, or organ dose, are used depending on the context;
- (14) “effluent” means gaseous, particulate or liquid emission which is discharged from the facility or a plant or a mine into its environment;
- (15) “employer” shall have the same meaning as assigned in the rules framed under the Act.
- (16) “environmental surveillance” or “environment monitoring” means continuous and systematic measurements of environmental media and biota to assess radiological impacts;
- (17) “exclusion zone” means an area extending up to a specified distance around a nuclear facility where no public habitation is permitted and the area shall be under the control of the licensee.
- (18) “exempt” means exemption from the requirement of safety authorisation of certain class or classes of radioactive material or radiation generating equipment, which do not warrant regulatory control, either in part or whole in accordance with clause (n) of sub-section (3) of section 24 of the Act;
- (19) “exposure situation”, in relation to radiation protection, includes-
 - (i) “Planned exposure situation” which means a situation of exposure that arises from the planned operation of source or from a planned activity that results in an exposure due to a source;

- (ii) “Existing exposure situation” which means a situation of exposure that already exists when a decision on the need for control from radiation protection considerations needs to be taken;
 - (iii) “Emergency exposure situation” which means a situation of exposure that arises as a result of an accident, a malicious act or other unexpected event and requires prompt action in order to avoid or to reduce adverse consequences;
- (20) “factory” has the same meaning as assigned to it in the Occupational Safety, Health and Working Conditions Code, 2020 (37 of 2020);
- (21) "medical exposure" means exposure incurred by –
- (i) patients as part of their own medical diagnosis or treatment;
 - (ii) carers and comforters; and
 - (iii) volunteers in biomedical research;
- (22) “mine” has the same meaning as assigned to it in the Occupational Safety, Health and Working Conditions Code, 2020 (37 of 2020);
- (23) “nuclear or radiological emergency” means an emergency in which there is, or is perceived to be, a hazard due to-
- (i) the energy resulting from a nuclear chain reaction or from the decay of the products of a chain reaction; or
 - (ii) radiation exposure;
- (24) "personnel monitoring" means determination or estimation of the dose received by an individual from external and/or internal radiation;
- (25) "potential exposure" means exposure that is not planned or expected to be delivered with certainty but which can be anticipated as a result from an accident involving a source or due to an event or sequence of events of a probabilistic nature including equipment failure and operating errors or from a malicious act;
- Explanation: If an event or a sequence of events that has been considered in the assessment of potential exposure actually occurs, it may be treated either as a planned exposure situation or, if an emergency has been declared, as an emergency exposure situation.*
- (26) "practice", in relation to radiation protection, means any human activity that introduces additional sources or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, which may increase the exposure or likelihood of exposure of people, or the number of people exposed;
- (27) "quality assurance" means the function of a management system that provides confidence that specified requirements will be fulfilled.

Explanation: Quality assurance includes any planned and systematic action necessary to provide adequate confidence to the Board that a structure, system, component or procedure will perform satisfactorily and includes quality control;

- (28) "quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality in relation to relevant standards, and includes monitoring, evaluation and maintenance at required levels of performance;
- (29) 'radiation source' means a radioactive material or equipment containing radioactive material or a radiation generating plant or equipment which may cause radiation exposure and includes sealed radiation source as well as unsealed radiation source.

Explanation:

- (a) "sealed radiation source" means radioactive material that is –
- (i) permanently sealed in a capsule; or in a solid form which is closely bounded;
and
 - (ii) is designed to meet the safety standards issued by or acceptable to the Board;
- (b) "unsealed source" means any radioactive material that is not a sealed source;
- (30) "Radiological Safety Officer" means a person who has been certified by the Board as qualified to discharge the duties and functions under the regulations;
- (31) "radiation surveillance" in context of radiation protection means measures, including measurements and reviews performed, towards ensuring adequate protection;
- (32) "radiation worker" means a worker who works, whether full time, part time or temporarily, for an employer of a facility or an occupier of factory or owner or agent of a mine and who has recognised rights and duties in relation to occupational radiation protection;
- (33) "regulatory constraint" means restriction on radiation protection parameters specified by the Board.
- (34) "regulatory hold point" means identified points in a safety authorisation process, by the Board, which require formal review of fulfilment of identified pre-requisites and permission from the Board before the activity can further progress;
- (35) "rules" means the SHANTI Rules, 2026 issued under the SHANTI Act, 2025
- (36) "schedule" means schedule under these regulations;
- (37) "shipment" means the specific movement of a consignment from origin to destination;
- (38) "supervised area" means any area not already designated as a controlled area but where occupational exposure conditions are kept under review even though specific protection measures and safety provisions are not normally needed;

- (39) 'waste authorisation' means authorisation for storage, transfer and disposal of radioactive waste granted by the Board;
- (40) Words and expression used in these regulations and not defined but defined in the Act shall have the meanings respectively assigned to them in the Act.

CHAPTER-II

FRAMEWORK FOR GRANT OF SAFETY AUTHORISATION

3. **Safety Authorisation:** Subject to provision of these regulations, safety authorisation shall be obtained from the Board for—

- (a) such nuclear facilities, plants and mines specified in S. No. 1, 2 and 3 of Schedule-I, for which licence has been granted by licensing authority;
- (b) such radiation facilities as specified in S.No.4 of Schedule-I;
- (c) such activities connected therewith or incidental thereto.

(2) Board may include or remove any facilities, plants or mines specified in the Schedule-I in accordance with the provision of regulation 82:

Provided that no new practice in relation to any planned exposure situation shall be included unless found to be justified in accordance with provision of the rules.

4. **Exemption:** (1) Any practice or radiation source within a practice associated with planned exposure situations may be exempted in accordance with the notification under clause (n) of sub-section (3) of section 24 of the Act, from some or all aspects of regulatory control, where, in the opinion of the Board—

- (i) the exposure and the potential exposure due to the source or practice is too small to warrant any elaborate system of regulatory control; or
- (ii) no reasonable regulatory control would achieve any worthwhile returns in terms of reduction in individual doses or health risk:

Provided that no exemption shall be granted for any practice which is not justified.

(2) Where the levels of radioactivity are at or below such levels specified in the notification referred in sub-regulation (1), the radiation source or the practice shall be exempted from all regulatory control without further consideration.

(3) Where the levels of radioactivity are above the levels specified in the notification referred in sub-regulation (1), the Board, based on safety assessment, may specify the extent of regulatory control to be exercised including need for registration with the Board or may require applicant to obtain safety authorisation from the Board, as per the provisions of these regulations.

Explanation: For removal of all doubts, registration alone is sufficient where the exposure expected are unlikely to exceed a small fraction of dose limits or the likelihood and magnitude of potential exposure are negligible, for which only the information of

the intended practice shall suffice. Facilities and practices requiring registration are identified in Schedule-I.

(4) For the purpose of sub-regulation (3), application shall be made to the Board containing such information as specified in regulatory documents.

5. **Clearance:** The Board may issue clearance to any radiation source employed within any facilities, plants, mines or activities, for removal from its regulatory control, on the basis of the criteria, or levels notified in accordance with sub-regulation (1) of regulation 4 and subject to such other conditions as it may specify.

PART-A

NUCLEAR POWER PLANTS OR REACTORS

6. **Pre-condition for application:** A person possessing a valid licence to build-own-operate-decommission a nuclear power plant or a reactor shall obtain design approval in accordance with regulation 7 and safety authorisation in accordance with regulation 8.
7. **Design Approval:** (1) In respect of design approval of nuclear power plant or reactor, the licensee shall submit such documents and information containing design related information with such details and quality, as specified in relevant regulatory documents and such other information as may be sought for assessment by the Board, including but not limited to—
- (a) A Design Document containing details on:
 - (i) plant description, site characteristics considered for design, design of structures, systems, and components including plant life, reactor, reactor coolant and auxiliary systems, engineered safety features and systems & features for design extension conditions, instrumentation and control, electrical power supply systems, plant auxiliary systems, steam and power conversion system, radioactive waste management, radiation protection, conduct of operations, commissioning;
 - (ii) accident analysis, technical specifications for operation, management of safety and quality assurance, human factors engineering, probabilistic safety assessment;
 - (iii) decommissioning aspects, herein referred as Generic Design Document;
 - (b) proposed limiting performance criteria for structures, systems and components and hold points (with respect to design) requiring verification during construction and commissioning phase, interface (site specific) requirements, summary of site parameters and their bounding values considered for design, etc. herein referred as Performance Criteria and Verification Document;
 - (c) Technical reports as required during review, in support of the design including data and results of experiments conducted to establish the technology, and supporting research programmes.
 - (d) List and description of computer codes used for stress analysis, safety analysis, releases and dispersions, etc., and their verification and validation;

- (e) list and description of industry codes and standards used for design and construction
- (f) design calculations including but not limited to stress analysis, thermal hydraulics analysis, reactor core physics aspects, fuel management and shielding;
- (g) security aspects having bearing on safety and aspects related to safety security interface
- (h) review findings of the regulatory body on design certification in the country of origin for imported design, and during grant of operation licence in country of origin/ foreign country, if operational;
- (i) operating experience of the plant at rated power for imported design operational in foreign country, especially nuclear safety and radiological performance covering fuel, primary heat transport system, control and safety systems:

(2) If the proposed nuclear power plant or reactor is of a design which is already under construction or operation in the country, the relevant documents and information to be submitted may be limited as per scoping evaluation covered in sub regulation 4 of regulation 45 and for ascertaining compliance with current safety requirements specified in regulatory documents or and directions issued by the Board.

(3) For the purpose of design approval, wherever necessary, provision shall be made by the Licensee for on-site visits and technical discussions by the representatives of the Board to operational plant or, as the case may be, test facilities, pilot plants, experimental facilities, manufacturing facilities, premises of technology developer, etc. and the like.

(4) Notwithstanding the grant of design approval, the Board may make additional safety related recommendations emanating from the safety review and assessment during the subsequent stages and the licensee shall comply with the same.

(5) Nothing in these regulations shall prevent the Board to alter the validity of design approval in view of emergence of new safety requirements or experience.

Explanation: Design Approval is issued by the Board based on the review and assessment of the design for acceptability with respect to the specified design and safety requirements. This allows the Licensee to obtain safety authorisation for various stages. The design approval may be issued with additional hold points to be complied with and any technical issues to be resolved prior to identified sub-stage of construction.

8. **Stages for Safety Authorisation:** For nuclear power plant or a reactor, safety authorisation shall be required for various stages of its lifetime starting from siting, construction, commissioning, operation and decommissioning in support of which such documents and information as specified in regulation 9, 10, 11, 12, 15 respectively shall be submitted
9. **Safety Authorisation for Siting:** (1) For the purpose of obtaining safety authorisation for siting, as referred in regulation 8, of nuclear power plant or reactor, the Licensee shall demonstrate safety with regards to impact of plant on the region including site, impact of

site characteristics on safety of plant and feasibility for implementation of emergency response;

Provided that where nuclear power plant or reactor is proposed at an existing site for which safety authorisation for siting has already been granted and remains valid, only such updated information related to site, as specified, shall suffice.

Provided that for nuclear power plant or reactor, safety authorisation for siting shall not be granted unless design approval has been obtained as specified in the rules.

Explanation: Review for design approval and review for safety authorisations for siting may be undertaken in parallel and may overlap, but design approval needs to be available before grant of safety authorisation for siting.

(2) For the purpose of evaluation of the site as referred in sub-regulation (1), the licensee, shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) valid design approval of the proposed design obtained from the Board or application for design approval admitted by the Board;
- (b) site characteristics including geography, demography and topography;
- (c) evaluation of the site against rejection and engineerability criteria including associated investigations;
- (d) geological and seismological characteristics of the site and surrounding region based on investigations;
- (e) geotechnical and foundation characteristics based on investigations;
- (f) data and information on meteorological, hydrological and hydro-geological characteristics, based on investigations;
- (g) arrangements for collection of site specific meteorological and hydrological data;
- (h) availability of ultimate heat sink;
- (i) radio-ecology and thermal pollution;
- (j) identification of site specific external hazards including both natural and human induced;
- (k) arrangements for radioactive waste management;
- (l) radiological impact assessment for all plant states and compliance to dose criteria;
- (m) dose apportionment considering all pathways, and all facilities;
- (n) feasibility for implementation of emergency response;
- (o) establishment of zones such as exclusion zone and emergency preparedness and response zones;
- (p) quality assurance measures adopted during siting process;

- (q) conceptual plan for onsite storage of spent fuel;
- (r) compliance to Performance Criteria and Verification Document submitted for obtaining design approval relevant to the stage of siting;

Provided that where nuclear power plant or reactor is proposed at an existing site for which safety authorisation for siting has already been granted and remains valid, only such information as specified by the Board in regulatory documents shall suffice.

10. Safety Authorisation for Construction: For the purpose of obtaining safety authorisation for construction as referred in regulation 8, the licensee shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) compliance to terms and conditions of safety authorisation for siting;
- (b) compliance to Performance Criteria and Verification Document submitted for obtaining design approval, relevant to stage of construction;
- (c) estimation of design basis and beyond design basis parameters for both internal and external hazards and confirmation of site specific design basis parameters to be in conformance with the design approval, including for external hazards and radiological impact assessment;
- (d) confirmation of floor response spectra and load combination within the design basis;
- (e) Preliminary safety analysis report with updates;
- (f) validated emergency response plan as relevant;
- (g) security aspects having bearing on safety and aspects related to safety security interface;
- (h) construction methodology and construction schedule;
- (i) management system for safety including organisational structure for construction, clearly defining roles, responsibilities, and reporting lines, during the construction phase;
- (j) availability of trained, qualified and certified persons for construction and quality assurance;
- (k) arrangement for control of supply chain including quality assurance;
- (l) quality management system including arrangements for adhering to approved design and compliance to quality assurance program for procurement, manufacturing and construction,
- (m) quality management system for control of documents and records.

11. Safety Authorisation for Commissioning: For the purpose of obtaining safety authorisation for commissioning, as referred in regulation 8, the licensee shall submit

such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) compliance to terms and conditions of safety authorisation for construction;
- (b) compliance to Performance Criteria and Verification Document submitted for obtaining design approval relevant to the stage of commissioning;
- (c) confirmation on completion of construction in conformance with the approved design including pre-service inspection and status of construction completion certificates;
- (d) commissioning program covering phase A(without nuclear fuel), Phase-B(with fuel and at low power), and Phase-C(power raising up to and at rated power), including schedule, applicable commissioning procedures and test program and acceptance criteria;
- (e) quality assurance in commissioning;
- (f) safety management system including organisational structure;
- (g) independent verification and validation of computer based systems;
- (h) preliminary safety analysis report reflecting ‘as-built’ plant design;
- (i) technical specifications for operation;
- (j) confirmation of establishment of operating organization;
- (k) availability of trained, qualified and certified persons including Radiological Safety Officer;
- (l) programme for life management including in-service inspection, programmes for operational safety management, radiation protection, knowledge management;
- (m) programmes for training, retraining of plant personnel
- (n) emergency preparedness and response plan including conduct of emergency exercise;
- (o) radiation protection programme and procedures, and environmental monitoring including surveillance programme;
- (p) security aspects having bearing on safety and aspects related to safety security interface;
- (q) valid waste authorisation obtained from the Board.

12. Safety Authorisation for Operation: For the purpose of obtaining safety authorisation for operation, as referred in regulation 8, the licensee shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) compliance to terms and conditions of safety authorisation for commissioning;
- (b) compliance to specific design information submitted for obtaining design approval relevant to stage of operation;

- (c) commissioning results;
- (d) performance of plant operation within commissioning period;
- (e) waste authorisation obtained from the Board;
- (f) Final Safety Analysis Report, updated and approved technical specifications for operation, radiation protection procedures, updated in-service inspection programme, life and ageing management programme, emergency preparedness and response plans and conceptual decommissioning plan;
- (g) quality assurance programme for operation including management for safety and organization structure;
- (h) availability of normal operating procedures, emergency operating procedures and severe accident mitigation;
- (i) availability of trained, certified and qualified persons including Radiological Safety Officer;
- (j) programmes for training, retraining of plant personnel
- (k) security aspects having bearing on safety and aspects related to safety security interface;

13. Renewal of Safety Authorisation for Operation: For renewal of safety authorisation for operation of nuclear power plant or reactor, the licensee shall conduct a periodic safety review and submit a report, as specified in relevant regulatory documents, containing a comprehensive assessment for continued operation in a safe manner in compliance with the relevant regulatory documents, taking into account such factors, including but not limited to the following, namely—

- (a) plant design against current safety requirements and good practices, to identify safety improvements;
- (b) condition, qualification and ageing management of system, structure and components, to demonstrate their continued capability to perform safety functions;
- (c) deterministic and probabilistic safety assessment, including internal and external hazards, to demonstrate adequate safety margins;
- (d) safety performance, operating experience and research findings, to confirm operational effectiveness and identify safety improvements;
- (e) organization, management systems, human performance and emergency preparedness, to demonstrate effective management of nuclear safety;
- (f) radiological impact on the environment, to demonstrate continued protection of the public and the environment;
- (g) integrated safety assessment, safety improvements and justification for continued operation, to demonstrate overall plant safety until the next periodic safety review.

- 14. Life extension of nuclear power plant or reactor:** (1) For the purpose of renewal of safety authorisation beyond the design life of a nuclear power plant or a reactor, the application seeking a written confirmation for safe operability for the period proposed for extension, shall be submitted sufficiently well in advance, before expiry of the design life, in such form and manner and accompanied by such documents and fees as specified by the Board, along with a referral from the Central Government seeking a written confirmation from the Board for safe operability of the plant for the period proposed for life extension.
- (2) Decision on the application referred in sub-regulation (1) shall be based on review and assessment by the Board, of the demonstration of continued safe operability of the nuclear power plant or reactor and compliance to the applicable provisions of the regulatory requirements specified by the Board, in the submissions made in support of the application, supplemented with findings of inspections and reports.
- (3) Based on the assessment, Board shall decide on the issuance of a written confirmation of safe operability of the nuclear power plant or reactor for the period proposed for life extension or otherwise.
- (4) The Licensee shall obtain safety authorisation subsequent to receipt of extension of license beyond the design life
- 15. Safety Authorisation for Decommissioning:** For the purpose of obtaining safety authorisation for decommissioning as referred in regulation 8, the licensee shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—
- (a) valid permission from Central Government for undertaking decommissioning;
 - (b) decommissioning plan;
 - (c) technical specification for decommissioning;
 - (d) plan for safe management of spent fuel at site;
 - (e) plan for control over waste disposal facility at site;
 - (f) availability of trained, qualified and certified persons including Radiological Safety Officer;
 - (g) waste management plan and waste authorisation;
 - (h) quality assurance programme for decommissioning;
 - (i) safety management system including organization structure;
 - (j) Plan for delivery of spent fuel to the Central Government.

PART-B

OTHER NUCLEAR FACILITIES AND PLANTS

- 16. Pre-condition for application:** A person possessing a valid licence to set up such nuclear facilities and plants as specified in S.No.2 of schedule-I shall obtain safety authorisation.
- 17. Stages for Safety Authorisation:** For facilities and plants referred in regulation 16, safety authorisation shall be required for various stages of its lifetime starting from siting, construction, commissioning, operation and decommissioning in support of which such documents and information, as specified in regulation 18, 19, 20, 21, 23 respectively shall be submitted.
- 18. Safety Authorisation for Siting:** (1) For obtaining safety authorisation for siting as referred in regulation 17, the Licensee shall demonstrate safety with regard to impact of plant or facility on site, impact of site on plant or facility and feasibility for implementation of emergency response where off-site consequences are likely, including that from release of hazardous substances from the factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- (2) For the purpose of evaluation of the site as referred in sub-regulation (1), the provisions of sub-regulation (2) of regulation 9 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes and release of chemical pollutants for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- 19. Safety Authorisation for Construction:** (1) For obtaining safety authorisation for construction of facilities and plants referred in regulation 17, the licensee shall ensure that the design meets all the relevant safety requirements.
- (2) In support of the requirements specified in sub-regulation (1), the provisions specified in regulation 10 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes and release of chemical pollutants, for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- 20. Safety Authorisation for Commissioning:** (1) For obtaining safety authorisation for commissioning of facilities and plants referred in regulation 17, the licensee shall ensure that the plant or the facility has been constructed and equipment installed in accordance with design specifications and is capable to meet the safety performance criteria.
- (2) In support of the requirements specified in sub-regulation (1), the provisions of regulation 11 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes and release of chemical pollutants, for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.

- 21. Safety Authorisation for Operation:** (1) For obtaining safety authorisation for operation of facilities and plants referred in regulation 17, the licensee shall ensure that the plant or the facility, the purpose for which it was constructed, is capable for operation in a safe manner and has implemented necessary measures to minimise the risk to worker, public and environment during normal operation and in accidental conditions.
- (2) In support of the requirements specified in sub-regulation (1), provisions of regulation 12 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes and release of chemical pollutants, for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- 22. Renewal of Safety Authorisation for Operation:** (1) For renewal of safety authorisation for operation of facilities and plants referred in regulation 17, the licensee shall carry out a comprehensive safety assessment that the facility or plant is capable for further continued safe operation without posing any undue risk to the plant, worker, public and the environment, both from radiological safety, and non-radiological safety considerations for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- (2) For comprehensive safety assessment referred in sub-regulation (1), the factors specified in regulation 13 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes, and release of chemical pollutants for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.
- 23. Safety Authorisation for Decommissioning:** (1) For obtaining safety authorisation for decommissioning of facilities and plants referred in regulation 17, the licensee shall ensure that the plant or the facility is finally taken out of operation in a manner that provides adequate protection to the health and safety of workers, the public and of the environment.
- (2) In support of the requirements specified in sub-regulation (1), provisions of regulation 15 shall apply *mutatis mutandis* commensurate with the radiological hazard potential of the facility or plant and with due consideration to the risks associated with handling of hazardous substances, management of hazardous wastes, and release of chemical pollutants for those factories owned or controlled by the Central Government in accordance with notification issued under section 42 of the Act.

PART-C

MINES

- 24. Pre-condition and stages of Safety Authorisation:** A person possessing a valid licence for working of such mines as specified in S.No.3 of Schedule-I shall obtain safety authorisation for—

- (a) working of mine;
- (b) decommissioning or closure of mine.

Provided that safety authorisation may also be required for exploration activity unless exempted in accordance with the notification issued by the Board under clause (n) of sub-section 3 of section 24 of the Act.

- 25. Safety Authorisation for working of mines:** (1) In respect of safety authorisation for working of mines referred in regulation 24, the licensee shall ensure that during development and production phase, there is no undue radiological risk to the workers, public and the environment

Explanation: For removal of all doubts, the safety authorisation referred in this sub-regulation is solely from radiological safety considerations and the provisions of the Occupational Health Safety and Working Conditions Code, 2020 shall be enforced by Directorate General of Mine Safety in such mines, as applicable.

(2) For obtaining safety authorisation for working of mine, the licensee shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) mine development and production plan;
- (b) design basis for mine ventilation;
- (c) radiation protection procedures to control external exposure and internal exposure from radon and thoron, their progeny and mine dust;
- (d) mine water treatment;
- (e) radioactive waste management plan for waste rock, tailings or rejects and overburden and waste authorisation;
- (f) availability of Radiological Safety Officer.

- 26. Safety Authorisation for closure or decommissioning of mine:** For obtaining safety authorisation for the closure or decommissioning of mine, the licensee shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) valid permission from Central Government for undertaking the closure or decommissioning of the mine;
- (b) mine closure plan including implementation schedule;
- (c) radiation protection procedures to control external exposure and internal exposure from radon and thoron, their progeny and mine dust;
- (d) waste management plan and valid waste authorisation;
- (e) availability of Radiological Safety Officer.

PART-D

RADIATION FACILITIES

- 27. Pre-condition for Safety Authorisation:** (1) Safety authorisation or related approvals for such radiation facilities as listed in S.No.4 of Schedule-I may be granted to—

- (a) a citizen of India;
- (b) a company or a firm registered in India;
- (c) a trust or an institute or any other organisation having valid certificate of registration in India,

for which the documentary evidence as admissible as proof of legal status of the applicant shall be submitted to the Board.

Explanation: For such facilities various stages of safety authorisation are namely, siting and construction or site and layout approval, procurement approval, commissioning, operation and decommissioning.

- (2) For the purpose of sub-regulation (1), such documents and information in respect of—

- (a) type approval shall be submitted in accordance with regulation 28;
- (b) safety authorisation for siting, construction, shall be submitted in accordance with regulation 29;
- (c) procurement approval shall be submitted in accordance with regulation 30;
- (d) safety authorisation for commissioning, operation or decommissioning shall be submitted in accordance with regulation 31, 32 and 33, respectively;
- (e) approval for transfer of decayed or disused radiation source in accordance with regulation 34.

- 28. Type Approval:** (1) Type approval from the Board for design of sealed sources, radiation generating equipment or equipment containing radioactive material or any other radiological device used for purpose of imaging, shall be necessary for import, domestic transfer by sale or otherwise, or commercial manufacturing and supply:

Provided that for import or acquisition of any new sealed sources, radiation generating equipment or equipment containing radioactive material or any other radiological device used for purpose of imaging, where type approval has not been granted, a no objection certificate shall be obtained from the Board for facilitating its import or acquisition for demonstration of performance tests for type approval.

- (2) For obtaining type approval referred in sub-regulation (1), the applicant shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to the following, namely—

- (a) compliance to the regulatory documents issued by the Board or such standards acceptable to the Board from radiological safety considerations;

- (b) conformance with relevant national/International Standards to which the equipment conforms;
- (c) technical specifications and design safety provisions;
- (d) designs safety aspects ;
- (e) quality assurance programme in design and manufacture including quality control of product;
- (f) sealed source classification, as applicable;
- (g) performance test report and evaluation of test results;
- (h) manual(s) for operation, servicing, maintenance, disposal and emergency procedures;
- (i) requirement of source handling modules such as hot cell, as applicable;
- (j) type approval certificate or equivalent document from the relevant authority of country of design/manufacture to the effect that the equipment is approved for the intend purpose;
- (k) design of transport package for radioactive source, as applicable.

29. Safety Authorisation for siting and construction: (1) For obtaining safety authorisation for the siting and construction including site and layout approval, as the case may be, the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—

- (a) ownership of land or possessory or utilisation rights of the property where the facility is to be located;
 - (b) in case of a property on lease, an undertaking from the lessor that, the radiation source will not be moved out of the property till the radiation source is disposed of safely or transferred to the supplier;
 - (c) site assessment report including geological, metrological and other site characteristics, as applicable;
 - (d) design of the installation along with site layout, floor plan showing adjacent areas and elevation plans;
 - (e) assessment of shielding adequacy for the proposed facility;
 - (f) layout of source storage room as applicable
 - (g) specifications of source handling modules such as hot cell, if applicable;
 - (h) safety analysis report;
 - (i) quality assurance programme during construction of the facility, as applicable.
- (2) In case of certain radiation facilities or plants, depending on their hazard potential, only site and lay out approval may suffice prior to their siting and construction.

- 30. Procurement Approval:** Prior to acquisition of any radiation source, the user shall obtain procurement approval from the Board, for which the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—
- (a) type approval obtained from the Board referred in regulation 28 and where type approval is not issued, a valid no objection certificate from the Board;
 - (b) availability of valid safety authorisation for siting and construction or site and layout approval, as the case may be and compliance to terms and conditions specified therein;
 - (c) compliance with the financial security requirements as provided for in rules for safe disposal of the radiation source, decommissioning and towards settlement of claims for radiation damage;
 - (d) compliance with the security provisions as specified by Central Government;
 - (e) availability of valid safety authorisation with the supplier of radiation source or equipment;
 - (f) availability of safety infrastructure including approved layout for the radiation sources;
 - (g) functional performance of the equipment and safety systems and component;
 - (h) availability of trained, certified and qualified persons;
 - (i) plan for safe management of the radiation sources after useful life;
 - (j) decommissioning plan;
 - (k) legally binding undertaking and arrangements for transfer of the disused or spent source to the supplier for its safe disposal in accordance with regulation 34;
 - (l) in case of biomedical research, approval from ethics committee established by the employer of the facility.
- 31. Safety Authorisation for Commissioning:** For obtaining safety authorisation for the commissioning, the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—
- (a) compliance to terms and conditions of procurement approval or regulatory hold points specified by the Board;
 - (b) implementation of security measures as prescribed by Central Government;
 - (c) emergency preparedness plan;
 - (d) quality assurance programme for commissioning;
 - (e) radiation protection programme;

- (f) calibrated radiation measuring and monitoring instruments, devices or tools;
- (g) availability of trained, certified and qualified persons including Radiological Safety Officer;
- (h) radioactive waste disposal measures.

32. Safety Authorisation for Operation: For obtaining safety authorisation for operation, the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—

- (a) compliance to terms and conditions of safety authorisation for commissioning specified by the Board;
- (b) commissioning test results;
- (c) results of quality assurance tests performed either by applicant or by recognised agencies or institutions;
- (d) updated safety assessment report;
- (e) quality assurance programme for operation;
- (f) radiation protection programme;
- (g) calibrated radiation measuring and monitoring instruments, devices or tools;
- (h) radiation survey report;
- (i) availability of adequate trained, certified and qualified persons including Radiological Safety Officer;
- (j) safe operating and emergency procedures;
- (k) implementation and functionality of security provisions as prescribed by Central Government;
- (l) radioactive waste disposal measures:

Provided that for facilities engaged in radiation processing of food and allied products, the holder of safety authorisation is also required to comply with the following-

- i. the absorbed dose limits specified for food and allied products and use of suitable packaging material specified in schedule-II;
- ii. carry out dosimetry as specified in Schedule-II; and

requirements specified by Food Safety and Standards Authority (FSSAI) for maintaining the specified standards of the irradiated food.

33. Safety Authorisation for Decommissioning: For obtaining safety authorisation for decommissioning, the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—

- (a) intimation of decommissioning;
 - (b) decommissioning plan including strategy, implementation schedule, end state, as applicable;
 - (c) concurrence from disposal agency for accepting the disused source;
 - (d) acceptance from authorised supplier for decommissioning or dismantling of the equipment;
 - (e) availability of trained, certified and qualified persons including Radiological Safety Officer;
 - (f) safety infrastructure (radiation monitoring instruments and devices/tools);
 - (g) survey related to radiation protection;
 - (h) procedures for decommissioning including the end state, as applicable in case of certain type of radiation facilities.
- 34. Approval for transfer of disused/decayed source:** Approval shall be obtained by the holder of safety authorisation, from the Board, for transfer of disused or spent sealed radiation source(s) to the supplier, in accordance with the provision of rules, for-
- (a) its repatriation, in case of imported radiation source;
 - (b) safe management and disposal, in case of indigenous radiation source.

PART-E

ACTIVITIES

- 35. Radioactive waste management:** (1) For planned exposure situations, the holder of safety authorisation of a facility or a plant or a mine shall obtain a waste authorisation from the Board, for—
- (a) storage of radioactive waste in the facility or plant or mine;
 - (b) transfer of radioactive waste from the facility or plant;
 - (c) disposal of radioactive waste by the facility or plant or mine:
- Provided that a person granted safety authorisation to use small amount of radioisotopes of very short effective half-life (such as in medical practice and tracer application) may dispose of the waste containing short lived isotopes, contaminated materials and contaminated effluents in accordance with procedures and conditions specified in Schedule-III.
- (2) For obtaining waste authorisation, the holder of safety authorisation shall submit such documents and information, as specified in relevant regulatory document, including but not limited to the following, namely—
- (a) radioactive waste management programme including waste generating processes, sources, strategy for waste minimisation, management and disposal
 - (b) inventory, classification, and characterisation of radioactive wastes;

- (c) the equipment and systems provided to monitor and control the radioactive waste generation including management of interdependencies among all steps in radioactive waste generation;
- (d) the processes and equipment for conditioning, pre-treatment, treatment, storage and disposal of radioactive waste as specified by the Board and its effectiveness;
- (e) details regarding interim or transit storage of waste;
- (f) safety devices incorporated to contain the radioactive effluents and control their release to environment during normal operations, including anticipated operational occurrences and to keep these releases as low as reasonably achievable;
- (g) monitoring equipment incorporated in the waste disposal or storage to control the release of radioactivity in the event of accidents;
- (h) procedures to be followed for safe collection of radioactive wastes in all conditions;
- (i) environmental surveillance incorporated or otherwise provided to monitor the normal releases of activity and those released in the event of an accident;
- (j) estimates of the quantities of each of the principal radionuclides expected to be released in the environment annually (in solid, liquid and gaseous form) during normal operations and analysis of their anticipated environmental impact;
- (k) site safety assessment of solid waste management facility;
- (l) organisation, staffing, training, management system, quality assurance, security, and administrative controls.

Explanation: The application for waste authorisation may be combined with the application for safety authorisation for the relevant stage of the facility or plant or mine.

36. Pre-condition for import, export or domestic trade of any radiation source: For import, export or domestic trade including transfer by sale or otherwise, of any radiation source, safety authorisation shall be obtained from the Board by—

- (a) a citizen of India;
- (b) a firm, a company registered in India;
- (c) trust or an institute or any other organisation having valid certificate of registration in India

for which documentary evidence as admissible as proof of legal status of the applicant shall be submitted to the Board:

Provided further that the applicant shall additionally possess a valid licence for—

- (a) import and export of such category or class of radiation sources as notified by Central Government under sub-section 2 of section 4 of the Act, or
- (b) such prescribed substance which is radioactive in nature or

(c) import and export of such prescribed equipment which is also a radiation source,

37. Safety Authorisation for import of any radiation source: (1) For obtaining safety authorisation for import of any radiation source as referred in sub-regulation (1) of regulation 36, the applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to, the following, namely—

- (a) type approval or no objection certificate obtained from the Board;
- (b) compliance with national rules and regulations, and international obligations;
- (c) assessment of adequacy of the package for the purpose;
- (d) availability of trained, certified and qualified persons;
- (e) proof of legitimacy of the consigner and consignee, as applicable;
- (f) legally binding undertaking and arrangements for repatriation of the source intended to be imported including compliance with the financial security as provided for in the rules:

Provided that any default to repatriate the source shall attract the provision of offences and penalties under the Act

(2) Notwithstanding anything contained in sub-regulation (1), in case of import of any

—
(a) prescribed substance which is likely to subject an individual to radiation exposure, a confirmation of adequacy of the package by the Board based on assessment of aspects specified in sub regulation 2 of regulation 41, shall suffice;

(b) prescribed equipment which is also a radiation source, type approval or no objection certificate from the Board, as specified in regulation 28, shall suffice;

38. Safety Authorisation for export of any radiation source: (1) For obtaining safety authorisation for export of any radiation source as referred in sub-regulation (1) of regulation 36, the applicant shall submit such documents and information, as specified in relevant regulatory documents, including but not limited to, the following, namely—

- (a) compliance with national rules and regulations and international obligations;
- (b) assessment of adequacy of the package for the purpose;
- (c) proof of legitimacy of the consigner and consignee, as applicable.

(2) Notwithstanding anything contained in sub-regulation (1), in case of import of any

—
(a) prescribed substance which is likely to subject an individual to radiation exposure, a confirmation of adequacy of the package by the Board based on assessment of aspects specified in sub regulation 3 of regulation 41, shall suffice;

(b) prescribed equipment which is also a radiation source, type approval or no objection certificate from the Board, as specified in regulation 28, shall suffice;

- 39. Safety Authorisation for domestic trade of any radiation source:** (1) For obtaining safety authorisation for the domestic trade of any radiation source as referred in sub-regulation (1) of regulation 36, the applicant shall submit such documents and information, as specified in relevant regulatory documents including but not limited to, the following, namely—
- (a) copy of registration in India as per applicable law;
 - (b) letter from original equipment manufacturer authorising the local supplier/ vendor for marketing/supply of the radiation equipment/source in India;
 - (c) undertaking letter from original equipment manufacturer with respect to training, supply of spare parts, safety tools/gadgets, and decommissioning support;
 - (d) availability of trained personnel by original equipment manufacturer and radiation safety certification from agency or institution, recognised by the Board;
 - (e) undertaking letter from original equipment manufacturer to take back disused/decayed radiation sources as applicable;
 - (f) radiation measuring and monitoring instruments and personnel monitoring devices.
- (2) Notwithstanding anything contained in sub-regulation (1), the provisions of sub-regulation (2) of regulation 37 shall apply mutatis mutandis for domestic trade of any prescribed substance or prescribed equipment.
- 40. Pre-condition for transport of radioactive material:** (1) Safety authorisation for transport of radiation source shall be issued to a holder of safety authorisation or has been so directed by Licensing Authority, the Board or the Central Government.
- (2) Notwithstanding anything contained in sub-regulation (1), for transportation of such prescribed substance which is radioactive in nature-the applicant shall possess a valid licence.
- 41. Safety Authorisation for transport:** (1) For transport of radiation source, shipment approval for radioactive consignments and approval or acceptance of package design in which the radiation source is intended to be transported, shall be obtained from the Board.
- Explanation: Availability of package design approval and shipment approval shall be together construed as safety authorisation for transport and shall have the same meaning as under the Act.*
- (2) Notwithstanding anything contained in sub-regulation (1), for transport of prescribed substance which is radioactive in nature, only a package design approval or acceptance from the Board, as specified in sub regulation 2 of regulation 37 shall suffice and the subsequent permission from licensing authority for transport shall be deemed to be the shipment approval.
- (3) In respect of approval for package design, package designer shall submit such documents and information, as specified in relevant regulatory document, including but not limited to—

- (a) Safety assessment covering areas such as impact, thermal, shielding and criticality;
 - (b) quality assurance;
 - (c) maintenance and ageing related aspects depending on type of package;
 - (d) general and specific requirements for packaging;
 - (e) additional requirements for transport by air.
- (4) In respect of shipment approval, applicant shall submit such documents and information, as specified in relevant regulatory document, including but not limited to:
- (a) compliance with national regulations of other applicable regulators;
 - (b) assessment of adequacy of the package for the purpose;
 - (c) assessment of consigner and consignee, for legitimacy;
 - (d) arrangement for handling nuclear or radiological emergency during transport of radioactive material.

PART-F

APPLICATION AND ITS PROCESSING

- 42. Form and manner of application:** (1) Application for safety authorisation, approvals or waste authorisation, in such form and manner and accompanied with such fees, along with such documents and information in support of conditions precedent as specified in PART-A to PART-E of Chapter-II of these regulations, shall be made to the Board.
- (2) Application may be made for safety authorisation for a single stage or for composite safety authorisation for combination of various stages of lifetime of the facility or plant or for combination of stage(s) and activities incidental to such stage(s).
- (3) Notwithstanding anything contained in sub-regulation (1) and (2), the Board may seek such information as it may consider necessary to administer the provisions of the Occupational Safety, Health and Working Conditions Code, 2020 (37 of 2020) in such factories and to such extent as notified by the Central Government under section 42 of the Act.
- (4) Before submitting the application and such documents and information referred in sub-regulation (1) to (2), the applicant should ensure that independent review and verification of safety assessment of the facility of activity, commensurate with associated hazard potential, is carried out in accordance with regulatory documents and the applicant shall, if sought by the Board, also submit the outcome of such independent review and verification.
- Explanation: For removal of all doubts, such independent review and verification of safety assessment may be carried out by a third party or by an internal team of the applicant which is not involved in preparation of such safety assessment.*
- (5) The applicant shall ensure quality assurance of the documents and information submitted in support of the application.

(6) Applicant shall make proper arrangements with designer, vendor, supplier, and contractor, as the case may be, to ensure availability of all required such documents and information to the Board, in support of safety review and assessment for approval or waste authorisation or safety authorisation and such arrangements shall not relieve the applicant of the obligations for ensuring prime responsibility for safety.

Explanation: The applicant shall establish a formal process within the organisation for ensuring requisite knowledge on the design to enable discharge the prime responsibility for safety. It shall also be responsible for maintaining integrity of design of the plant throughout lifetime and shall be responsible for approving design changes.

(7) Applicant shall declare and delineate any information contained in the application and accompanying documents that is strategic, sensitive, proprietary or is of commercial confidence or trade secrets, and which should be treated as restricted information.

(8) Application and accompanying such documents and information shall be submitted electronically or by hard copy or dedicated web-portal or in such manner as specified by the Board.

(9) Application referred in sub-regulation (1) shall be made in such form and format as specified by the Board in its website.

(10) Application form shall be signed or authenticated by the applicant or his authorised representative, accompanied with a valid letter of authorisation:

Provided that such authorised representative shall not be a consultant or vendor or supplier, etc. and shall be an employee of the applicant with necessary authority and competence to take required decisions.

Provided further that the first of such application for a facility, facility, plant or mine or activity shall be from the position who has the ultimate control over the affairs of the facility, plant or mine or activity.

(11) For any change or modification in an application or information and documents which have already been reviewed, the applicant shall submit necessary documents and information, in such form and manner, and accompanied with such fees as specified by the Board.

43. Levy of fees: (1) The application for

- (a)safety authorisation including its extension, renewal or transfer or modification;
- (b)waste authorisation including its extension, renewal or transfer or modification;
- (c)approvals including its extension, renewal or transfer or modification.

shall be accompanied by such fees as may be notified by the Board from time to time, which shall *inter alia* take into account, nature and type, and complexity involved, new or repeat design etc.

(2) All fees and charges payable to the Board shall be paid in the mode as may be notified by the Board.

(3) Where the applicant withdraws the application before admittance, the entire fees shall be returned back:

Provided that the no fee shall be refunded after admittance of application by the Board.

(4) In case the application is made for composite safety authorisation or for combination of stages, the fee levied shall be the arithmetic sum of the corresponding stages or activities, unless otherwise specified by the Board.

44. Admittance of application: (1) Upon receipt of the application, the Board shall undertake an initial scrutiny for admittance of the application on consideration of the following aspects, namely—

- (a) applicant satisfies the eligibility criteria set out in these regulations in respect of facilities, plants, mines and activities;
- (b) the applicant satisfies with the requirements regarding the form, manner and fee for the application specified in these regulations;
- (c) relevant documents and information is complete in all respects.

(2) Where the Board is of the opinion that the information furnished is incomplete or inadequate, it shall return back the application within a period ninety days or as notified by the Board.

45. Safety Review and assessment: (1) Upon admittance, the Board shall undertake evaluation of application and for the purpose of safety review and assessment may—

- (a) conduct inspections;
- (b) visit test facilities or pilot plants and technical discussions;
- (c) visit operating plant;
- (d) visit manufacturing facilities;
- (e) review reports from accredited quality assurance agencies or other recognised agencies;
- (f) undertake any other act as may be necessary.

(2) In case it is considered necessary during the review, Board may seek additional documents and information, submissions on specific issues for carrying out the safety review and assessment.

Provided that the additional details or documents etc. sought by the Board, if not submitted within the time frame mentioned by the Board, the assessment time will be extended or the application may be rejected in case of significant delay in submission.

(3) For the purpose of safety review and assessment, the Board may finalize a safety review plan, considering the nature, type, stage of facility, plant, activity or mine, operational and regulatory experience as well as safety issues involved.

(4) Safety review plan referred in sub-regulation (3) may provide for scoping of the safety review following graded approach, specifying intermediate sub-stages, applicable

regulatory documents or other requirements, conduct of inspections, etc. and arriving at an indicative timeframe for completion of reviews:

Provided that the indicative timeframe may be further modified in case of additional information sought under sub-regulation (2).

Explanation: For removal of all doubts in case of application for composite safety authorisation, the safety review plan shall cover all the relevant aspects of stages and intermediate sub-stages for which the application is made.

Scoping of safety review and assessments for design of plants that have not been reviewed by the Board earlier and where specific requirements on the technology are not covered in detail in existing regulatory documents would be an involved step and would require detailed discussions with the applicant and additional submissions, as required.

(5) Such indicative timeframe may be made known to the applicant by the Board

(6) Safety review and assessment of the application shall be carried out through review mechanism established by the Board under clause (e) sub-section 3 of section 24 of the Act.

(7) Review mechanism may comprise utilization of various groups, committees, external experts, specialists, institutions, agencies, consultants, laboratories, professionals of integrity and outstanding ability and technical support Organisation(s) in a multi-tier review structure, may following a graded approach commensurate with their hazard potential and complexity, as deemed appropriate.

(8) During the process of review, the Board may invite the applicant or his authorised representative(s) to present the safety case, provide clarification and make presentations as may be required in support of the application and any commitments made thereon shall be binding on the applicant;

Provided that such authorised representative shall not be a consultant or vendor or supplier, etc. and shall be an employee of the applicant with necessary authority and competence to take required decisions.

(9) Board may, after requisite safety review and assessment, identify regulatory hold points at any stage in the life time of facility, plant or mine or during conduct of activity and further progress beyond such regulatory hold point shall be subject to verification of the relevant conditions and with a written permission from the Board.

PART-G

SAFETY ASSESSMENT AND DECISION MAKING

- 46. Document and information:** For submission of the documents and information specified in regulation 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 33, 35, 37, 38, 39, 40, 51, 59 and 60, the applicant shall comply with relevant regulatory documents as specified by the Board:

Provided that requirements in relevant regulatory document may vary based on hazard potential or complexities.

Provided further that in case regulatory document is not available on whole or part of the subject matter, the submissions of documents and information shall be based on guidance from the Board.

47. Issuance of Safety Authorisation, waste authorisation and approvals: (1) Decision on issuance of—

- (a) the safety authorisation for a stage or composite safety authorisation for combination of various stages or activities, for facilities, plants or mines and their extension or renewal;
- (b) safety authorisation for import, export, or domestic trade of radiation source;
- (c) confirmation in regard to life extension of nuclear power plant or reactor;
- (d) authorisation for storage, transfer and disposal of radioactive waste;
- (e) approval for—
 - i. design of nuclear power plant or reactor ;
 - ii. type approval for design of sealed sources, radiation generating equipment or equipment containing radioactive material or any other radiological device used for purpose of imaging;
 - iii. approval of package design and shipment for transport of radioactive or nuclear material;
 - iv. approval for procurement of radiation source;
 - v. approval for transfer of decayed or disused radiation sources.

(f) Recognition of persons and

(g) Certification of individuals

for which application is received under Part-A, shall be based on review and assessment by the Board, of the demonstration of safety and compliance to the applicable provisions of the Act, rules, regulations, regulatory documents, notifications, orders, directions and such other requirements specified by the Board, supplemented with findings of inspections, reports from accredited quality assurance agencies or other recognised agencies, etc;

(2) Where specific regulatory document is not available, the Board shall verify compliance with appropriate regulatory requirements or guidance specified in other regulatory documents or relevant international standards or requirements or documents as identified by it:

Provided that in case no applicable regulatory document or Board identified international standard or requirement or document exists, the Board shall evolve required regulatory document(s) / requirements on such subject:

Provided further that for such purpose, the Board may interact with the applicant.

Explanation: In situations where regulatory requirements need to be evolved, the knowledge base available in scientific and technical domain, will be utilized.

(3) If the compliance is demonstrated adequately to the satisfaction of the Board may consider issuing a safety authorisation for various stages, approvals or waste authorisation, as the case may be, with such terms and conditions as outlined in Schedule-IV:

Provided that having the safety authorisation by the Board does not diminish the prime responsibility for safety of employer of the facility or occupier of a factory or owner of a mine or any other person as provided in section 10 of the Act.

(4) Board may specify intermediate sub-stages or regulatory hold points, at any stage in the lifetime of facility or plant or mine or at any stage in the entire duration of the activity, as it may consider necessary and work cannot proceed beyond such regulatory hold point or intermediate sub-stage without satisfactory verification of compliance to specified condition.

Explanation: The intermediate sub-stage referred above in case of a nuclear power plant or a reactor may be excavation or first pour of concrete etc., for the stage of construction; and non-nuclear commissioning, initial fuel loading, first approach to criticality, power ascension testing (and related tests), and full power operation for limited duration for the stage of commissioning.

(5) Before granting any Safety Authorisation, Approval or Waste Authorisation the Board may, as necessary, confirm the status of compliance to the relevant hold points identified in the Licence for the respective stage of Safety Authorisation.

(6) If there is any material change in information or commitments or undertaking based on which a safety authorisation or waste authorisation or approvals was granted, the holder of safety authorisation shall obtain a prior permission from the Board:

Provided if such change is not of material nature, only prior information shall suffice.

(7) If the Board is of the opinion that the compliance is not adequately demonstrated or confirmation of compliance with licensing hold points from licensing authority has not been received, the Board may refuse to grant safety authorisation or approvals or waste authorisation, with reasons recorded in writing.

- 48. Amendments in the terms and condition of safety authorisation, waste authorisation or approvals:** Board may, on an application or otherwise in the public interest, make amendments in the terms and conditions of the safety authorisation, or approvals or waste authorisation, as may be deemed fit.
- 49. Issuing Authority:** Board may grant safety authorisation, approvals or waste authorisation either by itself or delegate the power by an order issued under section 27 to the Chairperson or Whole-time Member or such of its officer as specified in that order.

- 50. Validity of safety authorisation, waste authorisation or approvals:** (1) Unless otherwise specified by the Board, safety authorisation shall remain valid for a period of ten years and in no case shall exceed the validity period of the licence.
- (2) Approvals or waste authorisation granted by the Board shall remain valid for a period as specified by the Board.
- (3) The design approval granted to a nuclear power plant or a reactor shall remain valid for a period of 10 years or till commencement of its construction, whichever is earlier:
- Provided that where construction of the nuclear power plant or reactor has not commenced, the design approval may be renewed on its expiry based on requisite application, for further such duration as determined by the Board, after assessing conformance to the current regulatory requirements.
- 51. Regulatory oversight:** (1) Consequent to grant of safety authorisation (including approvals and waste authorisation) Board shall have suitable mechanism(s) of oversight, which may include but not limited to the following—
- (a) imposing reporting obligations including periodic or otherwise;
- (b) safety review and assessment of various reports and submissions;
- (c) verifying compliance to safety of the facilities and activities for which the safety authorisation, approval and/or waste authorisation is granted and the terms and conditions of such safety authorisation, approvals and waste authorisation;
- (d) verifying compliance to applicable provisions of the Act, rules, regulations, regulatory documents, notifications, orders and directions through necessary submissions, resident officers and employees at site, inspections, and investigations.
- (2) The reporting obligations mentioned in sub-regulation (1) include but not limited to the following-
- (a) periodic reports on safety performance of facility, plants or mine;
- (b) periodic reports on radiation protection aspects such as radiation doses to worker, public and the environment, radiation surveillance within plant or facility boundary, environmental surveillance report;
- (c) results of emergency exercises;
- (d) reports on events in facility, plant, mine or during activity;
- (e) periodic returns of radioactive waste and effluent discharge;
- (f) any proposed modification affecting safety;
- (g) health surveillance of workers;
- (h) response to observations or recommendations made during inspections or as part of continual safety review and assessment;
- (i) any other report or sought by the Board.

(3) For aspects specified in sub-regulation (2), the holder of safety authorisation shall comply with relevant regulatory documents as specified by the Board.

(4) During the oversight, if the Board may assess so, it shall decide to modify the terms and conditions of safety authorisation (including approvals and waste authorisation), in the interest of safety and the holder of the safety authorisation shall comply with the same.

(5) Notwithstanding anything above, the holder of safety authorisation may also seek modification of terms and condition of safety authorisation (including approvals and waste authorisation) by submitting an application specified by the Board.

52. Extension or renewal of safety authorisation, waste authorisation or approvals: (1)

An application for extension of validity or renewal of safety authorisation for operation of a facility or plant or mine or approval or waste authorisation shall be submitted to the Board well within the validity period as specified in the regulatory document, of existing safety authorisation along with such documents and information as specified by the Board in regulatory documents, in accordance with graded approach commensurate with hazard potential;

Provided that during safety review and assessment of application for extension of validity or renewal, licensee or holder of safety authorisation, as the case may be, shall continue to comply with the terms and conditions of existing safety authorisation and such other directions as issued by the Board, towards maintaining safety.

Provided further that safety authorisation beyond envisaged design life, Board may require additional safety assessment(s), apart from periodic safety review, as specified by it.

(2) No extension of validity or renewal of safety authorisation can be granted for a period beyond validity of licence for facilities or plants or mines specified in Sr. No. 1, 2 and 3 of Schedule-I or activities for which licence is required.

Explanation: for removal of all doubts, application for extension beyond lifetime of the nuclear power plant or reactor is dealt in regulation 14.

(3) Where the holder of safety authorisation does not apply for renewal or extension within the validity period as provided in sub-regulation (1), then on expiry of the safety authorisation, all authorised activities shall cease thereon and the person who had been granted the safety authorisation shall comply with directions of the Board with regards to safety

(4) Notwithstanding anything specified above, on expiry of the validity of safety authorisation, the Board may accept a delayed application for renewal or extension, within the period specified by it, for the reasons recorded in writing

Provided that after expiry of the aforesaid period, a fresh application for safety authorisation shall be submitted with such information and documents as specified in regulatory documents for recommencement of the authorised activity.

(5) Decision on extension of validity or renewal of the safety authorisation or approval or waste authorisation shall be based on review and assessment by the Board, of the demonstration of safety and compliance to the, applicable provisions of the Act, rules, regulations, regulatory documents, notifications, orders, directions and such other requirements specified by the Board, for the period for which the extension or renewal is sought and supplemented with findings of inspections, reports from accredited quality assurance agencies or other recognised agencies, etc.

- 53. Transfer of safety authorisation, waste authorisation or approvals:** (1) Safety authorisation, waste authorisation or approvals, shall not be transferable without prior permission of the Board;

Provided that for facilities, activities or mine specified in Sr. No. 1, 2 and 3 of Schedule-I, which require licence from the Licensing Authority, the transfer of safety authorisation shall be allowed, only if the licence has already been transferred by the Licensing Authority, in accordance with the relevant rules.

(2) Decision on transfer of the safety authorisation waste authorisation or approvals, shall be based on review and assessment by the Board, of the demonstration of compliance to safety and the applicable provisions of the Act, rules, regulations, regulatory documents, notifications, orders, directions and such other requirements specified by the Board and supplemented with findings of inspections, reports from accredited quality assurance agencies or other recognised agencies, findings made during oversight etc.

(3) With transfer of safety authorisation, waste authorisation or approvals, all existing terms and conditions including validity gets transferred to the transferee and on such transfer, the Board may modify the terms and conditions of safety authorisation, as considered necessary, in the interest of safety.

(4) In case of transfer of safety authorisation, waste authorisation or approvals, all obligation, commitments and responsibilities of the original holder of safety authorisation including the prime responsibility for safety shall get transferred to the person to whom the safety authorisation has been transferred.

- 54. Fees for transfer of safety authorisation, waste authorisation or approvals:** Wherein an application is made to the Board by the holder of safety authorisation, waste authorisation or approvals, for transfer of a safety authorisation, already issued to him, to another person, the application is to be accompanied with such fees and in such mode as notified by the Board in accordance with regulation 43.

- 55. Suspension, curtailment or cancellation of safety authorisation, waste authorisation or approvals:** (1) Board may curtail the operation of facility or plant or conduct of activity or may modify, cancel, suspend the safety authorisation including suspension or cancellation of waste authorisation or any approval, registration, exemption or clearance, in accordance with the provisions of the Act, with reasons recorded in writing, including where it has come to the knowledge that—

- (a) safety authorisation, waste authorisation, approval, registration or any exemption or clearance has been obtained by misrepresentation, or suppression of any material fact in accordance with clause (c) of sub-section (2) of section 8 of the Act; or
- (b) holder of safety authorisation, waste authorisation, approval, registration has been convicted by a court in India for in any offence under the Act:

Provided that decision on suspension or modification or curtailment or cancellation shall be taken after giving a show cause notice to the holder of safety authorisation and also giving an opportunity to make a representation within a period of thirty days from the date of receipt of the show cause notice.

(2) Upon suspension or cancellation of the said safety authorisation or waste authorisation or approval, the Board may give directions to the persons whose authorisation or approval has been suspended or cancelled in respect of safety and safe storage of the radioactive wastes, as the case may be and such person shall comply with such directions even during pendency of an appeal.

(3) In case of suspension or cancellation of the safety authorisation related to those facilities, plants or mines as specified in Sr. No. 1, 2 and 3 of Schedule-I, which are licenced under the Act, Board shall inform the Licensing Authority to take necessary action regarding aspects related to security, safeguard and liability, as applicable.

(4) In case of suspension or cancellation of the safety authorisation related to those facilities or radiation sources as specified in Sr. No. 4 of Schedule-I, for which licence from Licensing Authority is not required the Act, Board shall inform the Licensing Authority to take necessary action regarding aspects related to security of the source and its subsequent safe management.

PART-H

DUTIES AND RESPONSIBILITIES OF HOLDER OF SAFETY AUTHORISATION

- 56. Compliance with terms and conditions:** (1) Holder of safety authorisation shall be responsible for complying with the terms and conditions of the safety authorisation and for taking such measures as considered necessary to ensure safety of the facility or plant or activity or mine.
- (2) Holder of safety authorisation shall have the prime responsibility for safety and retains the prime responsibility throughout the lifetime of facility, plant, activity or mine, and this responsibility shall not be delegated.
- (3) Every holder of safety authorisation shall be responsible to make adequate arrangements for management of nuclear or radiological emergencies occurring in a facility or a plant or a mine or during transport of radioactive material including measures to prevent the occurrence of such emergencies and limit its consequences if they occur and share such data and reports, in accordance with the provisions specified in relevant regulatory documents

(4) Without prejudice to the generality of the foregoing provision, holder of safety authorisation shall-

- (a) ensure commission of only such acts for such purpose and at such location for which safety authorisation is granted and in accordance with the terms and conditions specified therein;
- (b) comply with the relevant provisions of the Act and rules, regulations promulgated thereunder and any orders, notification issued and such regulatory documents as specified by the Board and make the workers familiarise with the safety requirements provided therein;
- (c) comply with such directives or notice as may be issued or abide by such conditions or restrictions imposed by the Board including that in cases of exposures in excess of regulatory constraints and in an event of an accident;
- (d) not carry out any operation likely to result in a more hazardous accident than that envisaged in the safety analysis given by the applicant in his application;
- (e) ensure that quality assurance tests of structures, systems, components, as applicable are conducted;
- (f) maintain such records and submit such periodic reports and returns as specified by the Board;
- (g) investigate and inform the Board of safety related events including accidents involving radiation source as specified by the Board and maintain record of investigations;
- (h) provide the services of a physician with appropriate qualifications to undertake periodic medical tests of occupational workers in accordance with regulatory documents issued by the Board;
- (i) extend all assistance to authorised representative(s) of the Board to enable effective and unhindered inspection and investigation;
- (j) in case where a radiation source is located on a property on lease, holder of safety authorisation shall provide an undertaking from the lessor that, if he fails to exercise its control over the radiation source, due to any circumstances, then the lessor shall ensure that the radiation source is not moved out of the property and is maintained in safe and secured condition till the radiation source is safely transferred or safely disposed of;

57. Responsibilities for ensuring radiation protection: With respect to ensuring radiation protection of the workers and public and environment, the holder of safety authorisation shall-

- (a) establish written procedures and plans for controlling, monitoring and assessment of radiation exposure for ensuring adequate protection of workers, members of the public and the environment, and ensure compliance with dose limit notified and other regulatory constraints specified by the Board;

- (b) ensure that the workers are familiarised with radiation protection programme and procedures, provisions of relevant regulatory documents on radiation protection issued by the Board and emergency response plans;
- (c) ensure workers are subjected to personnel monitoring and health surveillance in accordance with regulatory documents and appropriate records are maintained;
- (d) arrange for preventive and remedial maintenance of radiation protection equipment/provision and monitoring instruments;
- (e) inform the Board promptly of the occurrence, investigation and follow-up actions in cases of exposure in excess of regulatory constraints, as specified in regulatory documents, including steps to prevent recurrence of such incidents;
- (f) comply with radiation surveillance requirements as specified in regulatory documents and verify the performance of radiation monitoring systems, safety interlocks, protective devices and any other safety systems in the radiation installation;
- (g) conduct or arrange for quality assurance tests of structures, systems, components and sources and related equipment;
- (h) inform the Board when either he or the Radiological Safety Officer or a worker leaves the employment;
- (i) inform employer, appropriate law enforcement agency in the locality and the Central Government and Board of any loss of radiation source;
- (j) prepare, in consultation with Radiological Safety Officer, emergency plans, in accordance with regulatory documents, for responding to accident, to mitigate their consequences and ensure emergency preparedness measures;
- (k) ensure that the radiation symbol or warning sign as per the specifications specified in Schedule-V to these regulations is conspicuously and prominently displayed at all times—
 - (i) on externally visible surfaces of radiation equipment, and containers for storage of radioactive materials; packages for radioactive materials and vehicles carrying such packages;
 - (ii) at the entrance to the room housing the radiation generating equipment; and
 - (iii) at the entrance of controlled area and supervised area.
- (l) ensure that the radiation symbol is not used for any purpose other than those mentioned in these regulations.

58. Responsibilities with respect to control of medical exposure, food irradiation and other non-power applications: (1) Every holder of safety authorisation shall ensure that the use of radiation for non-power applications are carried out in a responsible manner with due diligence to preserve the intended benefits while maintaining safety standards and in compliance with relevant laws.

(2) Without generality of the foregoing provisions, the holder of safety authorisation, shall, as applicable—

- (a) establish written process and plans to ensure the optimization of medical exposures;
- (b) maintain records of medical exposure and report to the Board any accidental exposure other than that arising out of clinical judgement;
- (c) obtain a valid licence under the Food Safety and Standards Act, 2006 and affix labels as specified by Food Safety Standards Authority of India on packages containing products processed by radiation;
- (d) ensure processing of food and allied products within the absorbed dose limits, use packaging material suitable for radiation processing of food and allied products and carry out dosimetry as specified in Schedule-II to these regulations;
- (e) maintain records of quantitative dosimetry of food and allied products for a period a five years in such form as may be specified by the Board and issue a certificate of radiation processing.

59. Responsibilities with respect to waste management: Every holder of waste authorisation shall—

- (a) ensure that storage, transfer or disposal of radioactive wastes is carried out in a manner in accordance with the terms and conditions laid down in the waste authorisation;
- (b) maintain records of waste disposal are maintained in accordance with regulatory document issued by the Board;
- (c) ensure personnel monitoring and environmental surveillance is carried out on a continued basis and to monitor the environmental impact of the waste disposal to evaluate the operations;
- (d) submit to the Board quarterly reports and such other periodical reports as specified in the waste authorisation and reports on any hazardous situation due to accidental release of radioactive waste and immediate remedial measures, in accordance with regulatory documents;
- (e) ensure that radioactive waste is not disposed
 - (i) in any location different from those specified in the waste authorisation;
 - (ii) in quantities exceeding those specified in the waste authorisation.

60. Supply of radiation source: The supplier of a radiation source possessing a valid safety authorisation-

- (a) assist the users in meeting the requirements specified by the Board;
- (b) supply only type approved radiation source to users having valid safety authorisation from Board;

- (c) facilitate in safe handling and periodic replacement, transport and disposal of the radiation sources including arrangements for return of decayed or disused radiation sources to original source supplier, within the country as well as abroad with due approval from the Board;
- (d) maintain detailed inventory of radiation sources supplied and safely disposed;
- (e) ensure that all personnel engaged have appropriate education, training and qualification for performing their intended tasks and implement appropriate management system for ensuring high standards in safety and quality.

CHAPTER-III

RECOGNITION AND CERTIFICATION

- 61. Recognition of persons:** (1) Board may, from time to time, recognise persons or agencies or institutes or laboratories meeting the qualifications and expertise, specified in the relevant regulatory documents, for the purpose of -
- (a) accepting the results of the services provided to the applicant or holder of safety authorisation;
 - (b) performing any of the functions entrusted by the Board to support or assist in discharge of its responsibilities.
- (2) The holder of safety authorisation shall make adequate arrangements to utilize the services of only such agencies, institutes, and testing and calibration laboratories or persons which having valid recognition from the Board.
- (3) Form and manner of application to obtain recognition shall be as provided in the website of the Board.
- (4) Board shall review the application(s) in order to assess compliance with the qualification and other requirements as specified in applicable regulatory document by the Board.
- (5) Board shall make available the information on recognised agencies, institutes, and testing and calibration laboratories or persons along with the purpose for which they have been recognised, available on its web-site.
- (6) The arrangements made under sub-regulation (2) shall inter-alia require that all safety related information pertaining the services rendered are maintained as records by the applicant or holder of safety authorisation.
- 62. Certification of persons:** (1) Only certified persons shall perform tasks or carry out functions entrusted to them in or in relation to a facility or plant or activity or mine,
- (2) Positions for which the persons need to be certified under sub-regulation (1) shall be notified by the Board taking into considerations actual or potential impact of the tasks performed on safety of the workers, public and environment.

- (3) Where required, Board may also permit holder of safety authorisation to self-authorise persons occupying such positions as may be specified by the Board following a qualification programme approved by the Board.
- (4) Persons occupying the positions as notified by the Board shall have qualification and training as specified by the Board in applicable regulatory documents.
- (5) In addition to the positions notified by the Board in sub-regulation (2), each holder of safety authorisation shall designate a person to perform the duties of Radiological Safety Officer in accordance with the qualifications specified in regulatory documents, who shall be certified by the Board.
- (6) For obtaining certification, the application shall be made in a form as available on web-site of the Board and certification shall be granted after evaluation against the qualifications and trainings and in manner specified in the applicable regulatory documents.
- (7) Certification of persons shall be valid for a period of three years and on expiry, shall be eligible for rectification in accordance with provisions of sub-regulation 6.
- (8) For self-authorisation as per sub-regulation (3), the qualification programme shall be prepared by applicant and submitted along with an application in accordance with the regulatory requirements specified in applicable regulatory documents, for approval by the Board.
- (9) Certified persons shall have such roles and responsibilities for carrying out the intended functions as specified in applicable regulatory documents and indicated in the certificate.
- (10) Applicant or holder of safety authorisation shall adhere with such provisions, as may be specified by the Board, relating to qualification, experience, training of persons and their fitness for duty under these regulations.
- (11) Holder of safety authorisation shall ensure that the persons for whom certificate has been issued by the holder of safety authorisation are adequately trained and their recertification is carried out in a manner as specified by the Board.
- (12) Holder of safety authorisation shall ensure that no person continues to act as a duly authorised person if, in the opinion of the Board, such person is unfit to act in that capacity and the Board has notified the holder of safety authorisation to that effect.
- (13) Holder of safety authorisation shall make and effectively implement adequate arrangements to ensure that only suitably qualified and experienced persons, who have undergone adequate training, perform any duties which may affect the safety of site operations, workers, public and environment with respect to any facility, activity or mine.
- 63. Suspension, modification, cancellation of recognition or certification of persons:** Board may suspend, modify or cancel the recognition of any recognised agency, institute, and testing and calibration laboratory or person, or certificate of any person; in case it is concluded that—

- (a) any term or condition has been violated or
- (b) certification or recognition has been obtained by misrepresentation, or suppression of any material fact in accordance with clause (c) of sub-section (2) of section 8 of the Act
- (c) the person has been convicted by a court in India for in any offence under the Act.

Provided that decision on suspension or modification or cancellation of recognition or certification shall be taken after giving a show cause notice to the recognised or certified person and also giving an opportunity to make a representation within a period of thirty days from the date of receipt of the show cause notice.

64. Duties and responsibilities of Radiological Safety Officer: (1) The Radiological Safety officer certified under these regulations shall be responsible for advising and assisting the employer, owner or occupier, and holder of safety authorisation on safety aspects aimed at ensuring that the provisions of rules, regulations, regulatory documents, directions, orders are complied with.

(2) Without generality to the foregoing provisions the Radiological Safety officer shall—

- (a) carry out routine measurements and analysis on radiation and radioactivity levels in the controlled area, supervised area of the radiation installation and maintain records of the results thereof;
- (b) investigate any situation that could lead to potential exposures;
- (c) advise the employer, owner or occupier regarding—
 - (i) the necessary steps aimed at ensuring that the regulatory constraints specified in regulatory documents and the terms and conditions of the safety authorisation are adhered to;
 - (ii) the safe storage and movement of radioactive material within the facility;
 - (iii) initiation of suitable remedial measures in respect of any situation that could lead to potential exposures; and
 - (iv) routine measurements and analysis on radiation and radioactivity levels in the off-site environment of the facility and maintenance of the results thereof;
- (d) ensure that -
 - (i) tests and calibration of sources, as applicable are conducted; and
 - (ii) monitoring instruments are calibrated periodically.
- (e) assist the employer or owner or occupier in instructing the workers on hazards of radiation and on suitable safety measures and work practices aimed at optimising exposures to radiation sources; and
- (f) advise the holder of safety authorisation on -
 - (i) the modifications in working condition of a pregnant worker or lactating mother; and

- (ii) the safety and security of radiation sources;
- (g) furnish to the holder of safety authorisation and the Board, the periodic reports on safety status of the facility;
- (h) assist employer, occupier or owner on developing suitable emergency response plans to deal with accidents and maintaining emergency preparedness;
- (i) inform the Board when he leaves the employment;
- (j) advise the holder of safety authorisation on the safe disposal of radioactive wastes;
- (k) advise the employer or owner or occupier regarding the safe handling and disposal of radioactive wastes and on the steps necessary to ensure that the regulatory constraints specified in regulatory documents, are not exceeded;
- (l) instruct the radiation workers engaged in waste disposal on the hazards of radiation and on suitable safety measures and work practices aimed at minimising exposures to radiation and contamination, and to ensure that adequate radiation surveillance is provided for all workers and the environment;
- (m) carry out such tests on conditioned radioactive wastes, as specified by the Board;
- (n) ensure that all buildings, laboratories and plants wherein radioactive wastes will be or are likely to be handled/produced, conditioned or stored or discharged from, are designed to provide adequate safety for safe handling and disposal of radioactive waste;
- (o) assess the radiation protection instruments required for an installation;
- (p) help investigate and initiate prompt and suitable remedial measures in respect of any situation that could lead to radiation hazards;
- (q) ensure that reports on all hazardous situations including accidental release of radiative waste along with details of any immediate remedial measures that may have been initiated are made available immediately to employer or occupier or owner and the Board;

CHAPTER-IV

TRANSACTION OF BUSINESS OF THE BOARD

- 65. Meetings of the Board:** (1) There shall be no less than four meetings of the Board in a financial year on such dates and at such places in India and through such modes (including virtual meetings, if situation demands) as the Chairperson may decide and the interval between any two meetings should normally not exceed five months.
- (2) Decision to convene a meeting of the Board shall lie with Chairperson of the Board.
- (3) Chairperson of the Board may also consider convening the meeting based on the request from any Member of the Board.

(4) Notice of every meeting of the Board shall ordinarily be given to each member of the Board at least 15 days in advance by Secretary or such other employee of the Board as authorised by Chairperson.

(5) Chairperson, may, in case of urgency, at any time, call a meeting of the Board at a lesser notice than fifteen days, provided that the same is acceptable to all members of the Board. However, where any member of the Board, communicates in writing that such date of meeting is not agreeable, the meeting can still be held provided that, number of members participating in the meeting, is not less than the quorum of the meeting stipulated in sub-regulation (1) of regulation 66.

(6) Notice shall be given to every member through e-mail or post or courier or other digital means or in person to facilitate speedy communication, stating therein the brief agenda of the meeting, setting out the items of business to be considered; provided that the acknowledgement of receipt is collected wherein the notice is given in person.

(7) If all the items of business to be transacted at a meeting of the Board cannot be completed in one sitting, the meeting may be adjourned and reconvened later:

Provided that only the unfinished items of business will be considered in the meeting being convened post the adjournment.

Provided further that Chairperson of the Board, may, if he considers it imperative, may add any new item of business in the agenda of that meeting.

(8) No business other than that for which the meeting of the Board was convened shall be discussed during the meeting, except with the consent of the Chairperson of the Board.

66. Quorum: (1) Quorum for any meeting of the Board shall be at least half of the numbers of members of the Board including the Chairperson and Whole-time member.

(2) If the quorum is not present at any meeting of the Board, the Chairperson may adjourn the meeting and the meeting shall be reconvened on such other date, time, place and mode as decided by Chairperson and in such reconvened meeting also if quorum is not present, the Members present at the said meeting, shall deemed to constitute the quorum for such meeting, to take up discussion and to dispose of only the items of business set out in the agenda for the initial meeting.

(3) Notwithstanding anything contained in sub-regulation (2), Chairperson may cancel the meeting in accordance with the regulation 69 if no quorum exists either within 30 minutes after the time fixed for the meeting or at some point during the meeting

(4) Chairperson may also decide to continue the meeting if the quorum is not met and where such meeting is continued, no regulatory decisions shall be made.

(5) Attendance of members shall be registered by the Secretary.

67. Conduct of meetings: (1) The Chairperson shall preside over the meetings of the Board.

(2) In case of inability of Chairperson to attend the meeting, the Whole-time member shall preside the meeting with prior concurrence of Chairperson and no regulatory decisions shall be taken in such meetings:

Provided that for any regulatory decision, if required to be taken, in case of exigency, it shall be in accordance with the regulation 74.

(3) Chairperson may also invite any officer of the Board or any expert to attend any meeting of the Board and such invitee may participate in the proceedings of the meeting but shall have no right to vote.

(4) Chairperson may also invite the applicant or any person holding the safety authorisation to the meeting, for particular agenda item, where the presence of such invitee is considered necessary in facilitating the deliberations on safety matters or for making presentation and such invitee shall have no right to vote.

(5) If for any reasons the Secretary is unable to attend any meeting of the Board, the Chairperson may, direct any other employee of the Board, to act as Secretary on behalf of the Secretary.

(6) Secretary may take the assistance of any officer or employee of the Board, with permission of the Chairperson, for the purpose of discharging his duties relating to the meetings of the Board

- 68. Agenda:** (1) Secretary shall be responsible for preparation of the agenda for each meeting of the Board and upon approval from Chairperson, issue and circulate to all the members of the Board, at least a period of seven days before the date of each meeting:

Provided that Secretary may, with the approval of Chairperson, amend or delete or add new item in the agenda of business subsequent to its issue.

(2) Secretary may circulate relevant items to the invitees, at least a period of seven days before the date of the meeting.

(3) At any meeting, the business shall normally be transacted in the order in which it is entered in the agenda:

Provided that Chairperson may either withdraw any item from the agenda or postpone the item to the next meeting or change the order of business wherever necessary.

- 69. Cancellation or rescheduling of meeting:** (1) Chairperson shall decide on cancellation or rescheduling of the meeting, in case, there is a need to do so.

(2) In case Chairperson desires to postpone or cancel any pre-scheduled meeting of the Board due to any unavoidable circumstances, the Secretary shall communicate to all concerned, the next date of the meeting (as relevant) along with the reason for postponement or cancellation.

- 70. Decision of the Board:** (1) Each Board member shall have equal authority and responsibility in all Board decisions.

- (2) Decisions of the Board shall be based on the provisions of the Act, rules, regulations, regulatory documents and in good faith and conscience.
 - (3) Board shall ensure that the regulatory decisions are fair, just and reasonable.
 - (4) If a member has an interest in any item of business to be transacted at a meeting, he shall not participate or vote on such item and in such case, the decision on such item shall be taken by majority of the votes of other members attending the meeting.
 - (5) Chairperson of the meeting shall endeavour at all times to arrive at decisions or recommendations through a consensus among members and voting shall be resorted to if attempts to arrive at a consensus fail and the dissenting views shall be recorded in the minutes of the meeting of the Board.
 - (6) For the purpose of voting, all members present including the Chairperson of the meeting shall have one vote each; provided if a member of the Board chooses to abstain from the voting, the counting of votes shall not include the same.
 - (7) Votes on every item of business to be transacted at a meeting of the Board shall be taken by a show of hands.
 - (8) In the event of equality of votes, the Chairperson of the meeting shall have a second or casting vote.
 - (9) The minutes of the meeting or any record of the decisions or deliberations of the Board shall be approved by the Chairperson before issue by the Secretary.
 - (10) Regulatory decisions taken at every meeting of the Board shall ordinarily be published on the website of Board, with due consideration to restricted information.
 - (11) Review application against decisions of the Board shall be submitted to the Atomic Energy Redressal Advisory Council established under section 47 the Act.
- 71. Closure of debates:** Chairperson may move for the closure of the debate or any item of business discussed at a meeting when he considers that all members have had the opportunity to express their views on any business discussed at the meeting.
- 72. Minutes of meeting:** (1) Secretary shall cause the draft minutes of each meeting of the Board to be prepared on conclusion of each meeting and submit the same to the Chairperson of the meeting, for his approval.
- (2) Draft minutes of each meeting of the Board approved by the Chairperson of the meeting shall be forwarded to each member.
 - (3) Draft minutes circulated shall be confirmed in a subsequent meeting of the Board and the decision of the Chairperson on the changes suggested by any member, if any, shall be final and the confirmed minutes shall be circulated by the Secretary and kept as record of the Board.
 - (4) Minutes of each meeting of the Board shall contain a fair and correct summary of the proceedings there at and the names of Members who did not participate in the discussion of, or vote on, any item of business transacted at the meeting

(5) Chairperson may decide the inclusion or non-inclusion of any matter in the minutes, if in his opinion, the same is not relevant or material to the proceedings or defamatory of any person.

- 73. Power of the Chairperson to take urgent actions:** (1) Chairperson may take such action or make such decision as may be necessary, in the interest of safety, in case of an exigency or circumstances warranting immediate action by the Board and when it is determined that calling a meeting of the Board is not feasible.

(2) Reason for not calling a meeting under sub-regulation (1) shall be recorded in writing.

(3) Any such action taken or decision made under sub-regulation (1), as the case may be, shall be communicated promptly and in any case within the period of seven days to all the members:

Provided that any such action shall be placed in the next meeting of the Board for its ratification.

- 74. Decision by circulation:** (1) Save as otherwise provided in regulation 67, where calling a meeting of the Board is not feasible and when the Chairperson decides, any item of business may be referred to members by circulation for resolution.

(2) A resolution shall be deemed to have been passed by the members when such a resolution circulated in the draft, together with necessary material, if any, to all the members and the resolution is approved by the majority of the members.

(3) Where no comments or views from any member are received within a period of seven days, it shall be deemed to have been approved by the member.

(4) Any resolution circulated under sub-regulation (1) and approved by the majority of such of those members entitled to vote thereon, shall have such effect and be binding as if such resolution was passed by the majority of the members at a meeting.

(5) Any resolution passed through circulation, shall be placed at the next meeting of the Board for its ratification.

- 75. Record of business:** (1) Secretary shall maintain the record of proceedings of all items of the business transacted during the meetings of the Board or through the decisions by circulation.

(2) Every decision, direction or recommendation of the Board shall be recorded in writing in the minutes of the meeting of the Board or record of deliberations of the meeting and such decisions along with the agenda papers shall be preserved as a record in physical or electronic form.

(3) Records related to business item(s) of the meeting of the Board and the correspondence in connection with transaction of the Business of the Board shall be marked as 'Confidential' and accordingly dealt with.

Provided that the decisions shall ordinarily be published on the website of Board in accordance with sub-regulation 10 of regulation 70.

(4) Members of the Board shall have access to the decisions made by the Board in the past.

76. Independence and confidentiality: (1) Members of the Board shall make a commitment to attend and participate in its meetings.

(2) Any member or any other participant, not including the interested party, in a meeting, who believes that his interests may undermine his independence, shall promptly inform the Chairperson in writing who thereon shall take a decision on his participation in the discussions at the meetings.

(3) Member and invitees shall maintain confidentiality of the business to be transacted during the meetings.

77. Honorarium, reimbursement of expenses, etc.: Experts who are invited under sub-regulation (3) of regulation 67 to any meeting of the Board shall be entitled to a payment of an honorarium, as per the government norms, for attending each meeting and the reimbursement of actual travel and subsistence expenses.

78. Review of decisions or orders: (1) Any person aggrieved by an order or decision of the Chairperson or Whole-time member or officer of the Board may file an application for review to the Board under sub-section (2) of section 27 of the Act.

(2) Review application referred in sub-regulation (1), shall be made as per the format specified by the Board.

(3) If the application is against the order or decision of Chairperson or Whole-time member of the Board then Chairperson or Whole-time member, as the case may be, shall abstain from voting on such item.

(4) Board shall, after giving the applicant(s) and the Chairperson or Whole-time member or officer of the Board, an opportunity of being heard, dispose of the application as expeditiously as possible, but not later than thirty days.

(5) If the Board determines that any order or decision imposed was unreasonable then, the Board may either annul such order or decision or may pass appropriate order or decision in the interest of safety.

CHAPTER-V

MISCELLANEOUS

79. Interpretation: In order to remove any difficulties in the application or interpretation of these regulations, the Board may issue clarifications through circulars or guidance notes after recording the reasons in writing.

80. Residuary power: Any matter, not expressly provided in these regulations, shall be referred to the Board for its decision, and the decision of the Board thereon shall be final.

81. Power to relax or waive or condone: The Board shall have power to relax the strict enforcement of any requirements in these regulations, without adversely affecting safety, with reasons recorded in writing.

- 82. Power to amend schedules:** The Board may, as and when considered necessary, by notification in the Official Gazette, amend the Schedules to these regulations.
- 83. Offence and penalties:** Any person who contravenes the provisions of these regulations or any of the terms of conditions of the safety authorisation, or any order or directions issued shall attract the provisions of offences and penalties under the Act.

SCHEDULE-I

[See Regulation 3(1), 3(2), 16, 24, 27,52(2), 53(1), 55 (3),55(4)]

FACILITIES, PLANTS AND MINES REQUIRING SAFETY AUTHORISATION

- (1) Nuclear power plants or any other reactor including Deuterium-Tritium reaction based fusion reactor
- (2) Other Nuclear Facilities and Plants, such as:
 - i) Facility for nuclear fuel fabrication including conversion, refining, and other associated activities as permitted under the Act;
 - ii) Facility for storage of nuclear fuel
 - iii) facility for storage of spent fuel
 - iv) plants for processing ores of uranium or thorium;
 - v) plants engaged in production, use, processing for disposal of such prescribed substances which are radioactive in nature as notified under subsection (2) of section 3 of the Act.
 - vi) Any other plant for processing of mineral or material which has been licensed by the Central Government under sub-section (3) of section 5 of the Act for isolation or extraction of uranium, thorium or such other prescribed substance which is radioactive in nature
 - vii) Plants engaged in the manufacture or storage of radioactive material or radiation generating equipment or equipment containing radioactive sources
 - viii) Any plant which may result in incidental radiation exposure
 - ix) Plants engaged in management or disposal of radioactive waste other than high level radioactive waste arising from reprocessing, recycling, separation of radionuclides
 - x) Facilities or plants engaged in management of tailings generated from processing of uranium and thorium ores
- (3) Mines
 - i) Mines of uranium or thorium including exploration as applicable;
 - ii) Any other mine which has been licensed by the Central Government under sub-section (3) of section 5 of the Act for isolation or extraction of uranium, thorium or such other prescribed substance which is radioactive in nature
- (4) Radiation Facility:
 - i) **Facilities and associated practices in Health care and Medical applications:**
 - (a) Telegamma and accelerators used in teletherapy
 - (b) Brachytherapy and Intra Operative Radiation Therapy
 - (c) Medical Cyclotron Superficial and contact radiotherapy

- (d) Computed Tomography (CT); PET-CT and SPECT-CT using unsealed sources
- (e) Interventional Radiology (Cath-lab)
- (f) Radionuclide Therapy using unsealed sources
- (g) Equipment or Sealed and unsealed sources for calibration and quality control
- (h) Gamma and X-ray irradiation chambers
- (i) Simulators in Radiotherapy* Diagnostic Radiology Imaging*
- (j) Positron Emission Tomography (PET) or Single-photon emission computed tomography (SPECT) or Gamma Camera using unsealed sources*
- (k) Unsealed sources used for non-imaging applications*
- Manufacture of Radioimmunoassay kits*
- ii) Facilities and associated practices in food irradiation applications:**
 - (a) Gamma Radiation Processing Facility
 - (b) Industrial Accelerator Radiation Processing Facility
- iii) Facilities and associated practices in industry, agriculture, water and environment applications:**
 - (a) Gamma Radiation Processing Facility
 - (b) Industrial Accelerator Radiation Processing Facility
 - (c) Gamma and X-ray irradiation chambers
 - (d) Industrial radiography
 - (e) Container / Truck Scanner
 - (f) Neutron generators*
 - (g) Computed tomography*
 - (h) X-ray based portable scanner for security applications*
Radiation testing or handling facilities associated with the manufacturing of (1) X-ray inspection system used in Baggage, food and mail scanning, (2) X-ray based electron microscope, Printed Circuit Board analyser, (3) electron beam welding machine, (4) Analytical x-ray equipment, (5)
 - (i) consumer products containing radioactive substance* Nucleonic gauges and well logging*
Sealed and unsealed sources*
 - (j) Radiation sources for standardization and calibration*
- iv) Facilities and associated practices in research applications and education:**
 - (a) Particle accelerators
 - (b) Deuterium-deuterium reactions based fusion devices like tokamak, large helical devices plasma generators
 - (c) Neutron generators*

- (d) Sealed and unsealed sources*
- (e) Radiation testing or handling facilities associated with manufacturing of (1) Analytical x-ray equipment, (2) X-ray imaging devices*
- (v) Any other facility or activity notified by the central government under clause (g) of sub-section (2) of section 3 which is/are likely to subject an individual to radiation exposure.

Explanation: For the purpose of this schedule “consumer products” mean a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without the need for any special surveillance or regulatory control after sale.

Consumer products include items such as smoke detectors and luminous dials into which radionuclides have deliberately been incorporated, and also ion generating tubes. It does not include building materials, ceramic tiles, spa waters, minerals and foodstuffs, and it excludes products and appliances installed in public places (e.g. exit signs).

*** Facilities / practices requiring only Registration**

SCHEDULE-II

[See Regulation 32 and 58 (2)]

CLASSES OF FOOD PRODUCTS AND DOSE LIMITS FOR RADIATION PROCESSING

Class	Food	Purpose	Dose limit (Kilo Gray)	
			Minimum	Maximum
1.	Bulbs, stem and root tubers and rhizomes	Inhibit sprouting	0.02	0.2
2.	Fresh fruits and vegetables (other than Class I)	Delay ripening	0.2	1.0
		Insect disinfestation	0.2	1.0
		Shelf-life extension	1.0	2.5
		Quarantine application	0.1	1.0
3.	Cereals and their milled products, pulses and their milled products, nuts, oil, seeds, dried fruits and their products	Insect disinfestation	0.25	1.0
		Reduction of microbial load	1.5	5.0
4.	Fish, aquaculture, seafood and their products (fresh or frozen) and crustaceans	Elimination of pathogenic microorganisms	1.0	7.0
		Shelf-life extension	1.0	3.0
		Control of human parasites	0.3	2.0
5.	Meal and meat products including poultry (fresh and frozen) and eggs	Elimination of pathogenic microorganisms	1.0	7.0
		Shelf-life extension	1.0	3.0
		Control of human parasites	0.3	2.0
6.	Dry vegetables, seasonings, spices, condiments, dry herbs and their products, tea, coffee, cocoa and plant products	Microbial decontamination	6.0	14.0
		Insect disinfestation	0.3	1.0
7.	Dried foods of animal origin and their products	Insect disinfestation	0.3	1.0
		Control of moulds	1.0	3.0

		Elimination of pathogenic microorganisms	2.0	7.0
8.	Ethnic foods, military rations, space food, ready-to-eat, ready-to-cook/minimally processed foods	Quarantine application	0.25	1
		Reduction of microorganism	2	10
		Sterilization	5	25

DOSE LIMITS FOR RADIATION PROCESSING OF ALLIED PRODUCTS

Sr. No.	Allied Product	Purpose	Dose limit (Kilo Gray)	
			Minimum	Maximum
1	2	3	4	5
1.	Animal food and feed	Insect disinfestation	0.25	1.0
		Microbial decontamination	5.0	10.0
2.	Ayurvedic herbs and their products, and medicine	Insect disinfestation	0.25	1.0
		Microbial decontamination	5.0	10.0
		Sterilization	10	25
3.	Packaging materials for food/allied products	Microbial decontamination	5.0	10.0
		Sterilization	10	25
4.	Food additives	Insect disinfestation	0.25	1.0
		Microbial decontamination	5.0	10.0
		Sterilization	10	25
5.	Health foods, dietary supplement and nutraceuticals	Insect disinfestation	0.25	1.0
		Microbial decontamination	5.0	10.0
		Sterilization	10	25
6.	Body care and cleansing products	Microbial decontamination	5.0	10.0
		Sterilization	10	25
7.	Cut flowers	Quarantine application	0.25	1.0

		Shelf-life extension	0.25	1.0
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PACKAGING MATERIALS FOR RADIATION PROCESSING OF FOOD AND ALLIED PRODUCTS

Sr. No.	Packaging Material	Maximum Tolerable Dose Kilo Gray
1	2	3
1.	Kraft paper (flour packaging only)	0.5
2.	Biaxially oriented polypropylene (BOPP)	10
3.	Cardboard cartons with polyethylene liners	10
4.	Cardboard kegs	10
5.	Glassine paper	10
6.	Hessain sacks	10
7.	Multiply paper sacks	10
8.	Multiply paper sacks with polyethylene liners	10
9.	Nitrocellulose coated cellophane	10
10.	Nylone-11	10
11.	Polyethylene terephthalate film containing coatings comprising a vinylidene chloride co-polymer with one or more of the following co-monomers: acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.	10
12.	Polyethylene terephthalate film containing coatings of polyethylene	10
13.	Polyolefin film (eg. Polyethylene, BOPP)	10
14.	Polyolefin film containing coatings comprising a Vinylidene chloride co-polymer, with one or more of The following co-monomers: acrylic acid, acrylonitrile, Itaconic acid, methyl acrylate, and methyl methacrylate	10
15.	Polystyrene film	10
16.	Rubber hydrochloride film	10
17.	Vinylidene chloride copolymer-coated cellophane	10
18.	Vinylidene chloride-vinyl chloride co-polymer	10
19.	Wax-coated paperboard	10
20.	Woven polypropylene sacks	10

21.	Polyethylene coated multiply paper sacks	10
22.	Ethylene vinyl acetate co-polymer film	30
23.	Polyethylene polyester laminates	30
24.	Nylon-6 film	60
25.	Polyethylene film	60
26.	Polyethylene terephthalate film	60
27.	Vegetable parchment	60
28.	Vinyl chloride-vinyl acetate co-polymer	60
29.	Acrylonitrile copolymers	60

DOSIMETRY FOR FOOD AND ALLIED PRODUCTS

Dosimeter	Readout system	Usable absorbed dose range Gray
Alanine	Electron Paramagnetic Resonance spectrometer	$1-10^5$
Dyed polymethyl methacrylate	Spectrophotometer	10^2-10^5
Clear polymethyl methacrylate	Spectrophotometer	10^3-10^5
Cellulose acetate	Spectrophotometer	$10^4-4 \times 10^5$
Lithium borate, lithium fluoride	Thermoluminescence reader	$10^{-4}-10^3$
Lithium fluoride (optical grade)	Spectrophotometer	10^2-10^6
Radiochromic dye films, solution, Optical wave guide	Spectrophotometer	$1-10^5$
Ceric cerous sulphate	Spectrophotometer or Potentiometer	10^3-10^5
Ferrous sulphate solution	Spectrophotometer	$20-4 \times 10^2$
Potassium/Silver dichromate	Spectrophotometer	10^3-10^5
Ferrous cupric sulphate solution	Spectrophotometer	$10^3-5 \times 10^3$
Ethanol chlorobenzene solution	Spectrophotometer, color titration, high frequency conductivity	$10-2 \times 10^6$
Amino acids	Lyoluminescence reader	10^5-10^4
Metal Oxide Semiconductor Field Effect Transistor	Voltmeter	$1-10^2$

SCHEDULE-III

[See Regulation 35]

CONDITIONS AND PROCEDURES FOR DISPOSAL OF RADIOACTIVE WASTE BY INSTITUTIONS HANDLING SMALL QUANTITIES OF RADIOISOTOPES.

Institutions such as hospitals and tracer research laboratories, handling small quantities of radioisotopes of short effective half-life may, after obtaining the authorisation, under rule 3, undertake disposal of radioactive waste, in accordance with the following procedures :-

1. Disposal of Radioactive Waste by release into Sanitary Sewerage system - An authorised person may discharge radioactive waste into a Sanitary sewerage system, provided :-

- (a) the waste is readily soluble or dispersible in water;
- (b) the maximum quantity of radioactive material released in the sanitary sewerage system is less than the quantity prescribed in **Table I** of this Schedule and is not in excess of the quantity which, if diluted by the average daily quantity of sewerage released into the sewerage system by the authorised institution, will result in an average monthly concentration equal to the limits:-
 - (i) as specified in **Table 1**, or
 - (ii) as specified by the Board, on a case by case basis for radionuclides, not listed in **Table 1**,
- (c) the gross quantity of radioactive material released into the sewerage system by the institution does not exceed 37 GBq per year;
- (d) when more than one radionuclide is present in the liquid waste, the sum of the ratios of the individual quantities of each of the radioisotopes present and their respective maximum quantities allowed as per **Table 1**, does not exceed unity;
- (e) periodic maintenance and monitoring of the path-ways of the liquid effluents, till the effluents reach the sewerage system, is done by the Radiological Safety Officer, to ensure that the appropriate disposal limits and operational limits are not exceeded in and outside the drainage system;
- (f) a log book is maintained in such Form and manner as specified by the Board, recording the identity and quantity of each radioisotope disposed, its time of disposal, the name of the person who has supervised the waste disposal and the data on radiation surveillance.

2. Disposal of Solid Radioactive Waste — An authorised person may dispose of solid radioactive waste by burial into pits prepared in an exclusive burial ground, provided :

- (a) the burial ground is located in an isolated site owned by the said person;
- (b) the site is duly fenced off to prevent unauthorised entry;
- (c) the site is duly approved by the Board for burial of radioactive waste, the approval being governed by factors such as the nature of environment including topographical and geological characteristics of the burial site, usage of ground and surface waters in the general area around

the site, with a view to minimise the assessed anticipated risk of accidental dispersal of the waste to potentially affected locations or back to the environment;

(d) the total activity in the wastes buried in any one pit of the burial ground does not exceed —

(i) the limits specified in **Table 2** of this schedule; or

(ii) the limit specified by the Board on a case by case basis; for radionuclides not listed in **Table 2** of this Schedule;

(e) when more than one radionuclides is present in the solid waste, the sum of the ratios of the individual quantities of each of the radioisotopes present and their respective maximum quantities allowed as per **Table 2**, does not exceed unity;

(f) the depth of the burial pit is so chosen that the wastes have a top layer of compact earth of minimum 120 cm thickness when the pit head is closed;

(g) successive burial pits are separated by a distance of at least 180 cm;

(h) not more than 12 burials are made in any one year;

(i) a closed pit is not opened for reuse till 10 half-lives, of the longest lived radioisotope buried in that pit, have elapsed;

(j) the burial area is treated as restricted area and subjected to periodic environmental surveillance by the Radiological Safety Officer to ensure that the appropriate disposal limits and regulatory constraints are not exceeded;

(k) the material excavated from a closed pit is released for normal disposal, under the supervision of the Radiological Safety Officer before reusing the pit as laid down in (i);

(l) periodic monitoring of the burial ground and its environment is done by the Radiological Safety Officer to ensure that the operational limits on radioactive contamination are not exceeded;

(m) a log book is maintained in in such Form and manner as specified by the Board , recording identity and quantity of each radioisotope buried, description of waste, time of burial, name of the person who has supervised the burial operations and the data on radiation surveillance.

3. Incineration of Radioactive Waste — An authorised person may undertake incineration of radioactive wastes, including incineration of radioactive animal card cases, provided the Board is duly satisfied that —

(a) the design of the incinerator is suitable for the intended operations and provides for retention of solid and liquid combustion/scrubbing by products and for controlled discharge of liquid and gaseous effluents;

(b) the incineration operations will not result in air borne radioactive contamination in excess of the regulatory constraints specified by the Board, for unrestricted areas;

(c) the solid and liquid radioactive wastes arising from incineration operations will be duly collected and disposed off in accordance with these rules;

(d) adequate environmental surveillance, including air monitoring where necessary, will be provided to ensure that the operational limits are not exceeded;

(e) the incineration operations are undertaken under direct supervision of the radiological safety officer;

(f) up-to-date records are maintained, in such Form and manner as specified by the Board of the incineration operations indicating the names of radionuclides and their amounts finally disposed in gaseous, liquid and solid form, the details of such disposals, names of the persons involved in these operations and the date of radiation surveillance.

4. Records, etc. — Quarterly records, in respect of the disposal operations, shall be submitted to the Board, in such Form and manner as specified by the Board.

5. Other conditions — The authorised person shall abide by —

(i) such orders as may be issued by notifications, by the Board modifying the concentrations prescribed in **Table 1** or the quantities prescribed in **Table 1 & 2**.

(ii) any other safety measures stipulated by the Board in accordance with these rules.

TABLE-I

Disposal limits for sanitary sewerage systems

Radionuclide	Maximum limit on total discharge per day (MBq)	Average monthly concentration of radioactivity in the discharge (MBqM ⁻³)
H3	92.5	3700
C14	18.5	740
Na24	3.7	222
P32	3.7	18.5
S35	18.5	74
Cl36	0.37	74
Ca45	3.7	10.1
Co60	0.37	37.0
Sr89	0.37	11.1
Sr90+Y90	0.037	0.148
Zr95+Nb96	3.7	74
Mo99+Tc99m	3.7	185

Ru106+Rh106	0.37	14.8
Sb124	0.37	25.9
I125	3.7	22.2
I131	3.7	22.2
Cs137+Ba137m	0.37	14.8
Ba140+La140	0.37	29.6
Ce144+Pr144	0.37	11.1
Tm170	3.7	37.0
Ir192	3.7	37.0
Po210	0.037	0.74

TABLE-I

Disposal limits for Ground Burial

Radionuclide	Maximum activity in a pit (MBq)
H3	9250
C14	1850
Na24	370
P32	370
S35	1850
Cl36	37
Ca45	370
Co60	37
Sr89	37
Sr90+Y90	3.7
Zr95+Nb96	370

Mo99	370
Ru106+Rh106	37
Sb124	37
I125	37
I131	37
Cs137+Ba137m	37
Ba140+La140	37
Ce144+Pr144	37
Tm170	370
Ir192	370
Po210	3.7

SCHEDULE-IV:

[See Regulation 47 (3)]

TERMS AND CONDITIONS OF SAFETY AUTHORISATION

Part-A: General Conditions

(1) The holder of safety authorisation shall abide by all the applicable provisions laid down in:

- a) The SHANTI Act, 2025;
- b) Rules and Regulations made thereunder
- c) Orders, directions, specifications issued by the Board or the Central government, under the Act
- d) The requirements of the applicable regulatory documents as specified in Part B.

(2) The holder of safety authorisation shall not handle any radioactive material or radiation generating equipment:-

- a) other than those specified in the safety authorisation;
- b) for any purpose other than those specified in the safety authorisation; and
- c) in any location except as specified in the safety authorisation.

(3) This safety authorisation may be suspended or cancelled, if any declaration(s) made or information given in the application is found to be false or if any undertaking given in such application is not complied with.

(4) Obtaining a safety authorisation from the Board alone does not exonerate any employer of a facility, occupier of a factory, owner of a mine or any other person in possession of radioactive substance or radiation generating equipment, prime responsibility for safety.

(5) The safety authorisation shall not be transferable without the prior approval of the Board.

(6) Certified persons are available for performing the identified tasks or carrying out the functions, at all times.

(7) No modification to the facility, plant, activity or mine affecting safety or for disposal of radioactive waste or no change in working conditions therein affecting safety shall be done without the prior approval of the Board.

(8) Radioactive waste shall be disposed of in accordance with the limits specified by the Board.

(9) In case of a decommissioned radioactive waste management/disposal facility, institutional controls as stipulated by the Board shall be maintained.

(10) Holder of safety authorisation shall ensure that all other necessary Statutory Clearances are obtained and are valid for the present safety authorisation.

(11) If any development impacts the basis of a safety authorisation during its validity period, the holder shall promptly report the change with an updated safety assessment report and a request to amend the terms and conditions of the safety authorisation.

Additional conditions applicable for radiation facility as identified in Schedule I

(1) Holder of the safety authorisation shall maintain sufficient financial security and ensure arrangements for safe disposal of disused sources or their repatriation to the original supplier and decommissioning of the facility.

(2) The radioactive material or radiation generating equipment shall not be transferred by sale or otherwise without obtaining prior safety authorisation from the Board

(3) Inform the Board when a radioactive material in his possession is no longer intended to be used for the authorised purpose.

Part-B: Specific Conditions

Sr. No.	Conditions	
I	Conditions and stipulations emanating from Safety Review and Assessment of the Application	1. 2. 3. 4.
II	Conditions as part of the basis documents for Safety Authorisation	1. Eg. Technical Specifications for Operation, Radiation Protection Programme, etc. 2.
III	Requirements from relevant regulatory documents (as identified during the course of Safety Review and Assessment)	1. List of applicable Safety Codes 2. List of applicable Safety Standards 3. List of Part or whole of applicable Safety Guide as identified

SCHEDULE-V

[See Regulation 57]

SPECIFICATION FOR RADIATION SYMBOL/WARNING SIGN

1. The radiation symbol for radioactive sources other than medical diagnostic and industrial x-ray radiography equipment shall conform to the specifications given hereunder;
 - a. The relative dimensions of the trefoils and the central circle shall be as shown in Fig. 1.
 - b. The trefoils and the circle shall be of magenta colour.
 - c. The background of the above symbol shall be yellow.
 - d. The symbol should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry, e.g. CAUTION – RADIOACTIVITY.
 - e. Small objects, containing radioactive material may, however, have on them only the aforesaid trefoil symbol engraved in a conspicuous colour when their dimensions do not permit compliance with (d) above.

2. The radiation symbol for radiation generating equipment such as medical diagnostic x-ray equipment, industrial x-ray radiography equipment and accelerators shall have a warning sign as illustrated in Fig. 2 and the warning sign shall conform to the specifications given hereunder;
 - a. The triangle shall be equilateral.
 - b. The ratio of the outer to the inner sides of the triangle shall be 1.5.
 - c. The area between the outer and inner triangle shall be in yellow colour on white background.
 - d. The printing on the area between the outer and inner triangle and figure inside the inner triangle shall be bold, proportional and red in colour.
 - e. The area between the outer and inner triangle should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry.

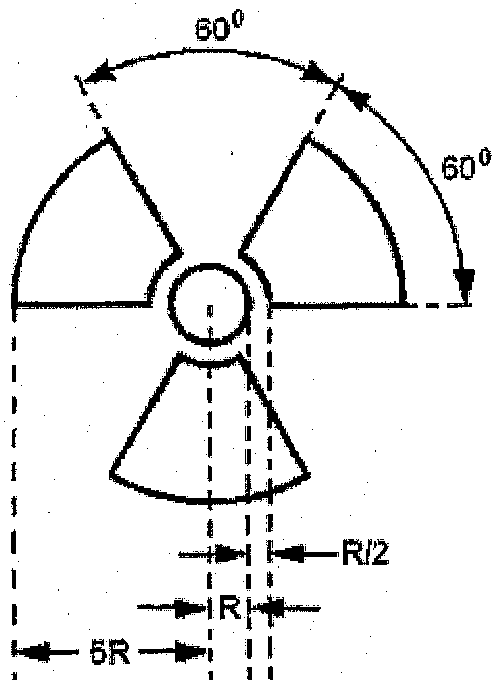


Fig. 1

Radiation Symbol for Radioactive Sources

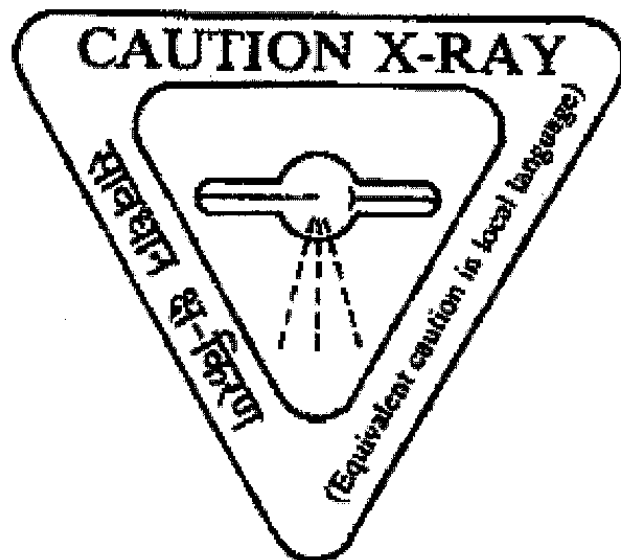


Fig. 2

Radiation Symbol and Warning Sign for Radiation Generating Equipment