QUALITY ASSURANCE MANUAL (QAM) FOR
GAMMA RADIATION PROCESSING FACILITY (GRAPF)

A. QUALITY ASSURANCE PROGRAM (QAP)

(i) An adequate quality assurance (QA) program, including appropriate quality control measures, shall be established for the design and manufacture, construction, operation and industrial safety of irradiators. Compliance with the ISO 9000 or IS 14000 series is desirable. Records of all QA procedures shall be maintained for the entire life of the irradiator.

(ii) Follow the quality assurance requirement specified in Appendix-B of AERB safety standard titled 'Land Based Stationary Gamma Irradiators' [AERB/RF-IRRAD/SS-6 (Rev.1); 2007].

B. QUALITY ASSURANCE IN DESIGN OF GRAPF

1. Quality Assurance Programme

The responsible organization shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of the GRAPF. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures should be defined by the responsible organization for control of design activities to ensure that the design of the GRAPF fulfils the specified requirements.

1.1 Grading

A graded approach based on the relative importance to radiological safety of each item, service or process shall be used.

1.1.1 The design activities, which could be graded, include:

(a) The level and detail of analysis of design
(b) The need for and level of design review and approval
(c) The degree of verification of design
(d) The controls applied to design change
(e) The detail of design records and their retention times
(f) The need for alternative calculations to be carried out
(g) The need to qualify or test the design output
(h) The need for qualification tests for design

1.2 Organisation

The responsible organisation shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.

1.3 Interfaces

Interface arrangements shall be agreed between organisations involved in design activities. Interface that should be addressed are for example:

(a) Interfaces between technical disciplines within the design organisation
(b) Principal designer with:

(i) Siting organisation
(ii) Construction organisation
(iii) Commissioning organisation
(iv) Operating organsiation
(v) Decommissioning organsiation
(vi) Regulatory body

1.4 Planning

Plans used in design should include the following where appropriate:

(a) Scope of work, including work carried out by other organisations
(b) Design methods
(c) Software requirements (software to be developed or software codes to be validated for use)
(d) Test requirements, including qualification tests, prototype, seismic, etc.
(e) Design review, verification and validation requirements
(f) Resource requirements
(g) Special training requirements
(h) Schedule of activities
(i) Points at which checks of the design process will take place and the frequency of such checks
(j) Inputs from safety, reliability, maintainability, human factors, standardization and other disciplines.

1.5 Non-conformance Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established.

1.6 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents shall be established.

C. QUALITY ASSURANCE DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES OF GRAPF

1. Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of civil engineering structures for gamma irradiators during construction. This programme should provide the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

1.1 Grading

Work procedures should be defined for control of construction activities at site and it should be reviewed and approved before use. A graded approach based on the relative importance to safety of each item, service or process shall be used. The construction activities, which could be graded, include:

(a) Qualification of special construction processes and the personnel to carry them out
(b) Detail and need for inspection plans
(c) Level of traceability
(d) Level of in process controls and need for hold points
(e) Records and archived samples

1.2 Organisation

The responsible organisation should formally appoint a person on its staff to be responsible for construction activities. The appointed person should have the necessary resources within the construction organisation to discharge the following responsibilities:

(i) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.
(ii) Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work.
(iii) Controlling access to the construction site.

1.3 Interfaces

Interface arrangements should be agreed between the construction organisation, suppliers and other organisational units performing the work. They should be defined in writing and should be included in procurement documents. Interfaces that should be addressed are:

(a) Construction organization with supplier
(b) Construction organization with operating organisation
(c) Suppliers with sub-suppliers
(d) Construction organisation with the principal designer
(e) Construction organisation with siting organization
(f) Interfaces between construction organisation and the regulatory body

1.4 Planning

All construction activities should be planned. The plan should define:

(a) The activities to be performed in manageable units
(b) The planned sequential order and duration of these activities
(c) The resource allocation for each activity

1.5 Non-conformance Control and Corrective Actions

The non-conformances that are required to be reported to the construction organisation should be identified. Suitable corrective action should also be recorded.

1.6 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Records should include all those, which record the as-built condition of structures, systems and components.

1.7 The civil engineering construction should be carried out following the relevant Indian standard codes/specifications. Quality of civil construction should satisfy the requirements of appropriate Indian standard codes/specifications and that of product specifications. Typical list of topics to be covered in QA programme for the civil engineering construction is given as below:

(a) Formwork, shuttering and pre-construction activities
(b) Concreting & curing
(c) Post concrete inspection
(d) Repair
(e) Fabrication and erection of embedded parts (EP)
(f) Fabrication & erection of structural steel
(g) Brick work
(h) Grounding network
(i) Painting for steel structure
(j) Finishing & repair control
(k) Painting of main plant structures/concretes faces
(l) List of procedures
(m) Miscellaneous items such as organisation chart of QA civil, flow chart showing production of good uniform concrete, schematic diagram on procedure of concrete mix design etc.
(n) Density of the concrete in construction of walls and roof of irradiation cell shall be maintained at least 2.5 g/cc and it shall be ensured that no voids or air gaps are present during concrete filling.

D. INDUSTRIAL SAFETY DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES

A policy reflecting industrial safety regulations should be established for all personnel, including suppliers and visitors. These should be in line with the prevailing factory rules. The policy should include arrangements for the effective planning, organisation, monitoring and review of the preventive and protective measures.

Management should provide all necessary support to the Contractor to ensure health and safety of the construction personnel.

(i) Job hazard analysis should be prepared before the start of construction.
(ii) Industrial safety at the construction site should be enforced by a safety officer.
(iii) All construction equipment should be tested prior to its use.
(iv) Construction personnel should be given orientation program on industrial safety.

(v) Accident statistics should be maintained at the construction site.
(vi) Appropriate arrangements for fire safety and first aid should be available.

E. QUALITY CONTROL--RESPONSIBILITY OF MANUFACTURER / DESIGNER

(i) Equipment and Instrument quality & certification
(ii) Manufacturing material quality, tolerance of parts, fabrication specifications, inspection manufacturing & tests adopted, quality assurance procedures.
(iii) Quality of components used
(iv) Certification of wiring, electrical and mechanical safety
(v) Documentation of quality assurance and control procedures
(vi) Specifications of wire rope, source rack, hydraulic piping and pumps, sensors and their quality assurance.