



Documentation for Review and Assessment with Respect to Applicant and Regulator

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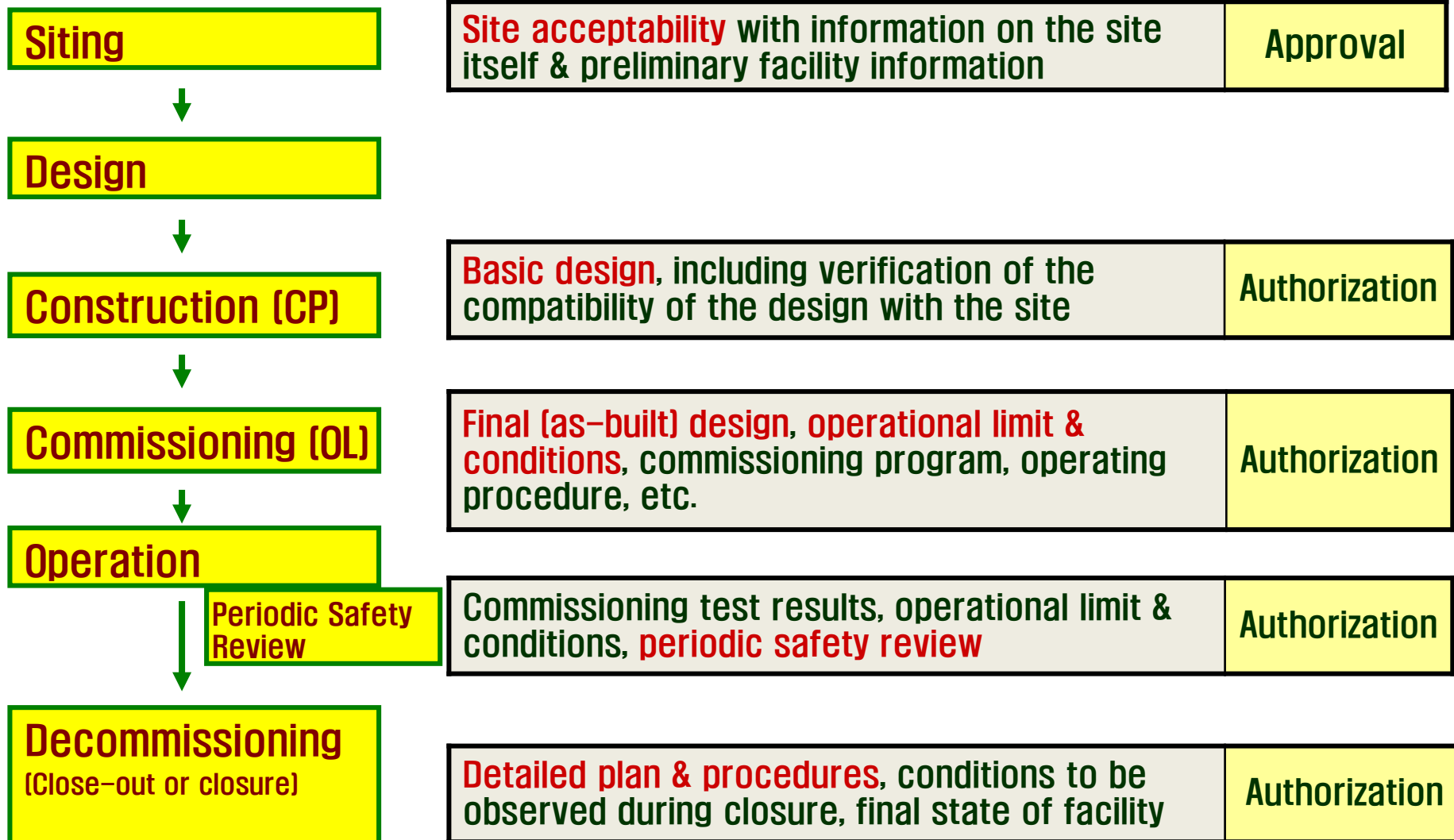
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Typical Licensing Process

- *Approval of the site*
- *Authorizing construction, manufacture and installation*
- *Authorizing commissioning*
- *Authorizing operation*
- *Authorizing modification*
- *Authorizing decommissioning or closure*

Typical Licensing Process



Documents Produced by Operator

❖ Three categories of documents:

(IAEA GS-G-1.4 (superseded by GSG-13))

- Documents **required** to be **submitted to the regulatory body** for formal approval at the various stages of the **authorization process**
- Reports which **should** be **submitted to the regulatory body periodically** or, for events, incidents or accidents, should be specified in the regulations
- Documents which **should be prepared for the conduct of activities** relating to the facility and which should be made available to the regulatory body upon request

2. Documents produced by Operator

❖ For the Authorization Process

▪ Basic information to be provided

- A **description of the site** in terms of geography, demography, topography, meteorology, hydrology, geology and seismology;
- A **description of the facility**, including the layout of buildings and equipment;
- **Applicable safety regulations**, guides and industrial standards;
- The **safety concepts** and criteria used in the design;
 - the classification of SSC
 - the application of the defense in depth principle
 - the multiple barriers to prevent radioactive releases
 - the human–machine interface
- A **description of the facility** including their design criteria, the design processes, and the modes of operation and testing.

Documents Produced by Operator

❖ For the Authorization Process

▪ Information on Safety Analysis Results

- Acceptability of the design;

- Facility
- Radiation protection
- Waste management
- Effluent limits, etc.

- Prevention of accidents and mitigation of consequences

- Limits and conditions for safe operation, etc.



Covered by a Class on SAR

Documents Produced by Operator

❖ For the Authorization Process

- Information on **Organizational Matters**
 - Management structure and resources
 - Quality assurance arrangements, including internal and external audits
 - Organizational structure for each stage of authorization
 - Qualification and training of personnel
 - Development of procedures
 - Documents and records control.

Documents Produced by Operator

❖ For the Authorization Process

▪ Information on **Safety Activities**

- Radiation protection programme (ALARA principle)
- Environmental monitoring programme
- **Emergency preparedness**
- Fire protection
- Radioactive waste management
- R&D in relation to the safe design, operation of the facility
- **Feedback of operating experience**

Documents Produced by Operator

❖ For the Reporting

- **Periodic Reporting and Progress Reporting**
 - During site evaluation and construction
 - Progress of site studies
 - Progress of construction
 - Result of pre-operational environmental monitoring program
 - Result of commissioning test
- **Reporting of Events, Incidents and Accidents**
- **Reporting of Changes and Modification**

Documents Produced by Operator

❖ For the Records Keeping

- **Records of Site Evaluation and Construction**
 - Result of site evaluation studies
 - Construction design records
 - Manufacturing records (including shop QC results)
 - Erection records (including QC results and as-built design records)
- **Commissioning Records**
 - Test records of SSC
 - Test procedures and test results

Documents Produced by Operator

❖ For the Records Keeping

▪ **Operational Records**

- Output and performance records/Operating log book
- Inventory of fissile and radioactive materials
- Records of periodic calibration of equipment
- Records of periodic test/ in-service inspections
- Records of personnel training
- Records of personnel radiation monitoring
- Records of radioactive waste management
- Records of effluent discharge and of environmental monitoring program

▪ **Records of Modifications to the Facility**

▪ **Records and Evaluation of Events**

Documents Produced by Regulatory Body

❖ Results of Review and Assessment

▪ Records for Information Exchange

- Request for additional information (RAI)
- Responses by operator (including its contractors)
- Records of meeting

▪ Documentation of Review and Assessment

(* Safety Evaluation Report SER))

- Reference to the documentation submitted by the operator;
- Basis for the evaluation;
- Evaluations performed;
- Conformance with regulatory requirements and guides;
- Comparison with similar (reference) facilities;
- Independent analysis performed by the staff of the regulatory body or by consultants on its behalf;
- Conclusions with respect to nuclear safety;
- Reasons for the decisions made;
- Any additional conditions to be fulfilled by the operator

Documents Produced by Regulatory Body

❖ Results of Review and Assessment

- **Records of Inspection Activities**

- **Inspection report** of all inspection activities
- **Notification** of inspection findings

- **Records of Enforcement Actions**

- Records of **actions taken** in the event of non-compliance with the regulation

Documents Produced by Regulatory Body

❖ License Document

▪ **Format of Licenses for a given Stages**

- Statutory authority & Issuing authority
- Fulfillment of requirements
- Documentary basis
- The operator and licensed activity
- Period of authorization
- The operator's responsibility for compliance

▪ **General License Condition**

- Access of regulatory body personnel
- Information on changes
- Corrective action
- Records relating to the safety of the facility
- QA program
- Report on modification
- Report on all accidents, incidents and events

Documents Produced by Regulatory Body

❖ License Document

- License Condition Relevant to Stages of Authorization process (**Contents of license documents**)
 - Site preparation
 - Construction
 - Designed in accordance with the relevant site parameters
 - Constructed in accordance with the approved design
 - Initiate a radiological study of the region
 - Commissioning
 - Perform in accordance with an approved program
 - Put into service only after inspection, test and approval
 - Provide approved storage facilities for nuclear materials
 - Operate in accordance with approved operational limits and conditions
 - Provide an approved emergency plan

Documents Produced by Regulatory Body

❖ License Document

▪ License Condition Relevant to Stages of Authorization process (continue)

- Operation

- Operate inside the design limits
- Provide a procedure for modification
- Perform in-service inspection and test in an approved time schedule
- Make changes only after approval of regulatory body
- Operate only under control and supervision of authorized personnel in adequate numbers

Documents Produced by Regulatory Body

❖ Document Control

- *Document control system shall be established for the preparation, review, approval, issuance, revision, distribution and storage of documents*

Regulations and Guides

❖ Information to be included in regulation needed for a nuclear program

- Category 1 : safety objectives, principles and criteria
- Category 2 : requirements for structuring and conducting the authorization process
- Category 3 : technical and managerial requirements relating to the stages of the authorization process

Regulations and Guides

❖ Source of Information

- **Considered in the development of regulations**
 - Standards and recommendations of international org. (such as IAEA, ICRP, ISO, IEC, etc.)
 - Regulations and guides produced in other states
 - Industrial standards developed in other states
 - Experience in the nuclear industry
 - Results of research in nuclear safety
- **In adapting IAEA Safety Standards or regulations of other States**
 - make it compatible with national legal and regulatory framework
 - include requirements specific to national conditions such as special site characteristics and electrical grid conditions.
 - evaluate amendments of regulations or standards

Summary

- **Documents for Review and Assessment;**
 - Documents produced by Applicant/Operator
 - PSAR, FSAR, QAP, ER, TS etc.
 - Documents of Regulatory Body
 - SER, SRG, MS etc.