AERB SAFETY CODE NO. AERB/SC/G

REGULATION OF NUCLEAR AND RADIATION FACILITIES

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This document is subject to review, after a period of one year from the date of issue, based on the feedback received

> Atomic Energy Regulatory Board Mumbai 400 094

Price:

Orders for this Code should be addressed to:

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

FOREWORD

The establishment and operation of nuclear and radiation facilities, and the use of radioactive sources, contribute to the economic and social progress of the country. However, while undertaking such activities, the safety of the workers concerned, the general public and the environment at large, is to be ensured, and this is possible through compliance with the relevant provisions of the Atomic Energy Act, 1962.

Since the inception of the atomic energy programme in the country, importance has been given to the adoption and maintenance of high safety standards. In order to enforce such standards, the Government of India constituted the Atomic Energy Regulatory Board (AERB), in November 1983.

The Board is entrusted with the responsibility for laying down safety standards and framing rules and regulations covering regulatory and safety functions envisaged under the above Act. AERB has therefore undertaken a programme of developing safety standards, codes, guides and manuals for both nuclear and radiation facilities, covering all aspects such as siting, design, construction, operation, quality assurance, decommissioning and regulation.

Safety Standards contain internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities. Safety Codes are intended to establish objectives and to set minimum requirements that shall be fulfilled to provide adequate assurance for safety in nuclear and radiation facilities. Safety Guides provide guidelines and make available the methods for implementing specific requirements as prescribed in line with the relevant Safety Code(s). Safety Manuals are intended to elaborate specific aspects and may contain detailed technical information and/or procedures.

Consistent with accepted practice, "shall" and "should" used in these documents distinguish between firm requirements and a desirable option respectively, for the benefit of the user.

Emphasis in the above documents is on protection of site personnel, the public and the environment from unacceptable radiological hazards. For aspects not covered, applicable and acceptable national and international codes and standards shall be followed.

Industrial safety in nuclear and radiation facilities is to be ensured throug compliance with the applicable provisions of the Factories Act, 1948 and th Atomic Energy (Factories) Rules, 1996.

The Codes, Guides and Manuals will be revised as and when necessary in the light of the experience and feedback from users as well as new developments in the field

Based on its experience, AERB decided to issue this Safety Code on "Regulatio of Nuclear and Radiation Facilities", to spell out the minimum safety relate requirements/obligations to be met by a nuclear or radiation facility to qualify for the issue of regulatory consent at every stage leading to eventual operation. The Code also elaborates on the regulatory inspection and enforcement to be carried out by the Regulatory Body on such facilities. It is hoped that this will be of us to the Regulatory Body as well as the applicant of any nuclear or radiation facility.

The Code has been prepared by a Committee consisting of AERB staff and othe professionals. In drafting it, extensive use has been made of the informatio contained in the relevant documents of the International Atomic Energy Agenc (IAEA) under the Nuclear Safety Standards (NUSS) programme, specially the Cod on "Governmental Organisation for Regulation of Nuclear Power Plants (50-C-G)"

Experts have reviewed the Code and the AERB Advisory Committee has vette it before issue. The list of persons who have participated in the Committe meetings, along with their affiliations, is appended in the document.

AERB wishes to thank all individuals and organisations who reviewed the dra and helped in the finalisation of the Code.

A list of Guides being issued under the Code has also been added.

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DEFINITIONS

Accident

An unplanned event resulting in (or having the potential to result in) personal injury or damage to equipment which may or may not cause release of unacceptable quantities of radioactive material or toxic chemicals.

Anticipated Operational Occurrences

All operational processes deviating from normal operation which are expected to occur once or several times during the operating life of the nuclear/radiation facility and which, in view of appropriate design provisions, do not cause any significant damage to items important to safety nor lead to accident conditions.

Approval

A type of regulatory consent issued by the Regulatory Body to a proposal.

Audit

A documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, applicable codes, standards, specifications, established procedures, instructions, administrative or operational programmes and other applicable documents, and the effectiveness of their implementation.

Authorisation

A type of regulatory consent issued by the Regulatory Body for all sources, practices and uses involving radioactive materials and radiation generating equipment.

Atomic Energy Regulatory Board

The Regulatory Body that is currently functioning in India (see also 'Regulatory Body').

Certification (of personnel)

The formal process of certifying appropriate personnel for various activities by nuclear/radiation facility.

Clearance Levels

A set of values established by the Regulatory Body and expressed in terms of activity concentrations and/or total activity, at or below which sources of radiation may be released from regulatory control.

Commissioning

The process during which structures, systems and components of a nuclear or radiation facility, having been constructed, are made functional and verified to be in accordance with design specifications and to have met the performance criteria.

Consent

A written permission issued to the applicant by the Regulatory Body to perform specified activities related to nuclear and radiation facilities. The types of such consents are 'License', 'Authorisation', 'Registration' and 'Approval', and will apply depending upon the category of the nuclear/radiation facility, the particular activity and the radiation source involved.

Construction

The process of manufacturing, testing and assembling the components of a nuclear or radiation facility, the erection of civil works and structures, the installation of components and equipment.

Criticality

The stage of fissile material system where self sustained nuclear chain reaction is just maintained.

Decommissioning

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

Design

The process and results of developing the concept, detailed plans, supporting calculations and specifications for a nuclear or radiation facility.

Design Basis Information (DBI)

A document containing the information based on which design is made.

Dose

A measure of radiation received or 'absorbed' by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. The modifying terms are often omitted when they are not necessary for defining the quantity of interest.

Final Safety Analysis Report (FSAR)

Safety Analysis Report submitted to the Regulatory Body for obtaining consent for operation of a nuclear/radiation facility.

Inspector

A person who is authorised by the Regulatory Body to carry out regulatory inspection.

Irradiator

A facility that houses a particle accelerator, X-ray machine or large radioactive sources for imparting high radiation dose to materials.

Licence

A type of regulatory consent, granted by the Regulatory Body for all sources, practices and uses for nuclear facilities involving nuclear fuel cycle and certain categories of radiation facilities. It also means authority given by the Regulatory Body to a person to operate the above said facilities (see 'Licensed Person' and 'Licensed Position').

Licensed Person

A person licensed to hold certain licensed position of nuclear power plant after due compliance with the authorised procedure of certification by the Regulatory Body.

Licensed Position

A position held only by persons certified by the Regulatory Body or a body designated by it.

Limit

The value of a parameter or attribute (which is variable) used in certain specific activities or circumstances that must not be exceeded.

Nuclear Facility

All nuclear fuel cycle and associated installations encompassing activities covering from front end to back end of nuclear fuel cycle processes and the associated industrial facilities such as: heavy water plants, beryllium extraction plants, zirconium plant, etc.

Nuclear Fuel Cycle

All operations associated with production of nuclear energy, including mining, milling, processing and enrichment of uranium or thorium, manufacture of nuclear fuel, operation of nuclear reactors, reprocessing of nuclear fuel, decommissioning, and any activity for radioactive waste management and any research or development activity related to any of the foregoing.

Nuclear Power Plant (NPP)

A nuclear reactor or a group of reactors together with all the associated structures, systems and components necessary for safety and for generation of electricity.

Operation

All activities following commissioning and before decommissioning performed to achieve, in a safe manner, the purpose for which a nuclear/radiation facility was constructed, including maintenance.

Operational Limits and Conditions (OLCs)

Limits on plant parameters and a set of rules on functional capability and the performance level of equipment and personnel, approved by the Regulatory Body, for safe operation of nuclear/radiation facility.

Occupational Worker

Any person working full time or part time in a nuclear or radiation facility who may be employed directly by the applicant or through a contractor.

Practice

Any human activity that introduces additional sources of radiation or toxic chemical exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase exposure or likelihood of exposure of people or the number of people exposed.

Preliminary Safety Analysis Report (PSAR)

Safety Analysis Report submitted to the Regulatory Body for obtaining consent for construction.

Prescribed Limits

Limits prescribed by the Regulatory Body for specific activities or circumstances that must not be exceeded.

Qualified Person

A person who, having complied with specific requirements and having met certain conditions, has been approved by the Regulatory Body, where necessary, to discharge specified duties and responsibilities.

Quality Assurance

Planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service as per design specifications.

Radiation Facility

Any installation/equipment or a practice involving the use of radiation generating units, or the use of radioisotopes in research, industry, medicine and agriculture.

Radiation Generating Equipment

Device capable of generating radiation, such as X- rays, neutrons, electrons or other charged particles.

Radiation Surveillance

Monitoring measures to provide adequate radiation protection.

Radioactive Waste

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

Radiation Worker

Any worker occupationally exposed to radiation.

Registration

A type of regulatory consent issued in respect of sources that include (a) medical diagnostic X-ray equipment including computed tomography (CT) and therapy simulator, (b) analytical X-ray equipment used for research, (c) nucleonic gauge, (d) radioactive sources in tracer studies, and practices that include bio-medical research and (e) any other source and practice notified by the Regulatory Body.

Reliability

The probability that a device, system or facility will perform its intended function satisfactorily under stated operating conditions.

Regulatory Body

An Authority constituted and empowered by the Central Government to carry out the regulatory and safety functions as envisaged in the Atomic Energy Act, 1962, and the Rules issued thereunder.

The term is synonymous with the term 'Competent Authority', mentioned in the above said Rules.

Regulatory Clearance

A type of regulatory consent issued for a nuclear facility during intermediate stages of consenting process.

Regulatory Consent

See 'Consent'.

Regulatory Inspection

An examination by review of documents, observation, measurement or test undertaken by or on behalf of the Regulatory Body during any stage of the regulatory consenting process to ensure conformance of materials, components, systems and structures, as well as operational activities, processes, procedures, practices and personnel competence, with predetermined requirements.

Research Reactor (RR)

A critical/sub-critical assembly of nuclear fuel elements, used for purposes of research, education and/or production of radio-isotopes.

Safety Analysis Report

A document provided by the applicant to the Regulatory Body containing information on nuclear or radiation facility, its design, accident analysis and provisions to minimise the risk to public and site personnel.

Siting

The process of selecting a suitable site for nuclear or radiation facility including appropriate assessment and definition of related design bases.

Site Evaluation Report

A document indicating the impact of a nuclear/radiation facility on the environment and the impact of the environment on the same so as to establish the suitability of the site for safe operation of the facility.

Source

That which causes radiation exposure either by emitting ionising radiation or by releasing radioactive substances or materials.

Technical Specifications for Operation

A document approved by the Regulatory Body, covering operational limits and conditions, surveillance and administrative control requirements for safe operation of nuclear or radiation facilities.

Type Approval

A type of consent issued by the Regulatory Body based on evaluation of prototype of the device to ensure conformity with safety standards.

Unusual Occurrence

Any occurrence which impairs or has the potential to impair plant safety, radiological safety, industrial safety and environmental safety. Of these, those which are violative of the limits and conditions stipulated by Regulatory Body are termed safety-related unusual occurrences.

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1. INTRODUCTION

1.1 General

- 1.1.1 Past experience of AERB in administering the relevant Atomic Energy Statutes in the country has shown the need for publication of compact and cogent regulatory documents spelling out the obligations of the consentee and the responsibilities of the Regulatory Body. This has resulted in the necessity for writing the present Safety Code on "Regulation of Nuclear and Radiation Facilities".
- 1.1.2 This Safety Code has been prepared from considerations of protection of the nuclear/radiation facilities, their personnel, the public and the environment.

1.2 Objectives

- 1.2.1 The Code aims at formulating procedures for issuance of consents, regulatory inspection and enforcement of safety provisions for nuclear and radiation facilities. The main objectives of these procedures are to ensure that:
 - (a) only such practices are permitted which are justified in terms of their societal and/or individual benefits,
 - (b) radiation protection is duly optimised in all nuclear/radiation facilities.
 - (c) radiation doses to the personnel in these facilities, and to the members of the public in their vicinity, do not exceed the prescribed limits, and
 - (d) the potential for accidental exposures from the facilities remains acceptably low.

1.3 Scope

- 1.3.1 This Code covers the various facilities and activities given as under:
 - (a) mining and processing of radioactive ores and minerals,
 - (b) uranium/thorium processing and the fuel fabrication plants,
 - (c) heavy water plants,

- (d) research reactors, experimental reactors and critical assemblies,
- (e) nuclear power plants,
- (f) fuel reprocessing plants,
- (g) radioactive waste management facilities,
- (h) industrial facilities related to nuclear fuel cycle activities,
- (i) transport of radioactive materials,
- (j) medical applications of radiation,
- (k) industrial and agricultural applications of radiation,
- (l) research applications of radiation, and
- (m) all other practices involving the handling of radioactive sources.

2. CONSENTING PROCESS FOR NUCLEAR POWER PLANTS AND RESEARCH REACTORS

2.1 Consenting Process

2.1.1 General

The consentee is solely responsible for ensuring the safety in siting, design, construction, commissioning, operation and decommissioning of a Nuclear Power Plant (NPP)/Research Reactor (RR) and shall demonstrate to the Regulatory Body that safety is ensured at all times.

Control over safety in siting, construction, commissioning, operation and decommissioning of a Nuclear Power Plant or Research Reactor shall be established by the Regulatory Body primarily through a system of regulatory consents that allows activities with stipulated conditions.

2.1.2 Purpose of Consents

A Consent is an official document which will:

- (a) allow a specified activity or set of activities dealing with siting, construction, commissioning, operation or decommissioning of an NPP/RR, and
- (b) establish requirements and conditions governing the performance of these activities.

2.1.3 Stages of Consenting Process

- 2.1.3.1 The stages at which consents are required in respect of NPPs/RRs, are .
 - (a) Siting,
 - (b) Construction.
 - (c) Commissioning,
 - (d) Operation, and
 - (e) Decommissioning.

Consenting process is a continuing assessment covering all the above stages. The Regulatory Body has the discretion to combine two or more

- stages of activity in a single consent depending on the hazard potential of the NPP/RR.
- 2.1.3.2 Separate categories of consents shall be required at each stage of the consenting process. In addition, regulatory clearances may be required for activities at intermediate stages as specified in sub-section 2.3.3.2.3. Appendix-I gives categories of regulatory consents applicable to different facilities.
- 2.1.3.3 The Regulatory Body shall prescribe the format for application and regulatory consents for each of the above major stages (refer Guide No. AERB/SG/G-7)
- 2.1.3.4 In each consent to be issued by the Regulatory Body, the period of validity of the consent shall be mentioned.
- 2.1.3.5 There shall be a provision for periodic renewal of consent.
- 2.1.3.6 There shall also be a provision to amend the consent already issued, either on the basis of review of a request from the consentee or on the need felt by the Regulatory Body itself.
- 2.1.3.7 There shall be a time limit for issue of consent, after an application from the applicant complete in all respects is received by the Regulatory Body.
- 2.1.3.8 Any modification or change in regulatory consent may be carried out by the Regulatory Body in the light of experiences gained from operation of such NPPs/RRs or as a result of research and development.
- 2.1.3.9 Collection of siting and environmental data shall begin well in advance before construction. Before a site is approved, basic design including site relevant design basis information on the proposed NPP/RR shall be reviewed along with its environmental impact. Before consent for construction is issued, the design and design bases of the proposed NPP/RR shall be reviewed and approved. Review and assessment of the design in detail shall continue and should be completed before commissioning is completed.

2.2 Requirements to be Complied by the Applicant

2.2.1 General

The applicant shall submit necessary information as laid down in the Guide No. AERB/SG/G-1 issued by the Regulatory Body, in support of the application for consent.

2.2.2 Information Requirements

- 2.2.2.1 The applicant shall submit and make available to the Regulatory Body in due time all information specified by the Regulatory Body. It shall be the responsibility of the consentee to make proper arrangements with vendor(s) and/or contractor(s) to ensure availability of all required information. It shall also be the responsibility of the applicant to keep the Regulatory Body constantly informed of all relevant additional information or changes in the information submitted earlier.
- 2.2.2.2 Since the review and assessment of information by Regulatory Body is a continuing process, the applicant shall periodically submit relevant documents/reports as prescribed from time to time by the Regulatory Body.
- 2.2.2.3 Other requirements would be imposed by the Regulatory Body on the applicant, in particular through consents issued in respect of NPP/RR. These requirements should, inter-alia, include:
 - a baseline survey of the environment as related to radiological characteristics well in advance of the first fuel loading at NPP/ RR.
 - (b) periodic site and environmental surveys as related to their radiological characteristics,
 - (c) regular reports to the Regulatory Body on relevant subjects, including:
 - (i) senior staff changes,
 - (ii) radiological data,
 - (iii) operating and system performance data,
 - (iv) management of radioactive waste, and
 - (v) unusual occurrences,

- (d) report on modifications in the design, construction, commissioning, operation and decommissioning, as against the information already submitted by the applicant, and
- (e) report on accidents within the prescribed time frame.

Specific guidance on responsibilities of the applicant is provided in the Safety Guide on Consenting Process for Nuclear Power Plants and Research Reactors (AERB/SG/G-1).

2.2.2.4 The applicant should also provide:

- (a) information, obtained through investigation of safety-related unusual occurrences at the NPPs/RRs,
- (b) documentary evidence showing that activities carried out by the applicant at NPPs /RRs have not caused or will not cause any undue hazard to working personnel, public and the environment (refer Guide No. AERB/SG/G-8).

2.3 Safety Review and Assessment during the Consenting Process

2.3.1 General

The responsibility of the Regulatory Body is to ensure through appropriate safety review that the NPP/RR to be sited, constructed, commissioned, operated and decommissioned shall not result in unacceptable radiological, chemical or industrial risk to site personnel, the public and environment. The technical information contained in the project design basis and design reports, safety analysis reports, technical specifications for operations and operating procedures under normal and emergency conditions and other relevant documents submitted by the applicant forms the primary basis for review and assessment by the Regulatory Body. The Regulatory Body shall satisfy itself that all essential information required for the safe conduct of a particular activity has been furnished and compliance with the requirements of prescribed Codes, Standards and Rules are adhered to. If required, the Regulatory Body should also carry out independent checks of the design to ensure that design objectives are met.

2.3.2 Review and Assessment of Application

2.3.2.1 The primary basis for assessing the safety of proposed NPP/RR is the information contained in the various design and safety reports and related documents submitted by the applicant.

2.3.2.2 The Regulatory Body shall satisfy itself that:

- the applicant has acquired and supplied whatever information deemed necessary to demonstrate that NPP/RR can be safely sited, constructed, commissioned, operated or decommissioned as applicable;
- (b) the information contained in safety reports is in compliance with requirements of all applicable Statutes, Codes and Standards;
- (c) the information contained in the applicant's reports is based on adequate data and sound engineering practice;
- (d) in the light of current technology, engineering solutions are feasible and capable of achieving the design objectives; and
- (e) the design is as per current safety standards.

2.3.3 Programme for Review and Assessment

- 2.3.3.1 The Regulatory Body shall establish lead times for submission of various documents in support of regulatory consent application, during various consenting stages. Schedules of documents to be submitted including their contents, for various stages of consent are indicated in the relevant Guides issued by the Regulatory Body.
- 2.3.3.2 The following reviews and assessments specific to the particular stage of activity shall be performed:

- 2.3.3.2.1 Siting: At this stage, the consenting process involves, in general, review of design basis and issue of a clearance of the site for locating the project. This should require on the part of the applicant, submission of a Site Evaluation Report (SER), including the Design Basis Information (DBI) for review and assessment of site characteristics.
- 2.3.3.2.2 *Construction:* At this stage, the consenting process involves, in general, review of the overall design safety, including plant layout, plant buildings/structures, reactor systems, electrical systems, instrumentation and control systems, common services system and waste disposal systems. This should require, on the part of the applicant, submission of Preliminary Safety Analysis Report (PSAR), Design Basis Reports (DBRs), Quality Assurance (QA) during design, and applicant's construction Quality Assurance Programme and construction schedule for the proposed NPP/RR before the consent for construction is issued. This consent shall be obtained before starting construction of main plant buildings.
- 2.3.3.2.3 *Commissioning:* At this stage, the consenting process involves regulatory clearances at several intermediate stages/phases starting from hot conditioning stage to raising reactor power up to 100 % rated power. Following are the intermediate stages, typically involved with Pressurised Heavy Water Reactor (PHWR) type NPPs, in three phases of commissioning.:

Phase A:

- hot conditioning or passivation of the primary system and light water commissioning of all process systems;
- (ii) fuel loading* of the reactor core, and part borated heavy water addition to storage, cooling and moderator systems for flushing in specified limited quantity during which criticality is not possible;
- (iii) addition of heavy water to primary heat transport system; and

^{*} If fuel loading is to be taken up after bulk heavy water addition to moderator system, the regulatory consent shall be obtained prior to fuel loading.

(iv) bulk addition of heavy water to moderator system with minimum specified boron level in heavy water to prevent reactor criticality.

Phase B:

- (i) initial approach to criticality; and
- (ii) low power reactor physics tests and experiments.

Phase C:

- (i) initial system performance tests at low, medium and rated power levels as determined by the stable operation of the turbine; and
- (ii) system performance at rated power.

The documentary submissions for the various phases of this stage would include:

- (a) construction completion certificate,
- (b) quality assurance programme for commissioning and operation,
- (c) commissioning test procedures,
- (d) performance reports on commissioning,
- (e) training programme and availability of adequate qualified manpower,
- (f) emergency response plans and preparedness and a report of an off-site exercise, and
- (g) technical specifications for operation in addition to specific submission requirements for the intermediate stages.

The consent for commissioning stage shall be obtained after completing pre-commissioning tests and prior to taking up hot conditioning of coolant system and commissioning of reactor systems. The applicant shall demonstrate the readiness of systems to take up their commissioning to the satisfaction of the Regulatory Body as associated with the stage involved.

Each of the above phases under this stage has its own requirements for regulatory clearance. The Regulatory Body may modify the above-mentioned intermediate phases, or add new phases as considered necessary from safety considerations in specific cases.

Similarly, for other types of reactors, viz. Light Water Reactors (LWRs), Fast Breeder Reactors (FBRs), RRs etc., the necessary regulatory clearances as specified by the Regulatory Body shall be obtained.

- 2.3.3.2.4 *Operation:* This stage of consenting process involves allowing routine power operations up to rated power. For this consent, the applicant has to submit detailed test reports in support of his consent application, establishing that the unit is capable of sustained operation up to rated power.
 - (i) The submissions at this stage would include:
 - (a) Final Safety Analysis Report (FSAR),
 - (b) Technical Specifications for Operation incorporating the feedback from commissioning process,
 - (c) Conceptual Decommissioning Plan, and
 - (d) Certification that as-built drawings are available for all systems.
 - (ii) Prior to issue of consent for operation, the following should be checked and verified:
 - (a) the plant performance up to rated power should be reviewed and accepted from safety point of view,
 - (b) quality assurance of systems relevant to operation,
 - (c) documentation system, and
 - (d) the emergency plan and preparedness should have been well established. The emergency preparedness should be demonstrated to be effective through emergency exercises (refer Guide No. AERB/SG/G-5).

(iii) During operation of NPP/RR, as a result of operating experience or in the light of advances in reactor safety technology, a review and assessment by the Regulatory Body may be required. Such review and assessment may result in modifications to NPP/RR, systems or operating procedures, for which necessary approvals will be issued by the Regulatory Body.

After the above process, the Regulatory Body shall issue consent for regular operation at rated power for a specified period. Well before expiry of this period, the consentee is required to submit an application for renewal of consent. The renewal of consent will be based on periodic safety review as specified by the Regulatory Body. The key elements of this periodic safety review for renewal of consent (authorisation) are to assure that:

- (a) NPP/RR as a whole (including associated systems and facilities) continues to be capable of safe operation at power levels authorised for the plant within the operational limits and conditions as specified in Technical Specifications for Operation for designated period;
- (b) All structures, systems and components important to safety, have not shown undue signs of deterioration and are capable of reliably performing their intended design functions;
- (c) The plant is safe as judged by current safety standards and practices and adequate arrangements are in place to maintain safety;
- (d) The management of NPP/RR is alive to safety-related problems and a system has been established at the NPP/RR to provide prompt response for taking effective measures to resolve safety related problems; and
- (e) NPP/RR has operated in a safe manner during the reporting period and continued operation of NPP/RR till the next periodic review and renewal of authorisation stage (before the expiry period of authorisation), would not pose undue risk to the plant, plant personnel, public and environment based on review of its operation during the assessment period.

For further details of periodic safety review and assessment process, refer Guide No. AERB/SG/O-12.

- 2.3.3.2.5 *Decommissioning:* This aspect of NPP/RR shall be considered at all stages of consenting process. The necessary submissions in this regard for review by the Regulatory Body at the relevant consent stages are:
 - (i) Design Approval: Provisions to facilitate decommissioning shall be identified in the design report of NPP/RR.
 - (ii) During Consent for Operation: While submitting application for consent for operation of NPP/RR, a conceptual plan for decommissioning along with associated safety assessment shall be submitted to the Regulatory Body for review.
 - During operational phase of an NPP/RR, the above conceptual plan for decommissioning may be modified on the basis of operational experience and occurrences and shall be submitted to the Regulatory Body for review.
 - (iii) During Consent for Decommissioning: Consent by the Regulatory Body is necessary before undertaking decommissioning. At the end of the operational phase, before final shutdown, a detailed decommissioning plan supported by safety assessment shall be submitted to the Regulatory Body. This should, include:
 - (a) justification of the decommissioning option chosen viz. immediate or deferred decommissioning,
 - (b) identification of decommissioning organisation and management aspects,
 - (c) decommissioning activities,
 - (d) applicable quality assurance programme,
 - (e) safety assessment,
 - (f) radiological protection programme,
 - (g) radioactive waste management, and
 - (h) final radiation surveillance plans.

In case of deferred decommissioning, submission of detailed decommissioning plan can be in various stages.

- (iv) Completion of Decommissioning: On completion of decommissioning, a final decommissioning report shall be submitted to the Regulatory Body, which should include:
 - (a) deviations from planned activity along with necessary constraints encountered.
 - (b) audit report highlighting compliance with the regulatory stipulations,
 - (c) other statutory requirements if any and compliance,
 - (d) quality and acceptance criteria and non-conformance, if any,
 - (e) quantity and characterisation of radioactive waste, and characterisation of disposal site,
 - (f) individual and collective dose to occupational workers,
 - (g) types and quantities of materials released for re-use and clearance levels used,
 - (h) future use of decommissioned site with restrictions, if any, and
 - (i) plan to assure maintenance of safe conditions till the site is declared safe for unrestricted use.

2.4 Conduct of Safety Review and Assessment

Safety Review and assessment by the Regulatory Body may be carried out by itself or with the assistance of advisory committees or consultants. The scope and extent of these reviews, the assessment, and the procedures to be followed, are given in the Guide AERB/SG/G-1.

2.5 Consenting Decisions

2.5.1 General

- 2.5.1.1 The review and assessment of NPP/RR should be done on a continuing basis so as to ensure that the NPP/RR is operated as per conditions laid down in the consent.
- 2.5.1.2 The review and assessment process by the Regulatory Body gives rise to a series of decisions. Not all these decisions may be immediately accompanied by the issue of formal consents. However, at the conclusion

of one or more of the consenting stages (see sub-section 2.1.3), the Regulatory Body shall issue:

(a) formal consent permitting the undertaking of any of the activities with validity period and stipulations to be complied with,

OR

(b) refusal of such consents and reasons thereof.

2.6 Appeal against Decisions

- 2.6.1 Appeal against decisions of the Regulatory Body will rest with the Atomic Energy Commission whose decision shall be final.
- 2.6.2 The implementation of a consenting decision intended to protect site personnel, public and the environment from unacceptable radiological, chemical and industrial risks shall be mandatory even if the applicant wants to file an appeal with the Atomic Energy Commission for review of Regulatory Body's decision.

3. CONSENTING PROCESS FOR NUCLEAR FUEL CYCLE FACILITIES (OTHER THAN NPPs/RRs)

3.1 Consenting Process

3.1.1 General

Apart from Nuclear Power Plants and Research Reactors, the nuclear fuel cycle facilities under regulatory control for issue of regulatory consents can be broadly categorized under the following activities:

- (a) uranium/thorium mining and processing,
- (b) heavy minerals mining and processing,
- (c) uranium/thorium fuel fabrication,
- (d) heavy water production,
- (e) spent fuel reprocessing,
- (f) nuclear waste management,
- (g) plutonium recycling/fuel fabrication, and
- (h) zirconium, beryllium extraction and processing.

The applicant is solely responsible for ensuring safety in siting, design, construction, commissioning, operation and decommissioning of a nuclear fuel cycle facility and shall demonstrate to the Regulatory Body that safety is ensured at all times.

Facilities engaged in the above activities but operated with the scope of research and development or for special investigations shall also require a consent. As regards the uranium/heavy mineral mining industry, it may fall also under the jurisdiction of another government body empowered to ensure safety measures and for issuance of consent for mining activity. However, mine development including infrastructure, commissioning, operation and decommissioning of the mine shall be subject to control by the Regulatory Body for ensuring radiological safety in such activities.

Regulatory control over safety of nuclear fuel cycle facilities shall be exercised by the Regulatory Body primarily through issue of consent for a particular phase of activity such as siting, construction, commissioning, operation and decommissioning. The consent shall contain stipulations to ensure safety in performance of the authorised activity. The consent shall also specify a validity period for the activity after which the renewal of consent shall be necessary for the activity to be continued.

3.1.2 Purpose of Consents

A consent is an official document which will:

- (a) allow a specified activity or set of activities dealing with the siting, construction, commissioning, operation or decommissioning of nuclear fuel cycle facilities, and
- (b) establish requirements and conditions governing the performance of these activities.

3.1.3 Stages of Consenting Process

- 3.1.3.1 The major stages at which consents are required for nuclear fuel cycle facilities (other than NPPs/RRs) are:
 - (a) Siting,
 - (b) Construction,
 - (c) Commissioning,
 - (d) Operation, and
 - (e) Decommissioning.

The consenting process is a continuing assessment covering all the above stages. The Regulatory Body has the discretion to combine two or more stages of activity in a single consent, depending on the hazard potential of the proposed facility.

- 3.1.3.2 Separate consents shall be required at each major stage of consenting process. Appendix-I gives the categories of regulatory consents that are applicable to different facilities.
- 3.1.3.3 The Regulatory Body shall prescribe the formats for application and regulatory consents for each of the above stages (refer Guide No. AERB/SG/G-7)

- 3.1.3.4 In each consent to be issued by the Regulatory Body, the period of validity of the consent shall be mentioned.
- 3.1.3.5 There shall be a provision for periodic renewal of consent.
- 3.1.3.6 There shall also be a provision to amend the consent already issued, either on the basis of a review on the request from the consentee or on the need felt by the Regulatory Body itself.
- 3.1.3.7 There shall be a time limit for issue of consent, after receipt of an application from the applicant complete in all respects by the Regulatory Body.
- 3.1.3.8 Any modification or change in regulatory consent may be carried out by the Regulatory Body in the light of experiences from operation of such nuclear fuel cycle facilities or as a result of research and development.
- 3.1.3.9 An assessment of site-plant interaction is a pre-requisite for siting consent. Hence assessment of the site characteristics and the design bases of the nuclear fuel cycle facility proposed at the site should be carried out before the site is consented to. Before the construction/commissioning consent is issued, safety review and assessment of the plant design shall be carried out in detail.

3.2 Requirements to be Complied by the Applicant

3.2.1 General

The applicant shall submit necessary information as laid down in the Guide (AERB/SG/G-2) issued by the Regulatory Body, in support of his application for Consent.

3.2.2 Information Requirements

Information to be submitted in support of application for consent should cover comprehensively all aspects of safety in design and operation of the facility under normal conditions, anticipated operational occurrences and accidental conditions. Supplementary information in respect of

modifications to plant design and operation, having a bearing on safety and relevant to the consenting process, shall also be furnished to the Regulatory Body.

Other submissions that may be stipulated in the consent issued for a nuclear fuel cycle facility are periodic reports on :

- (a) plant performance and safety status of plant systems,
- (b) radiological, chemical, fire and industrial safety aspects,
- (c) management of radioactive wastes,
- (d) safety-related unusual occurrences,
- (e) modifications to plant design and operation that affect the safety status,
- (f) re-training/re-qualification of plant personnel, and
- (g) plant-site and environmental surveys on levels of radiation and of chemical pollutants, and assessment of public safety and such other activity that the Regulatory Body may consider essential to evaluate the safe operation of the facility.

3.3 Safety Review and Assessment during Consenting Process

3.3.1 General

The responsibility of the Regulatory Body is to ensure through appropriate safety review that the nuclear fuel cycle facility to be sited, constructed, operated and decommissioned shall not result in undue radiological, chemical and industrial risk to plant/site personnel, the public and the environment. The technical information contained in project design reports, safety analysis reports, technical specifications for operations, manuals on operating procedures under normal and emergency conditions and other relevant documents submitted by the applicant form the primary basis for review and assessment by the Regulatory Body. The Regulatory Body shall satisfy itself that all essential information required for safe conduct of a particular activity has been furnished and compliance with requirements of prescribed Codes, Standards and Rules have been adhered to. The Regulatory Body shall also carry out independent checks of the design to ensure that the design objectives are met.

3.3.2 Review and Assessment of the Application

3.3.2.1 The Regulatory Body shall evolve a programme of review and assessment, sequentially for all major stages of the consenting process. A schedule for submission of documents in support of the application for consent should be established. Infrastructure for monitoring the implementation of stipulations of the Regulatory Body should be established. Appropriate checks for compliance with approved design specifications and details during implementation stage of the facility should be carried out.

3.3.3 Programme for Review and Assessment

- 3.3.3.1 The Regulatory Body shall establish lead times for submission of various documents in support of the regulatory consent application during various consenting stages. Schedules for document submissions including their contents etc. for various stages of consent are to be indicated in the relevant Guides issued by the Regulatory Body.
- 3.3.3.2 The following reviews and assessments, specific to the particular stage of activity shall be performed:
- 3.3.3.2.1 *Siting:* Acceptability of the site from the standpoint of site characteristics vis-a-vis plant design basis.
- 3.3.3.2.2 *Construction:* Safety review to ensure that the design meets all the relevant safety requirements. Review of quality assurance programme and inspection.
- 3.3.3.2.3 *Commissioning:* The following aspects shall be checked:
 - (a) verification of compliance with approved design specifications during plant installation,
 - (b) review of the "as-built" design of the plant,
 - (c) commissioning tests and results,
 - (d) provision for radiation protection, chemical, fire and industrial safety,
 - (e) availability of approved technical specifications,
 - (f) limits and conditions for operation,

- (g) qualification/certification and training of plant personnel,
- (h) quality assurance organisation and its programme,
- (i) on-site and off-site emergency preparedness,
- (j) nuclear/radioactive material inventory, and
- (k) maintenance of records and systems of reporting to plant management and Regulatory Body.

3.3.3.2.4 *Operation:* The following aspects shall be checked:

- (a) performance reports,
- (b) safety status and surveillance reports,
- (c) over-exposures and investigation reports,
- (d) safety related unusual occurrences,
- (e) violation of technical specifications,
- (f) in-plant safety review scheme reports on regulatory inspections
- (g) environmental surveillance,
- (h) status of physical protection, and
- (i) plant modification relating to safety aspects.
- 3.3.3.2. *Decommissioning:* The proposed organisational structure, decommissioning procedures, disposal of radioactive wastes, recycling and reuse of materials.

3.4 Conduct of Safety Review and Assessment

Safety review and assessment by the Regulatory Body may be carried out by itself or with the assistance of advisory committees or consultants. The scope and extent of these reviews and assessment and the procedures to be followed are given in Guide No. AERB/SG/G-2.

3.5 Consenting Decisions

3.5.1 General

3.5.1.1 The review and assessment of nuclear fuel cycle facility should be done on a continuing basis so as to ensure that the facility is operated as per conditions laid down in the consent.

- 3.5.1.2 The review and assessment process by the Regulatory Body gives rise to a series of decisions. Not all these may be immediately accompanied by the issue of formal consents. However, at the conclusion of one or more of the consenting stages (see sub-section 3.1.3), the Regulatory Body shall issue:
 - (a) formal consent permitting the undertaking of any of the activities with validity period and conditions stipulated,

OR

(b) refusal of such consents and reasons thereof.

3.6 Appeal against Decisions

- 3.6.1 Appeal against the decisions of the Regulatory Body will rest with the Atomic Energy Commission whose decision shall be final.
- 3.6.2 The implementation of a consenting decision intended to protect the public, the site personnel and the environment from unacceptable radiological, chemical and industrial risks shall be mandatory even if the applicant wants to file an appeal with the Atomic Energy Commission for review of Regulatory Body's decision.

4. CONSENTING PROCESS FOR RADIATION FACILITIES

4.1 Consenting Process

4.1.1 General

Radioactive materials and radiation generating equipment are widely used in medical, industrial, agricultural, and research applications. The premises where some of the applications of radiation are carried out, and the equipment used in some of these applications are termed as "Radiation Facilities".

The Regulatory Body must, inter alia, ensure that radioactive materials and radiation generating equipment are used (a) only for such practices that are justified in terms of their societal/individual benefits and (b) in such a manner that radiation protection is duly optimised in their actual use in the radiation facilities.

The consentee is solely responsible for ensuring safety in siting, design, construction, commissioning, operation and decommissioning of a radiation facility and shall demonstrate to the Regulatory Body that safety is ensured at all times. In particular, he should ensure that requisite number of qualified staff is always available for carrying out the radiation work safely.

In view of the wide variety and nature of these applications involving various levels of radiation safety, the Regulatory Body should adopt a graded regulatory control over the radiation facilities, based on their hazard potential. Such graded control should be effected through a system of issue of three different forms of regulatory consents, viz. licence, authorisation and registration of sources in the descending order of hazard potential. The Regulatory Body should prescribe the type of regulatory consents required for different facilities. The requirements of operations of the facilities handling each of these categories of sources, should also be prescribed.

Apart from the above system of graded regulatory consents, there should also be the system of type approval of some radiation equipment, and approval of design in respect of packages meant for transport of fuels and high activity gamma sources. Type approval shall be accorded only after the Regulatory Body is satisfied that the equipment complies with the relevant national/international standards. Similarly, approval of design of packages shall be issued only after ensuring that the design is in accordance with national/international regulations on transport.

4.1.2 Purpose of Consent

A consent is an official document which will:

- (a) allow a specified activity or set of activities dealing with siting, construction, commissioning, operation or decommissioning of a radiation facility, and
- (b) establish requirements and conditions governing the performance of these activities.

4.1.3 Stages of Consenting Process

- 4.1.3.1 The major stages at which consents are required in respect of radiation facilities are:
 - (a) Siting.
 - (b) Construction,
 - (c) Commissioning,
 - (d) Operation, and
 - (e) Decommissioning.

Consenting process is a continuing assessment process covering all the above stages. The Regulatory Body has the discretion to combine two or more stages of activity in a single consent depending on the hazard potential of the radiation facility.

4.1.3.2 Separate consent shall be required at each stage of the consenting process. Appendix-I gives the categories of regulatory consents applicable to different facilities.

- 4.1.3.3 The Regulatory Body shall prescribe the format for application and regulatory consents for each of the above stages (refer Guide No. AERB/SG/G-7)
- 4.1.3.4 In each consent to be issued by the Regulatory Body, the period of validity of the consent shall be mentioned.
- 4.1.3.5 There shall be a provision for periodic renewal of consent.
- 4.1.3.6 There shall also be a provision to amend the consent already issued, either on the basis of a review, or on request from the consentee or on the need felt by the Regulatory Body itself.
- 4.1.3.7 There shall be a time limit for issue of consent, after an application from the applicant complete in all respects is received by the Regulatory Body.
- 4.1.3.8 Any modification or change in the regulatory consent may be carried out by the Regulatory Body as a result of experiences gained from various sources during operation of radiation facilities of similar type or as a result of research and development.

4.2 Requirements to be Complied by the Applicant

4.2.1 General

The applicant shall submit necessary information as laid down in the Guide No. AERB/SG/G-3 issued by the Regulatory Body, in support of his application for Consent.

4.2.2 Information Requirements

- 4.2.2.1 The applicant shall submit to the Regulatory Body detailed and relevant information in respect of safety of the radiation facility such as:
 - (a) design and layout of radiation facility,
 - (b) availability of:
 - (i) quality assurance documents,
 - (ii) qualified and approved staff,

- (iii) calibrated radiation survey instruments,
- (iv) personnel monitoring services,
- (v) physical protection arrangements,
- (vi) safe operating and emergency procedures, and
- (vii) waste disposal measures.
- 4.2.2.2 Any alteration in respect of radiation facility which could affect safety directly or indirectly shall be carried out only with prior approval of the Regulatory Body.
- 4.2.2.3 Safety Analysis Report (SAR) and relevant documents shall be submitted to the Regulatory Body to facilitate a systematic review and assessment of procedures. A standard format and content for preparation of SAR shall be provided by the Regulatory Body.
- 4.2.2.4 The requirements imposed on the applicant by the Regulatory Body through regulatory consent in respect of a radiation facility should include, periodic submission of safety reports covering:
 - (a) changes in qualified and certified staff,
 - (b) routine radiation protection surveys,
 - (c) inventory of radioactive substances,
 - (d) functioning of radiation instruments,
 - (e) operating and system performance data,
 - (f) disposal of radioactive wastes,
 - (g) unusual occurrences, and
 - (h) changes in design, construction, commissioning, operation and decommissioning.
- 4.2.2.5 Without prejudice to the generality of provisions of sub-sections 4.2.2.1 to 4.2.2.4, the Regulatory Body may prescribe specific requirements for each category of consent, as required.

4.3 Safety Review and Assessment during Consenting Process

4.3.1 General

The responsibility of Regulatory Body is to ensure through appropriate safety review that the radiation facility to be sited, constructed, operated and decommissioned shall not result in undue radiological, chemical and industrial risk to plant/site personnel, the public and the environment. The technical information contained in the project design reports, safety analysis reports, technical specifications for the operations, manuals on operating procedures under normal and emergency conditions and other relevant documents submitted by the applicant form the primary basis for review and assessment by the Regulatory Body. The Regulatory Body shall satisfy itself that all essential information required for safe conduct of a particular activity has been furnished and compliance with the requirements of prescribed Codes, Standards and Rules are adhered to. The Regulatory Body shall also carry out independent checks of design to ensure that design objectives are met.

4.3.2 Review and Assessment of the Application

- 4.3.2.1 The Regulatory Body shall satisfy itself that:
 - (a) information contained in the application is complete and acceptable as verified by independent checks; and
 - (b) information provided by the applicant demonstrates that the radiation facility can be safely sited, constructed, commissioned, operated or decommissioned.

4.3.3 Programme for Review and Assessment

- 4.3.3.1 The Regulatory Body shall establish lead times for submission of various documents in support of regulatory consent application during various consenting stages. Schedules for document submissions including their contents etc. for various stages of consent is given in the Guide No. AERB/SG/G-3.
- 4.3.3.2 The following reviews and assessments, specific to the particular stage of activity shall be performed:

- 4.3.3.2.1 *Siting:* The site characteristics shall be checked for acceptability of the site and of the relevant data used in the design of proposed radiation facility.
- 4.3.3.2.2 *Construction:* Continuing review of the radiation facility shall be carried out in accordance with procurement and construction schedule of the consentee.
- 4.3.3.2.3 *Commissioning:* During this stage the following shall be reviewed:
 - (a) results of commissioning tests,
 - (b) operating instructions and procedures,
 - (c) quality assurance organisation and programme,
 - (d) emergency procedures,
 - (e) radiation survey, and
 - (f) staffing.

Source Loading: This is an intermediate phase under commissioning stage and during this phase, the following shall be reviewed and verified:

- (a) 'as built' design of the radiation facility,
- (b) provisions for radiological protection,
- (c) source loading operations,
- (d) radiation survey, and
- (e) commissioning reports.
- 4.3.3.2.4 *Operation:* During this phase the following shall be reviewed and assessed:
 - (a) performance reports,
 - (b) unusual occurrence reports,
 - (c) radiation exposure distributions,
 - (d) source replacement/augmentation programme,
 - (e) modification in equipment, sources and procedures, and
 - (f) changes in operating procedure based on operating experiences.

4.3.3.2.5 *Decommissioning:* The proposed decommissioning procedures for source removal, decontamination and safe disposal of wastes, shall be reviewed before decommissionning.

4.4 Conduct of Safety Review and Assessment

Safety Review and assessment by the Regulatory Body may be carried out by itself or with the assistance of advisory committees or consultants. The scope and extent of these reviews and assessment, and the procedures to be followed, are given in Guide No. AERB/SG/G-3.

4.5 Consenting Decisions

4.5.1 General

- 4.5.1.1 The review and assessment of radiation facility should be done on a continuing basis to ensure that the facility is operated as per conditions laid down in the consent.
- 4.5.1.2 The review and assessment process by the Regulatory Body gives rise to a series of decisions. Not all decisions may be immediately accompanied by the issue of formal consents. However, at the conclusion of one or more of the consenting stages (see sub-section 4.1.3), the Regulatory Body shall issue:
 - (a) formal consent permitting the undertaking of any of the activities with validity period and conditions stipulated,

OR

(b) refusal of such consents and reasons thereof.

4.6 Appeal against Decisions

- 4.6.1 Appeal against the decisions of Regulatory Body will rest with the Atomic Energy Commission whose decision shall be final.
- 4.6.2 The implementation of a consenting decision intended to protect the public, the site personnel and the environment from unacceptable radiological, chemical and industrial risks shall be mandatory even if the applicant wants to file an appeal with the Atomic Energy Commission for review of Regulatory Body's decision.

5. REGULATORY INSPECTION OF NUCLEAR POWER PLANTS AND RESEARCH REACTORS

5.1 General

- 5.1.1 Regulatory Inspection is one of the responsibilities and functions of the Regulatory Body. It enables the Regulatory Body to ensure that the consentee has fulfilled the conditions stipulated in the Consent (see Guide No. AERB/SG/G-4).
- 5.1.2 The Regulatory Body shall plan its regulatory inspection to ensure:
 - (a) compliance with the safety provisions of the Atomic Energy Act, 1962, and the Rules framed thereunder;
 - (b) compliance with the provisions of the Factories Act, 1948, and the Atomic Energy (Factories) Rules, 1996, framed thereunder;
 - (c) that NPPs/RRs are sited, constructed and operated in conformity with design intent duly approved by the Regulatory Body;
 - (d) that safety-related structures, components and systems are of approved quality based on standards acceptable to the Regulatory Body;
 - (e) that the respective operating personnel are competent to operate the facility safely; and
 - (f) the NPPs/RRs operate within the approved Technical Specifications for Operation and as per stipulation laid down in the consent.
- 5.1.3 The regulatory inspection shall be carried out as necessary during all stages of consenting process, viz:
 - (a) Siting,
 - (b) Construction.
 - (c) Commissioning,
 - (d) Operation, and
 - (e) Decommissioning.

The regulatory inspections may also be carried out by consultants authorised by the Regulatory Body.

5.1.4 The consentee shall provide access to the plant and documents and extend required facilities to enable inspection whenever required by the Regulatory Body.

5.2 Objectives

- 5.2.1 The primary aim of regulatory inspection, amongst others, is to check that:
 - (a) the operating personnel satisfy prescribed qualification and/or are certified where applicable;
 - (b) the quality and performance of the structure, systems and components are maintained as required for safe operation;
 - (c) all applicable codes, standards specifications and practices for siting, design, construction, commissioning, operation and decommissioning of NPPs/RRs are complied with;
 - (d) quality and performance specified by the Regulatory Body are in fact attained and maintained in components, structures and systems at all stages of the consenting process; and
 - (e) deviations and deficiencies detected during the inspection activity are corrected by the consentee without undue delay.

5.3 Inspection Functions

- 5.3.1 The inspections shall include the following aspects:
 - (a) regulatory inspection of the site to facilitate assessment and evaluation of the data submitted by the applicant;
 - (b) regulatory inspection of design facilities;
 - (c) regulatory inspection of activities of the applicant during construction,
 - (i) to verify that the stipulations in the construction consent are complied with; and

- (ii) to obtain data necessary for continuing review and assessment of the proposed NPP/RR;
- (d) ensuring the effective implementation of the quality assurance programmes;
- (e) assessing and approving changes in the programme for quality assurance;
- (f) observing and reviewing the conduct and results of commissioning tests prior to issue of operating consent;
- (g) checking that operation of NPP/RR complies with all conditions of the operating consent and that the facilities and records are well maintained;
- (h) reviewing the procedure and results of conducting periodic tests and maintenance programme during the operational stage;
- (i) checking personnel exposure records and their distributions and investigation of overexposure cases;
- (j) checking the records of periodical medical examinations.
- (k) verifying compliance with operating limits and conditions set out by the Regulatory Body and checking that the releases of radioactive substances from the operating unit are as low as reasonably achievable and within the prescribed limits;
- (l) reviewing the results of environmental surveillance programmes; and
- (m) verifying the updating of technical specifications, operating procedures, design documents and on-site and off-site emergency response plans, and verifying the availability of emergency response equipment. Observing emergency response exercises and where necessary give directions to rectify the observed deficiencies or suggest improvements.

5.4 Special Regulatory Inspections

5.4.1 Besides the above routine regulatory inspection, the Regulatory Body may consider and carry out special regulatory inspections with specific objectives as deemed necessary.

6. REGULATORY INSPECTION OF NUCLEAR FUEL CYCLE FACILITIES (OTHER THAN NPPs/RRs) AND RADIATION FACILITIES

6.1 General

- 6.1.1 The inspection functions of the Regulatory Body shall cover the Nuclear Fuel Cycle and Radiation Facilities with a view to ensure that the consentee is complying with conditions stipulated in the consent letter (refer Guide No. AERB/SG/G-4).
- 6.1.2 The Regulatory body shall plan its regulatory inspection to ensure:
 - (a) compliance with safety provisions of the Atomic Energy Act, 1962, and the Rules framed thereunder;
 - (b) compliance with provisions of the Factories Act, 1948, and the Atomic Energy (Factories) Rules, 1996, framed thereunder;
 - (c) that nuclear fuel cycle facilities and radiation facilities are sited, constructed and operated in conformity with the design intent duly approved by the Regulatory Body;
 - (d) that the safety-related structures, components and systems are of approved quality based on standards acceptable to the Regulatory Body;
 - (e) that the respective operating personnel are competent to operate the nuclear fuel cycle facilities or radiation facilities safely; and
 - (f) that nuclear fuel cycle facilities and radiation facilities operate within approved Technical Specifications for Operation and as per stipulation laid down in the consent.
- 6.1.3 The regulatory inspection shall be carried out as necessary during all stages of the consenting process viz:
 - (a) Siting,
 - (b) Construction.
 - (c) Commissioning,
 - (d) Operation, and
 - (e) Decommissioning.

The regulatory inspections may also be carried out by consultants authorised by the Regulatory Body.

6.1.4 The consentee shall provide access to facilities and documents and extend the required assistance to enable inspection whenever required by the Regulatory Body.

6.2 Objectives

The objectives of regulatory inspections shall be to ensure that:

- (a) the operating personnel satisfy prescribed qualification and/or are certified, where applicable;
- (b) the quality and performance of structures, systems and components are maintained as required for safe operation;
- (c) all prescribed surveillance procedures, codes, standards and rules are complied with by the consentee;
- (d) facilities are operated as per approved technical specifications and as per the conditions stipulated in the consent; and
- (e) deficiencies as noted in the earlier inspections have been rectified.

6.3 Inspection Functions

6.3.1 Nuclear Fuel Cycle Facilities (other than NPPs/RRs)

The regulatory inspection shall include the following aspects:

- (a) site inspection and evaluation of data submitted by the consentee;
- (b) inspection during construction to verify compliance with conditions of consent;
- (c) ensuring effective implementation of quality assurance and in-service inspection programmes and assessing and approving changes required in them;
- (d) observing, where necessary, conduct of tests prescribed by the Regulatory Body and reviewing the results;
- (e) verifying compliance with the technical specifications for operation of the plants and other operating consent conditions;

- (f) reviewing results of periodic tests and maintenance programmes as specified;
- (g) checking that disposal of radioactive wastes is within the limits and as per conditions specified by the Regulatory Body;
- (h) verifying the updating of Technical Specifications, operating procedures, design documents and emergency plans, and reviewing the effectiveness of emergency exercises; and
- (i) checking the records of periodical medical examinations.

6.3.2 Radiation Facilities

The regulatory inspection shall include the following aspects:

- (a) site inspection to facilitate evaluation of data submitted by consentee;
- (b) verifying compliance with prescribed quality assurance programme during construction of radiation facilities designed for housing high activity radioactive sources and, of storage facilities for radioactive sources;
- (c) pre-commissioning inspection including performance tests on safety systems/sub-systems, and verifying availability of qualified staff and proper radiation monitoring instruments, personnel monitoring badges, emergency handling tools, emergency procedures/plans, contact numbers and communication chain etc. before issuance of regulatory consent for routine operation;
- (d) verifying compliance with standard procedures and planning during loading/unloading/transfer operations of high activity radioactive sources at the radiation facilities;
- (e) verifying compliance with conditions stipulated in the regulatory consent for routine operation of radiation facilities housing high activity radioactive sources and, ensuring compliance with regulatory procedures for safe handling and use of radioactive sources;
- (f) checking that safety systems/sub-systems of the radiation facility/ equipment and the radiation monitoring instruments are

- periodically tested/calibrated as per the conditions of regulatory consent and in accordance with directives issued by the Regulatory Body;
- (g) checking that disposal of radioactive wastes is within the limits and as per conditions specified by the Regulatory Body;
- (h) verifying that Technical Specifications, operating procedures, design documents and emergency plans are updated, and reviewing of the effectiveness of emergency exercises; and
- (i) checking the records of periodical medical examinations.

6.4 Special Regulatory Inspections

6.4.1 Besides the above routine regulatory inspection, the Regulatory Body may consider and carry out special regulatory inspections with specific objectives as deemed necessary.

7. REGULATORY ENFORCEMENT ACTIONS

7.1 General

- 7.1.1 Several graded enforcement options should be available to the Regulatory Body to ensure that the consentee takes timely corrective actions
- 7.1.2 The action to be taken by the Regulatory Body will have to be based on aspects such as safety significance of the deficiency, seriousness of violations, the repetitive nature and/or deliberate nature of the violations (refer Guide No. AERB/SG/G-4).

7.2 Bases for Enforcement

7.2.1 Enforcement actions by the Regulatory Body arise from review of documents submitted by the consentee or findings during review or inspection.

7.3 Methods of Enforcement

- 7.3.1 The enforcement actions may include one or more of the following:
 - (a) a written directive for satisfactory rectification of the deficiency or deviation detected during inspection;
 - (b) written directive to consentee for improvement within a reasonable time frame;
 - (c) orders to curtail or stop activity;
 - (d) modification, suspension or revocation of operating consents; and
 - (e) penalties.
- 7.3.2 The Regulatory Body should define the authority/powers to be assigned to inspectors.
- 7.3.3 The Regulatory Body should frame detailed procedures and issue detailed guidelines for enforcement action by various levels of inspectors. The inspectors should be conversant with these procedures and guidelines.
- 7.3.4 The procedures should cover time limit for corrective actions.

7.4 Appeal against Decisions

- 7.4.1 The consentee may be permitted to state his point of view on a regulatory decision.
- 7.4.2 In case of any disagreement, the consentee should be given an opportunity to appeal against enforcement actions to the Atomic Energy Commission, whose decision shall be final.

APPENDIX-I

CATEGORIES OF REGULATORY CONSENTS

1. Licence:

The Regulatory Consent shall be the "Licence" for all "Sources and Practices" involving the following:

- (i) Nuclear Fuel Cycle Facilities;
- (ii) Land Based High Intensity Gamma Irradiators other than Gamma Irradiation Chambers:
- (iii) High Energy Particle Accelerators used for Research;
- (iv) High Energy Electron Accelerators used for Industrial Research and Commercial Irradiation;
- (v) Commercial Production of Radioactive Materials or Radiation Generating Equipment; and
- (vi) Any other Source or Practice notified by the Regulatory Body.

2. Authorisation:

The Regulatory Consent shall be the "Authorisation" for all "Sources and Practices" involving radioactive materials and radiation generating equipment which include the following:

- (i) Medical Radiotherapy Sources and Equipment (Telegamma, Brachytherapy, Electron Accelerator);
- (ii) Industrial Radiography Sources and Equipment (Gamma Exposure Devices, Electron Accelerators, X-Ray, Neutron);
- (iii) Gamma Irradiation Chambers:
- (iv) Nuclear Medicine Facilities other than RIA Labs.:
- (v) Commercial Production of Nucleonic Gauges and Consumer Products containing Radioactive Materials; and
- (vi) Any other Source and Practice notified by the Regulatory Body.

3. Registration:

The Regulatory Consent shall be the "Registration" for "Sources and Practices" that include the following:

- (i) Medical Diagnostic X-Ray Equipment including Computed Tomography (CT) and Therapy Simulator;
- (ii) Analytical X-Ray Equipment used for Research;
- (iii) Nucleonic Gauges;
- (iv) Radioactive Sources in Tracer Studies;
- (v) Biomedical Research using Radioactive Materials;
- (vi) Any other Source and Practice notified by the Regulatory Body; and
- (vii) RIA Labs.

4. Approval:

The Regulatory Consent shall be the "Approval" for "Sources and Equipment" that include the following:

- (i) Type Approval of Sources and Equipment for purposes of manufacture and supply;
- (ii) Design Approval of Transport Packages in accordance with the Safe Transport of Radioactive Material;
- (iii) Any other Approval notified by the Regulatory Body.

Note: The structure and categories of Regulatory Consent are indicated in Fig. I.1.

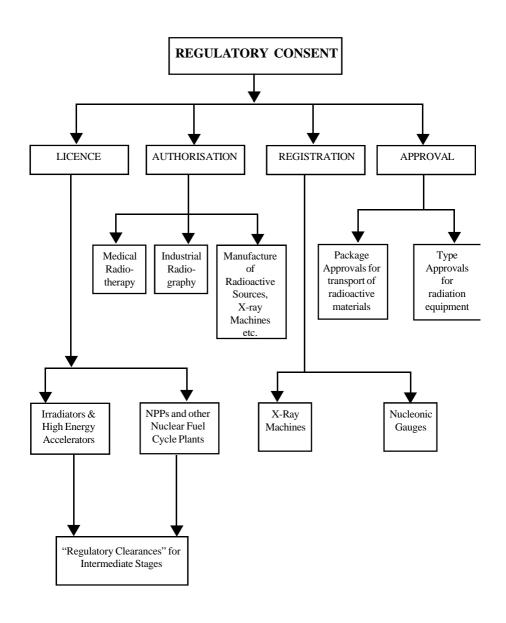


Fig. I.1 - STRUCTURE AND CATEGORIES OF REGULATORY CONSENT

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LIST OF PARTICIPANTS

ADVISORY COMMITTEE ON PREPARATION OF CODE AND GUIDES ON GOVERNMENTAL ORGANISATION FOR REGULATION OF NUCLEAR AND RADIATION FACILITIES (ACCGORN)

Dates of Meeting: May 5, 1995 November 30, 1995

June 19 & 20, 1995 December 4, 1995 July 13 & 14, 1995 June 4 & 5, 1996 August 24 & 25, 1995 April 3, 2000 September 28, 1995 May 5, 2000

Members and invitees participating in the meetings:

Dr. S.S. Ramaswamy (Chairman) : Formerly DG, FASLI

Shri G.V. Nadkarny : Formerly NPC

Shri A.K. Asrani : AERB

Shri T.N. Krishnamurthi : AERB

Shri N.K. Jhamb : AERB

Dr. K.S. Parthasarathy : AERB

Dr. I.S. Sundara Rao : AERB

Shri P.K. Ghosh : AERB

Shri A.S. Bhattacharyya : NPC

Shri S.T. Swamy (Permanent-Invitee) : AERB

Shri Y.K. Shah (Invitee) : AERB

Shri G.K. De (Member-Secretary,

till September, 1999) : AERB

Shri R.S. Singh (Member-Secretary,

since October, 1999) : AERB

LIST OF SAFETY GUIDES UNDER SAFETY CODE ON REGULATION OF NUCLEAR AND RADIATION FACILITIES

Safety Series No.	Title
AERB/SG/G-1	Consenting Process for Nuclear Power Plants and Research Reactors: Documents Submission, Regulatory Review and Assessment of Consent Applications
AERB/SG/G-2	Consenting Process for Nuclear Fuel Cycle and Related Industrial Facilities: Documents Submission, Regulatory Review and Assessment of Consent Applications
AERB/SG/G-3	Consenting Process for Radiation Facilities: Documents Submission, Regulatory Review and Assessment of Consent Applications
AERB/SG/G-4	Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities
AERB/SG/G-5	Role of Regulatory Body with respect to Emergency Response and Preparedness at Nuclear and Radiation Facilities
AERB/SG/G-6	Codes, Standards and Guides to be Prepared by the Regulatory Body, for Nuclear and Radiation Facilities
AERB/SG/G-7	Regulatory Consents for Nuclear and Radiation Facilities: Contents and Formats.
AERB/SG/G-8	Regulations and Criteria for Health and Safety of Nuclear Power Plant Personnel, the Public and the Environment

NOTES