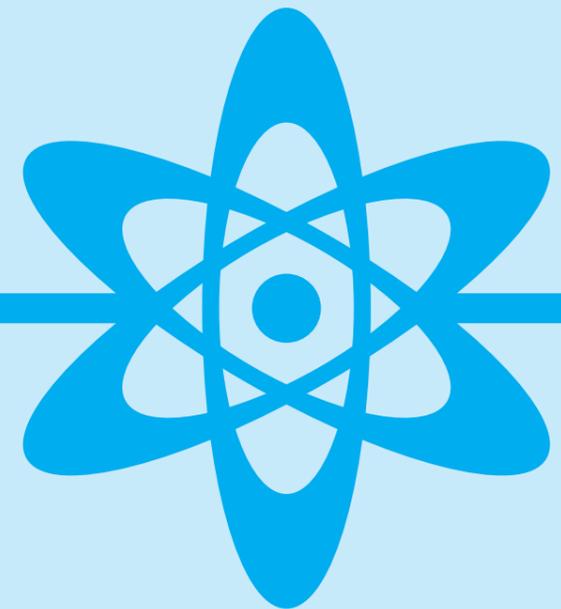




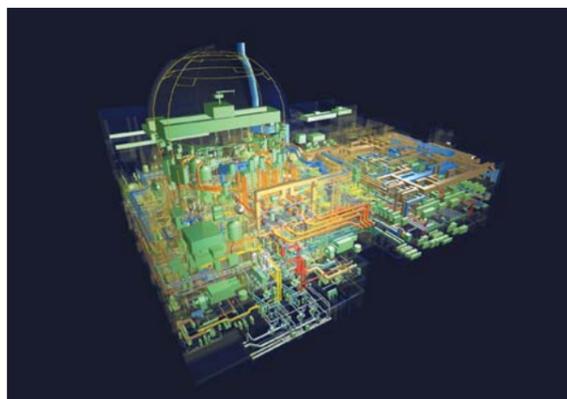
Quality Assurance Activities

for Nuclear Power Plants in Japan 2011

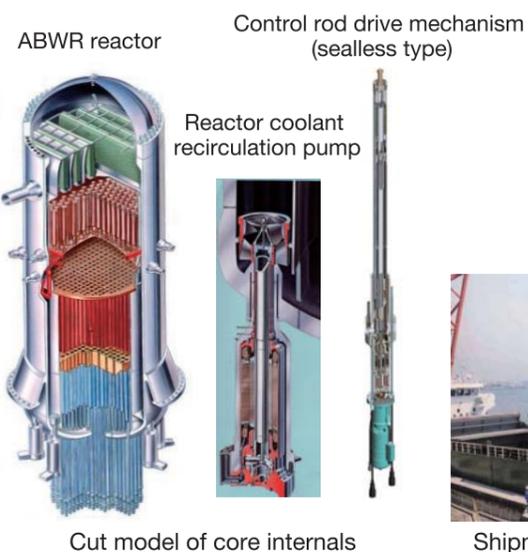




Bird's-eye view of nuclear power plant



Basic planning and design of plant based on three-dimensional CAD



Cut model of core internals



Shipment of steam generator



Installation of reactor vessel



Main Control Room Panel



Construction of nuclear power plant

Quality Assurance Activities for Nuclear Power Plants in Japan 2011

Issued in December, 2011

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Preface

We would like to express our heartfelt sympathy to those who suffered damages from the Great East Japan Earthquake.

We sincerely wish they would be restored earliest as possible.

The Quality Assurance Committee for Nuclear Power Plants of the Japan Electrical Manufacturers' Association (JEMA) identifies issues on the quality assurance of nuclear power plants, examines and discusses efforts to improve the safety and reliability of nuclear power plants from the standpoint of manufacturers, and conducts activities such as providing recommendations and coordination for not only JEMA members but also related organizations and groups.

This booklet, “Quality Assurance Activities for Nuclear Power Plants” was prepared with the aim of promoting understanding of nuclear power plants among JEMA members, and serves as a reference material for companies planning to get involved in nuclear related businesses and for companies of other industries that are interested in nuclear quality assurance.

The first edition of this booklet was issued in April 1994, and revised editions were issued in March 2001 and March 2006. To reflect the recent circumstances surrounding nuclear power generation, and from the standpoint of manufacturers, we reviewed the quality assurance system based on JEAG4101 and improved it to one based on ISO9001. As an outcome, we have now issued a third revised edition of the booklet.

[Terms used in this booklet]

- Unless otherwise required to make differentiation, the term “manufacturer(s)” is used without differentiating between (1) nuclear power plant manufacturers and (2) nuclear power plant manufacturers as well as specialized manufacturers of pumps, valves, instrumentations, etc.
- As terms to express nuclear power plant operators, “electric utility” or “electric utilities” is used when comparison with laws or regulations is important, and “utility” or “utilities” is used in other cases.

[Numeric data in this booklet]

The numeric data given in this booklet regarding the operation of nuclear power plants are as of February 2011, which predates March 11, 2011, when the 2011 Tohoku Pacific Earthquake occurred.

Contents

I. Present status of Nuclear Power Plants	3
1. Construction History of Nuclear Power Plants in Japan	3
2. Present Status of Power Generation Facilities	6
3. Plant Capacity Factors and Operating Performance	7
4. Code and Regulatory Systems for Constructing Nuclear Power Plants	8
5. Flows of Activities for Enhancing the Safety and Reliability of Nuclear Power Plants	9
6. Present Status of Advanced Reactors and Nuclear Fuel Cycle Facilities	10
7. Future Activities for Nuclear Power	11
II. Quality Assurance of Nuclear Power Plants	12
1. Characteristics of Quality Assurance of Nuclear Power	12
2. History of Quality Assurance Codes	14
III. Characteristics of Quality Management Systems at Nuclear Power Plants	16
1. General Requirements of Quality Management Systems	16
2. Control of Documents and Records	17
3. Quality Policy, Quality Objective and Management Review	20
4. Responsibilities, Authorities and Communication	22
5. Competence, Education, Training and Awareness	23
6. Customer-Related Processes	24
7. Design and Development	25
8. Procurement Control	27
9. Production and Service Provision	28
10. Control of Monitoring and Measuring Equipment	32
11. Internal Audit	33
12. Monitoring and Measurement of Products	34
13. Control of Nonconforming Products	35
14. Corrective and Preventive Actions	37

I. Present status of Nuclear Power Plants

1. Construction History of Nuclear Power Plants in Japan

Japan's nuclear power generation, which now occupies about 30% of the total electric power generation, has become a main source of electric power in the country.

Nuclear power plants in Japan consist mainly of light water reactors (LWRs). The technology for these reactors was first introduced from the United States to acquire practical skills, and then an era of digestion and domestication of the introduced technology followed. Meanwhile, the public and private sectors jointly embarked on LWR improvement and standardization programs based on their construction and operating experience, with the aim of enhancing plant safety and reliability through domestic technology, increasing plant availability factors, and reducing occupational radiation exposure. Improvements were made from the outcome of these programs. Since then, plant safety and reliability have been further improved on the basis of enhanced technology, and high capacity factors and low unscheduled shutdown rates in nuclear power plants have been pursued through the improvement of operating and maintenance technology.

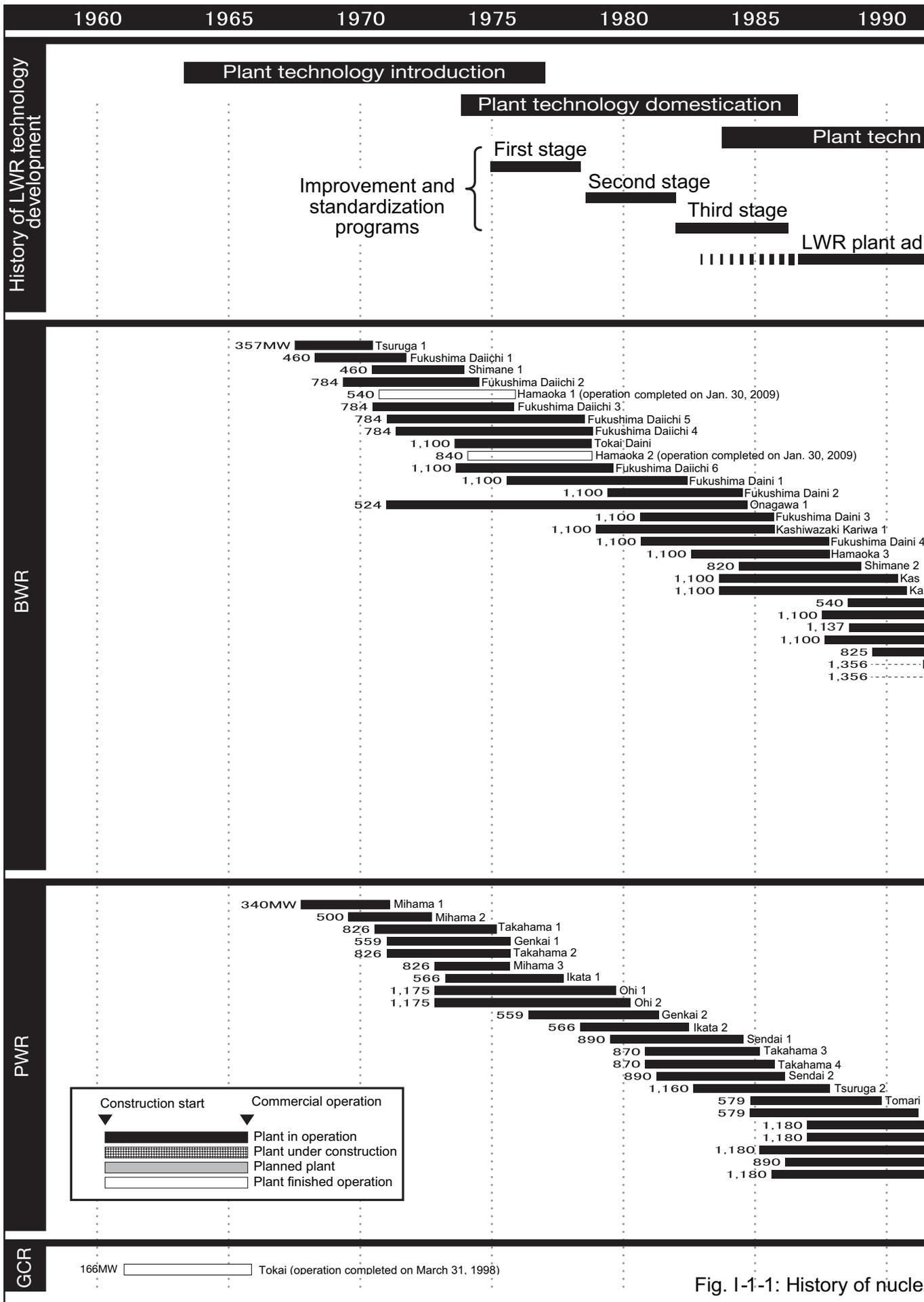
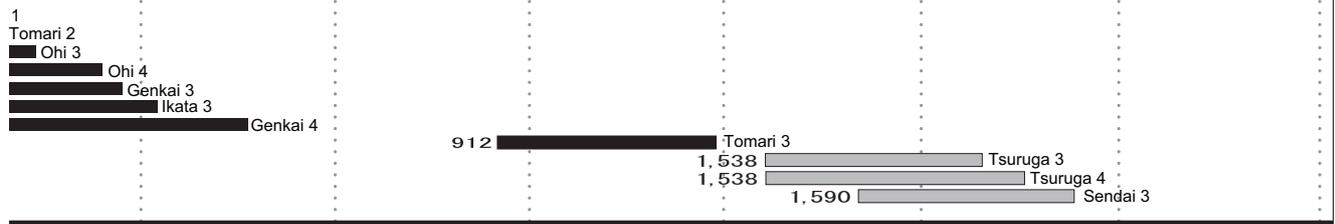
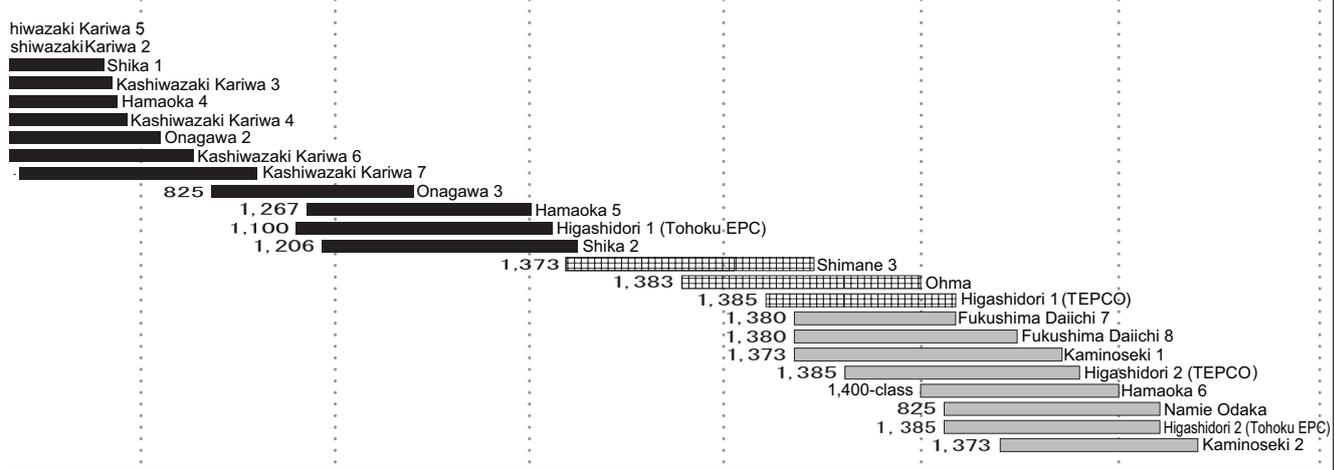
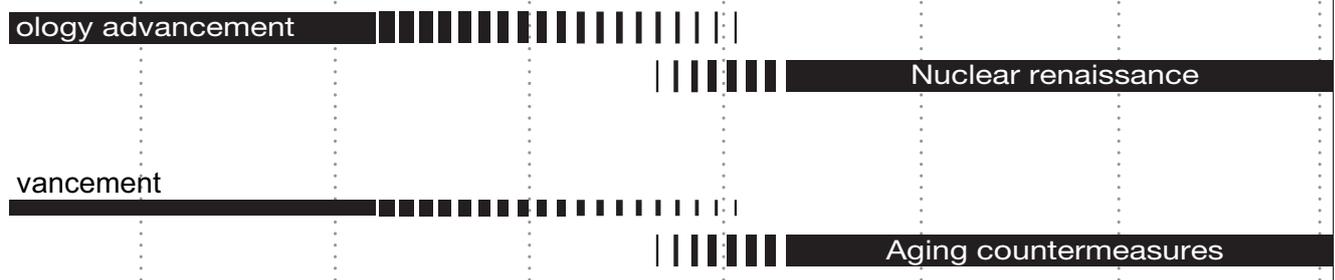


Fig. I-1-1: History of nucle

1995 2000 2005 2010 2015 2020 2025

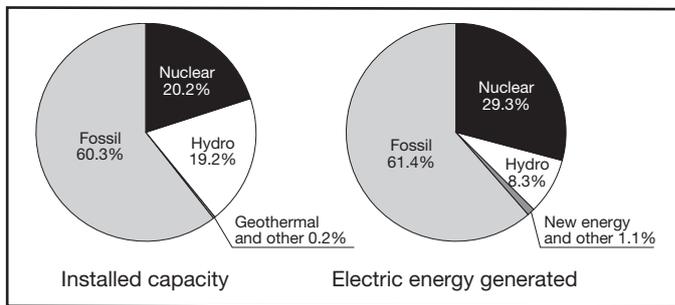


Nuclear power plant construction in Japan (As of February 2011)

2. Present Status of Power Generation Facilities

The ratio of electricity generated by nuclear power plants to the total electric power generation in Japan (954.7 TWh) is 29.3% as of FY 2009, or 20.2% in installed capacity. Nuclear power has thus established a core position in Japan as a petroleum alternative energy. In particular, the use of nuclear energy is recently being considered as an effective solution to energy security issues and environmental issues such as global warming.

The majority of nuclear power plants in Japan are LWR plants as of the end of FY 2009. Among them, 30 BWR units are operating, 2 are being constructed, 9 are planned, and Units 1 and 2 at the Hamaoka Nuclear Power Station of Chubu Electric Power Co., Inc. completed their operation in January 2009. As for the PWR units, 24 are operating and 3 are planned for construction. These nuclear power plants are located throughout the country from Hokkaido to Kyushu.



Note: The sum of the values shown in the graph may not be 100% because of rounding off.

Fig. I-2-1: Installed capacity and electric energy generated (in FY 2009)

Source: "Operational Status of Nuclear Facilities in Japan" (prepared based on the 2010 issue, containing FY 2009 results), Japan Nuclear Energy Safety Organization

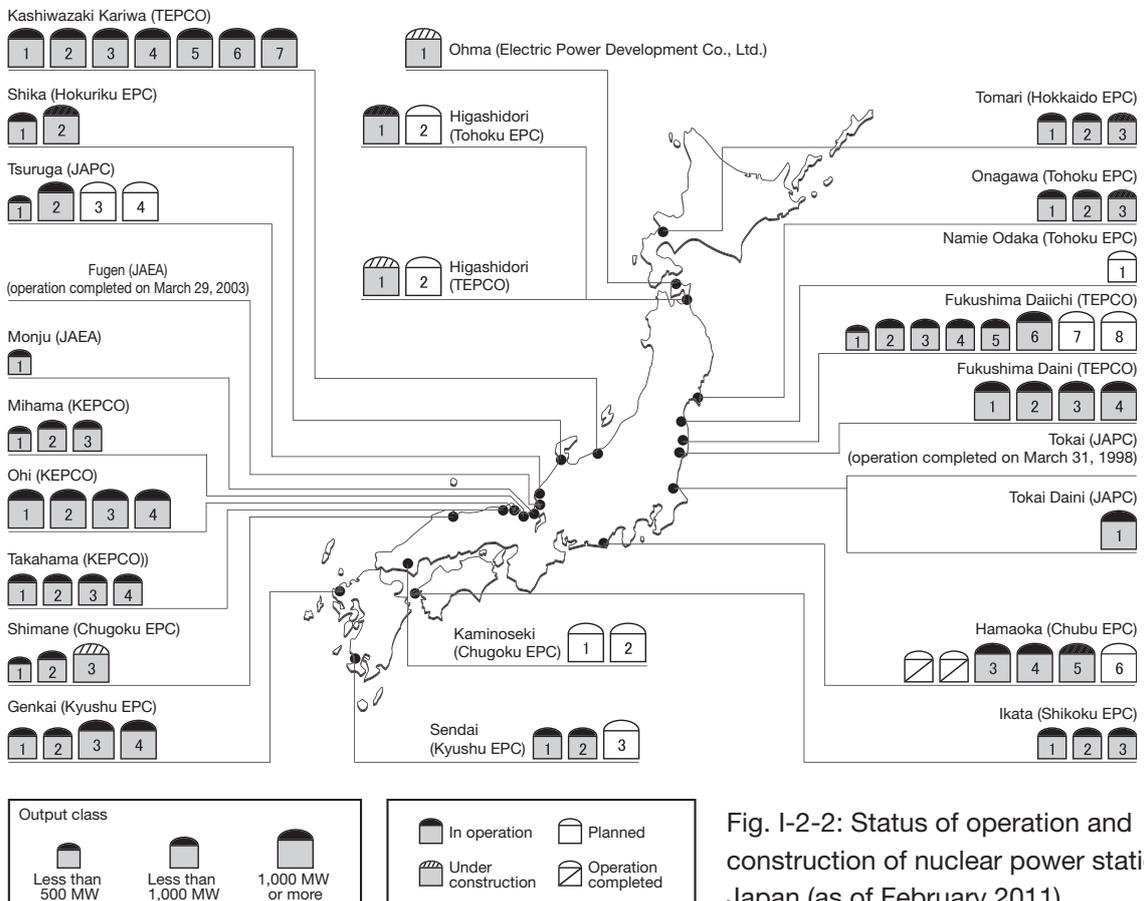


Fig. I-2-2: Status of operation and construction of nuclear power stations in Japan (as of February 2011)

3. Plant Capacity Factors and Operating Performance

The unscheduled shutdown rate among the operating nuclear power plants in Japan has been maintained at a level of about 0.2-0.4 times per reactor-year in the past several years. This rate is an order of magnitude lower than those in other countries.

The plant capacity factor had been constantly maintained at a level of 70% to 80% after it exceeded 80% in FY 1995. However, this figure dropped to 50% to 60% in FY 2003 and 2004.

The reason is that some deceptive records were found in self-controlled inspection conducted in August 2002. The plant capacity factor in FY 2007 and 2008 dropped to approximately 60% due to such factors as the shutdown of a power station resulting from the Niigataken Chuetsu-oki Earthquake, increased outage periods for periodic inspection and other problems.

Figure I-3-2 shows a breakdown of the operating performance in FY 2009.

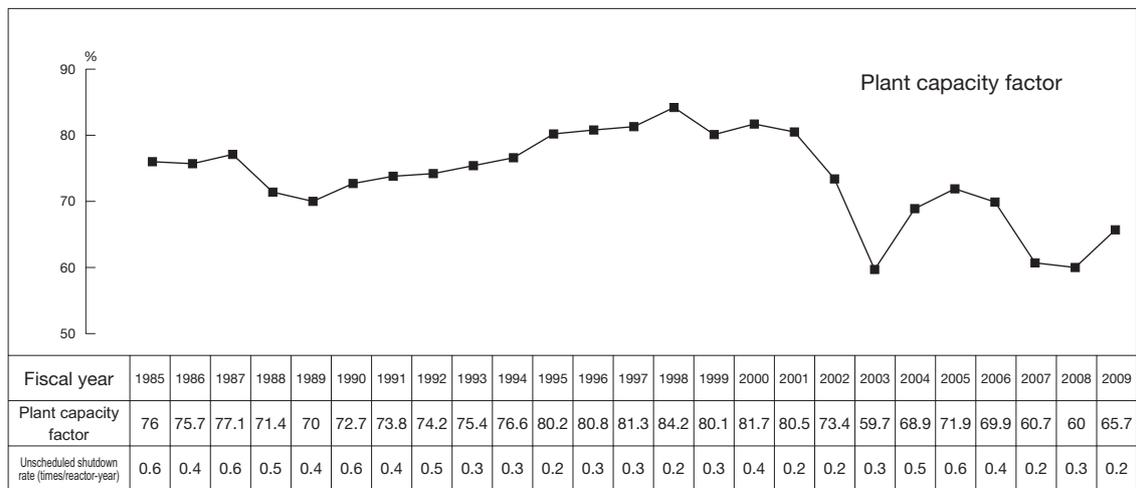
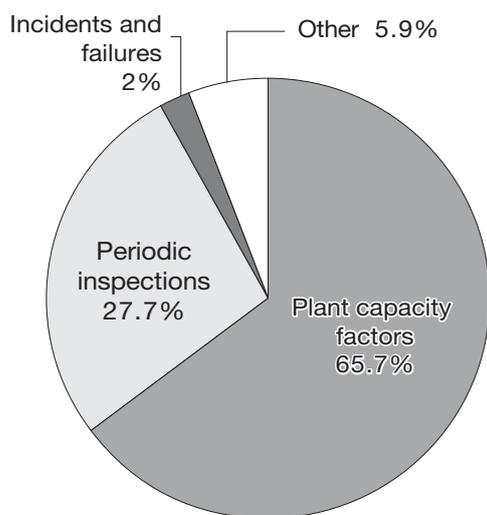


Fig. I-3-1: Trend of plant capacity factors and unscheduled shutdown rates in Japan

“Operational Status of Nuclear Facilities in Japan” (prepared based on the 2010 issue, containing FY 2009 results), Japan Nuclear Energy Safety Organization



Periodic inspection includes plant shutdown due to earthquakes and shutdown for upgrading.

Note: The sum of the values shown in the graph is not 100% because of rounding off.

Source: “Operational Status of Nuclear Facilities in Japan” (prepared based on the 2010 issue, containing FY 2009 results), Japan Nuclear Energy Safety Organization

Fig. I-3-2: Operating performance of LWRs in Japan (in FY 2009)

4. Code and Regulatory Systems for Constructing Nuclear Power Plants

Any electric utility planning to construct a nuclear power plant must submit an application for reactor establishment permit and an application for modification permit for electric power station equipment to the government and must undergo safety reviews to get the licenses. After the licenses are granted, the electric utility needs government approval for the design and construction methods. Following this approval, the electric utility is obliged to carry out various inspections for each construction process and receive supervision and checking by the government. In addition, the electric utility must also obtain approval from the government as to its fitness-for-safety programs before starting operation of its nuclear power plant. These programs describe important items for safety operations, such as power plant operation and management, patrol checking, radiation control and radioactive waste management, as well as items for quality assurance. Even after the power plant is strictly reviewed by the government as described above, and begins operation on a commercial basis, it must undergo inspections conducted by the government and Japan Nuclear Energy Safety Organization (JNES) on a periodic basis (within 13 or 18 months, under Article 91 of the revised Rules for the Enforcement of the Electric Business Act (hereinafter referred to as Electric Utility Industry Law) to confirm that its safety functions are maintained. In addition, it is also confirmed four times a year that the fitness-for-safety programs are complied with. This confirmation is performed along with safety inspection conducted by the government.

Furthermore, self-controlled inspections by electric utilities have been stipulated clearly by law as utilities' periodic inspection in October 2003. The scheme for implementing such inspections is verified by the JNES, which conducts periodic safety management review, and is evaluated by the government. Concerning welding inspection, since July 2000, nuclear power plants have been required to undergo welder inspections conducted by electric utilities, and the status of their implementation is checked through welding safety management review by the JNES and evaluated by the government.

Reviews, licensing, and other governmental inspections are conducted on the basis of two laws, Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter referred to as the Reactor Regulation Law) and the Electric Utility Industry Law, as shown in Fig. I-4-1.

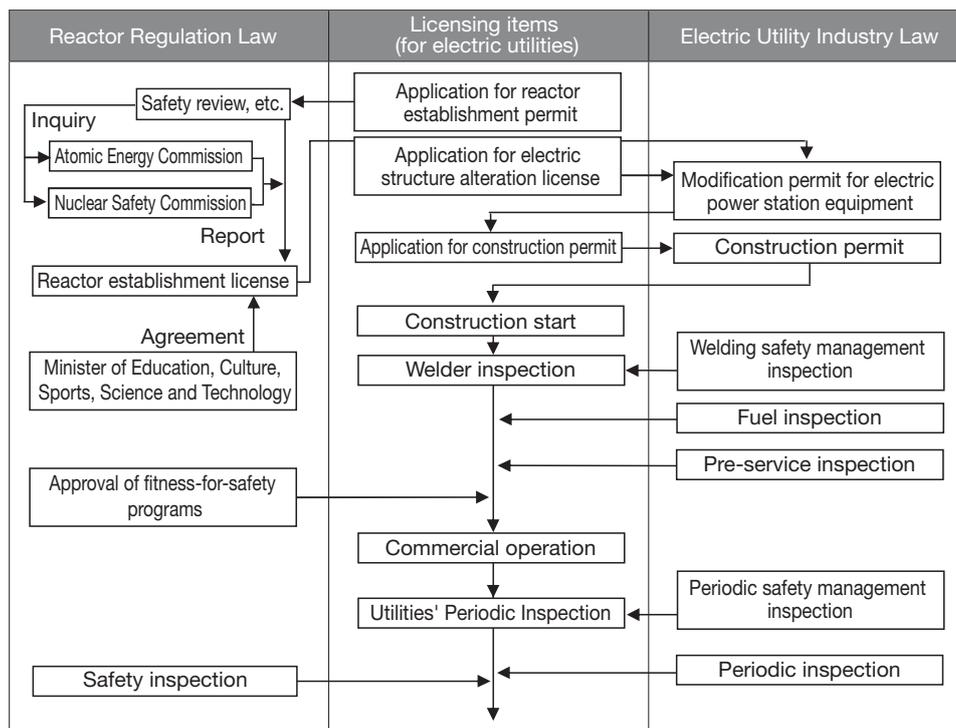


Fig. I-4-1: Code and regulatory systems for the construction of nuclear power plants

5. Flows of Activities for Enhancing the Safety and Reliability of Nuclear Power Plants

The government sufficiently reviews in terms of basic design and basic design policy with its safety review, and the findings are incorporated into nuclear power plants to enhance safety and reliability.

At the subsequent design stage, the electric utility and plant manufacturers (including the manufacturers of pumps, valves, instruments, etc.) will jointly verify their facilities and systems to obtain license from the government. In this process, they apply various reliability analysis techniques, such as the failure mode and effect analysis (FMEA) and fault tree analysis (FTA), for supporting the quality assurance of nuclear power plants.

At the subsequent stages of manufacturing, installation and pre-operation, quality checks by the electric utility, including weld inspection, and quality checks by the government, including pre-service inspection and welding safety management review, are performed according to the level of importance of equipment or facilities. Thus, joint efforts involving the public and private sectors are made to enhance safety and reliability.

Once plant construction is complete and operation is to begin, the electric utility's operating experiences are fed back to the plant manufacturer. When failure or a problem occurs, the causes of any troubled items are clarified and measures to prevent recurrence are taken. This information, in addition to corrective action, is spread and reflected in utilities' periodic inspection, and serves to maintain and improve equipment and facilities and achieve higher plant reliability.

The implementation of these quality assurance activities of the electric utility is ensured by both the government and the JNES, which conducts welding safety management reviews, pre-service inspections, periodic safety management reviews, etc., in order to maintain neutrality and fairness. This aims to further enhance safety and reliability.

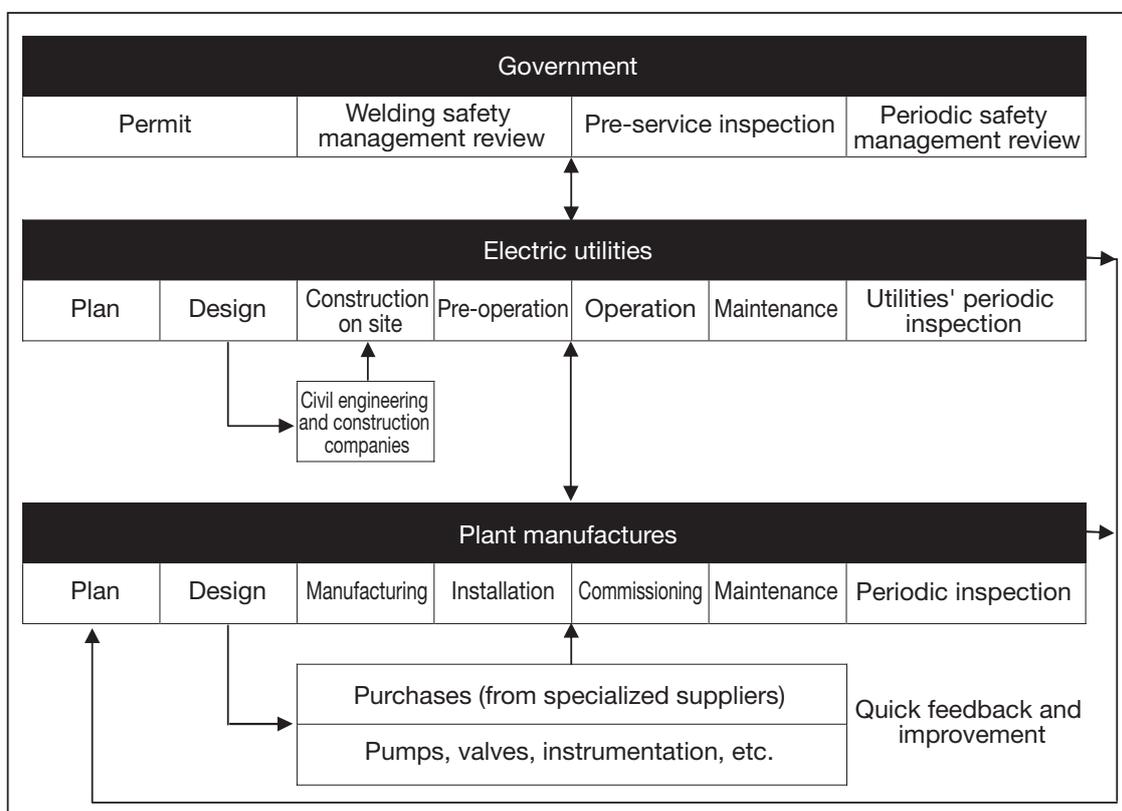


Fig. I-5-1: Flows of Activities for Enhancing the Reliability

6. Present Status of Advanced Reactors and Nuclear Fuel Cycle Facilities

In Japan, a country with scarce energy resources, nuclear power development is a very important task to provide a major alternative energy source replacing fossil fuel and make the country more energy self-sufficient.

LWRs, most widely used in the world as a reactor for power generation, are a reactor type already having a sufficient track record and will remain mainstream in future nuclear power generation in Japan.

A fast breeder reactor (FBR) is also being developed for practical use from the viewpoint of effective utilization of uranium resources, reinforcement of Japan's energy supply base, and securing of energy for international society.

The process of manufacturing fuel assemblies from uranium ores through conversion, enrichment, reconversion and fabrication, and the flow of reprocessing spent fuel and reusing the retrieved plutonium and uranium for nuclear fuel are referred to as the “nuclear fuel cycle,” which is essential for the effective use and stable supply of nuclear fuel.

In Japan, construction of a commercial spent fuel reprocessing plant is underway aiming at early materialization of the nuclear fuel cycle. In addition, as for FBR, performance testing has been conducted with the aim of starting the operation of the Monju prototype reactor, and the development of commercial and demonstration reactors has been in progress with the goal of achieving commercialization in around 2050.

The present status and future plans for nuclear fuel cycle facilities are shown in Fig. I-6-1.

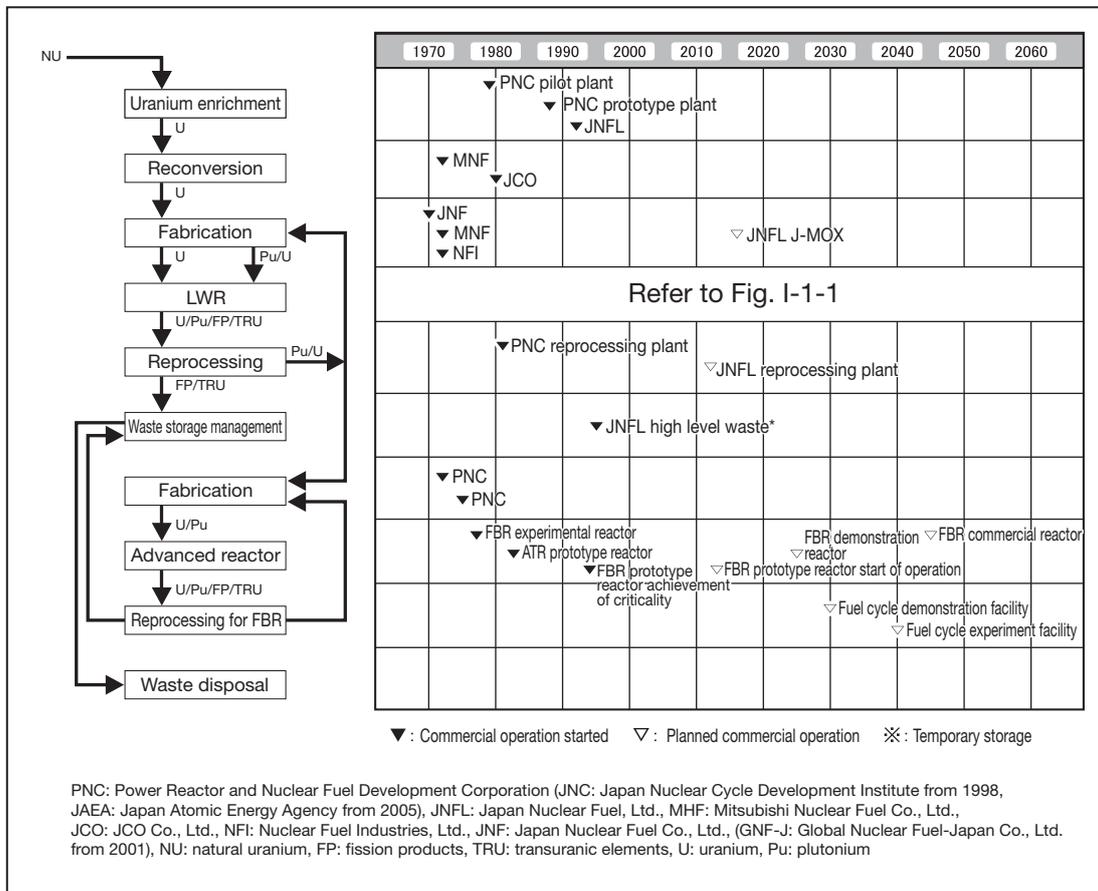


Fig. I-6-1: Timing of the start of operation of nuclear fuel cycle facilities (as of February 2011)

7. Future Activities for Nuclear Power

Concerning future activities for nuclear power, it is essential to pursue the research, development, and use of nuclear power according to the Atomic Energy Basic Act (hereinafter referred to as the Atomic Energy Basic Law) to secure energy resources for the future and facilitate academic and industrial advancement, so as to contribute to the welfare of human society and improvement of the national living standard.”

While observing these fundamentals and responding to the needs of the times, and with the aim of having nuclear installations widely accepted by society, it is necessary to address technological issues such as “sophistication,” “life extension,” “availability improvement,” “extended-cycle operation,” “power uprating,” and “decommissioning” of LWR power plants from the standpoint of manufacturers, and to establish and extensively conduct quality assurance activities in order to ensure and maintain safety and reliability at a high level in all stages from siting to decommissioning of nuclear installations.

One of the objectives of quality assurance activities at manufacturers is, in short, to “satisfy applicable statutes, standards, codes, and customer requirements for quality, and achieve, maintain and improve nuclear safety, which is the overriding objective, by providing highly safe and reliable products and services to customers.” To achieve this objective at a high level in an enormous system like a nuclear power plant, it is necessary to establish and strengthen a quality management system that allows a prompt and flexible response to changes in society, and to continuously improve the effectiveness of the quality management system through consistent quality assurance activities with social responsibility in mind.

To achieve, maintain and improve nuclear safety in terms of “attaching importance to compliance” and “fostering safety culture,” which will serve as the foundation for achieving the above objective, it is vital to remain trusted by society by thoroughly complying with the statutes, standards, and codes in good faith, fostering culture that gives the highest priority to nuclear safety while recognizing social responsibility as manufacturers, and responding to social demands for fulfilling the relevant accountability.

In addition to ensuring and maintaining nuclear safety by raising awareness of safety and compliance, improving ethics and sharing safety culture among those involved in the nuclear industry, we will continue to work on the disclosure of information, public acceptance (PA) activities, etc. for winning trust in and understanding of nuclear energy from local residents and the public.

II. Quality Assurance of Nuclear Power Plants

1. Characteristics of Quality Assurance of Nuclear Power

The “quality assurance” in the ISO9000 series is “part of quality management focused on providing confidence that quality requirements will be fulfilled” It is said that “demonstration” is required to provide a sense of trust. Put simply, this term is defined as “providing confidence in the ability to provide something promised through demonstration with evidence.”

The nuclear industry is strongly required to achieve “nuclear safety” because of its own characteristics.

Nuclear safety means “the achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards..” To achieve nuclear safety, it is necessary to give top priority to considering nuclear safety appropriately according to the importance of each duty when making individual decisions, and the attitude and status of an organization or individual who makes such individual decisions (concept of “safety culture”) are important.

“Safety” means that operating a nuclear installation, in a technical sense, will pose no possibility of accident such as radioactive leakage. “Safety” of a nuclear installation should be achieved through the integrity of the installation's facilities and the ensuring of “safety culture” by humans who operate and manage the installation. Furthermore, a “sense of safety” is provided to community people through the build-up of “safety” efforts and disclosure of information by utilities and regulatory agencies.

On the other hand, a “Study Group on Inspection Practices” under the Nuclear and Industrial Safety Subcommittee of the Advisory Committee for Natural Resources and Energy METI was inaugurated in 2002 to deal with problems such as dishonesty in self-controlled inspection records at nuclear power plants, and the Study Group proposed that quality assurance should be introduced in safety regulations. In response to this proposal, ministerial ordinances under the Reactor Regulation Law were revised in 2003, and quality assurance requirements for nuclear safety were placed on utilities as a national regulation.

Utilities aim to achieve “nuclear safety” by building their quality management systems in accordance with the “Quality Assurance Code for Safety in Nuclear Power Plants: JEAC4111,” which has been formulated as a private-sector standard conformable with this regulation.

Quality management systems in the nuclear industry are based on ISO9001, which is an international quality assurance code. They are characterized by the intention to achieve nuclear safety built on safety culture, management by grading (management according to the required safety and importance levels of products), independence of inspectors (strict inspection by personnel or divisions other than those involved in design or manufacturing), and verification in design control by those other than the original designers who actually did the designing.

This code is a direct requirement for utilities and not a requirement for manufacturers. However, manufacturers have established quality assurance systems that reflect the requirements provided by utilities, and are conducting quality assurance activities.

In quality assurance systems of manufacturers, the customer is a utility that asks for products or services. However, it is important for manufacturers to conduct quality assurance

activities while bearing in mind that achievement of nuclear safety through the utility is the goal. In other words, achieving nuclear safety, not just serving for short-term benefits to the customer, will lead to true benefits to the customer.

Manufacturers are also working on overseas nuclear power plants and preparing required quality management systems, as represented by the safety regulation system of the U.S. NRC.

NRC: U.S. Nuclear Regulatory Commission

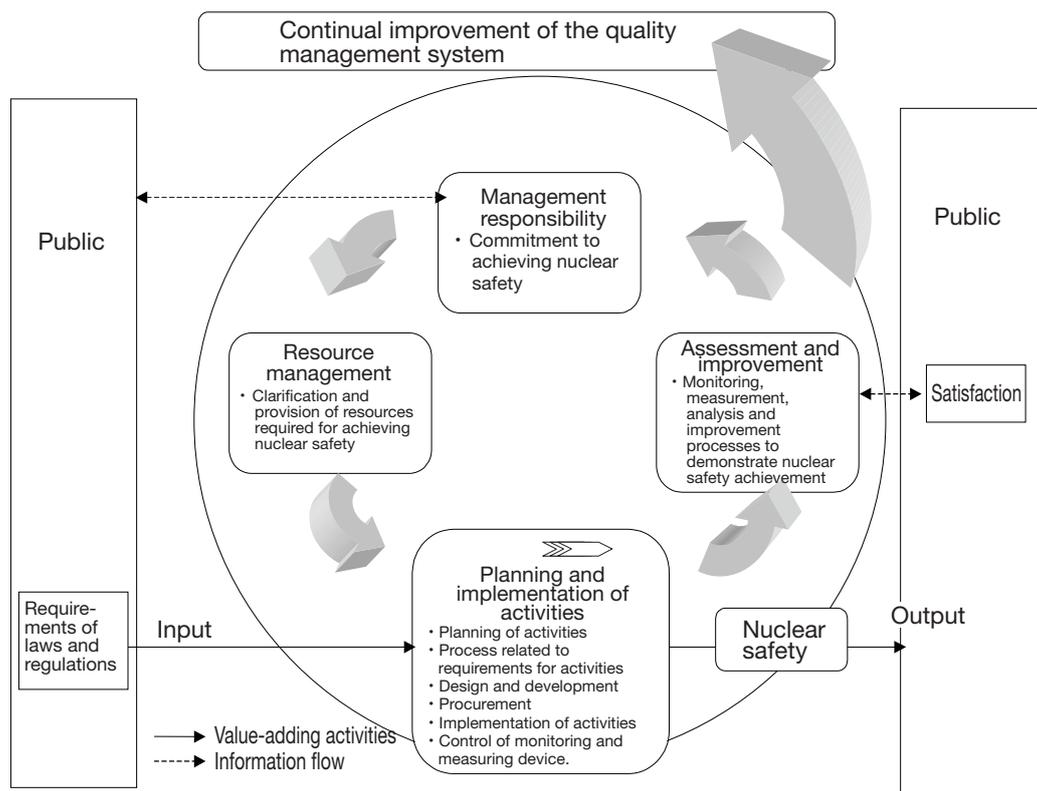


Fig. II-1-1: Model of quality management system for securing the safety of nuclear power plants

Source: "Quality Assurance Code for Safety in Nuclear Power Plants: JEAC4111-2009" of the Japan Electric Association Model based on adaptation of the ISO9001 model to nuclear safety

2. History of Quality Assurance Codes

As a guideline to quality assurance of nuclear power plants, the Japan Electric Association established the “Guide for Quality Assurance of Nuclear Power Plants” (JEAG4101-1972) in 1972 while referring to the Code of Federal Regulations (10 CFR 50 Appendix B). Afterward, the guideline was issued as the “Quality Assurance Policy for Nuclear Power Plants” (JEAG4101-1981) on the basis of the “Code of Practice for Quality Assurance for Safety in Nuclear Power Plants” (50-C-QA) established by the International Atomic Energy Agency (IAEA), and then revised four times until 1993.

The IAEA 50-C-QA was revised in 1996 and publicized as the “Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations: Code and Safety Guides” (50-C/SG-Q) in the same year. Following this revision, the guidelines were modified again on the basis of the revision, taking into account the knowledge, experience and results in Japan and reflecting the operating status and results, and were eventually issued as JEAG4101-2000, which is used widely in the nuclear industry as a quality assurance guideline for nuclear power plants and has made great contributions to the establishment of quality assurance systems and promotion of quality assurance activities (see “Fig. II-2-1 System diagram of quality assurance codes”). The ministerial ordinances under the Reactor Regulation Law were revised in October 2003, and quality assurance requirements for nuclear safety were specifically stipulated. To embody these regulatory requirements for quality assurance, the “Quality Assurance Code for Safety in Nuclear Power Plants” (JEAC4111-2003) was established, and JEAC4111-2009, which adopted subsequent ISO9001 revisions and other inputs, was issued. JEAC4111-2009 provides its policy for “products,” “customers” and “quality,” which are among the requirements of ISO9001:2008, so that it can be applied to nuclear power plants. JEAC4111-2009 has the following characteristics:

- a) It is based on ISO9001:2008, with modifications to facilitate its use at nuclear power plants.
- b) While being based on ISO9001:2008, it also adopts the contents of the IAEA's Code and Safety Guides on Quality Assurance 50-C/SG-Q (1996) to ensure consistency with the existing guidelines as well as the contents of the IAEA's safety standards series GS-R-3, GS-G-3.1 and GS-G-3.5.
- c) It contains definitions of terms that are specific to JEAC4111-2009 and different from the ISO9001:2008, such as setting a legislative limit for the top management required in ISO9001:2008.

In light of the above quality assurance regulations for utilities, Annex-1 “Standard Quality Assurance Specification Concerning Quality Management Systems” of JEAG4121 was issued as a quality assurance specification that should be observed by the suppliers and subcontract suppliers of utilities. This specification is based on ISO9001 in light of the fact that a third-party certification of ISO9001 has recently become common, and it contains additional requirements from JEAG4101, measures against recurrence of nonconformities, etc. In addition, the “Standard Quality Assurance Specification Concerning Quality Management Systems” serves as the basis of an applicable procurement specification when a utility requires its supplier to provide a quality management system.

In response to such procurement specifications of utilities, manufacturers (as suppliers to utilities) establish quality management systems in accordance with the “Standard Quality Assurance Specification Concerning Quality Management Systems” and manufacture the products to be supplied.

In response to this movement, the JEAG4101-2000 “Guide for Quality Assurance of Nuclear Power Plants” was abolished in FY 2008, which means that the Japan Electric Association will no longer maintain or manage the Guideline.

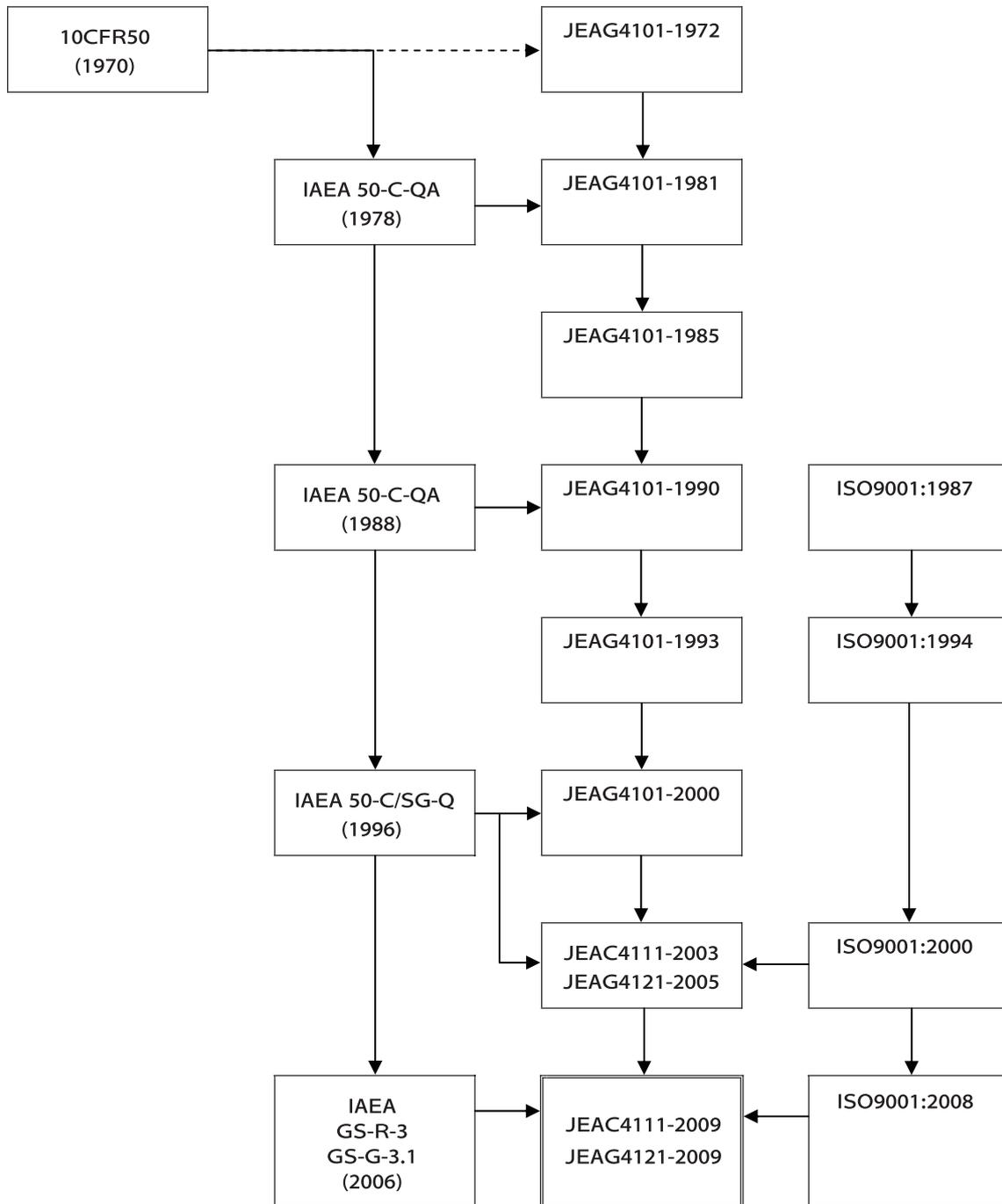


Fig. II-2-1: System diagram of quality assurance codes

III. Characteristics of Quality Management Systems at Nuclear Power Plants

This chapter describes the characteristics of activities that manufacturers conduct in accordance with ISO9001:2008 and Annex-1 “Standard Quality Assurance Specification Concerning Quality Management Systems” of JEAG4121-2009.

1. General Requirements of Quality Management Systems

A quality management system is defined as a “management system to direct and control an organization with regard to quality” in “3.2.3 Quality Management System” of JIS Q 9000, and as a “system to establish policy and objectives and to achieve those objectives” in “3.2.2 Management System” of JIS Q 9000. With these two definitions combined, the quality management system would be considered as a “system for supervising and managing an organization to set quality policies and quality objectives and to achieve the objectives.” In other words, it is a system that is based on determining policies, setting objectives, conducting activities for achieving the objectives, and continuously improving the effectiveness of the system.

Manufacturers have established, documented, implemented and maintained their quality management systems as described in the items below, have followed the PDCA (plan-do-check-act) cycle, and have continuously improved the effectiveness of the quality management systems.

- a) Determine the processes needed for the quality management system and their application throughout the organization (quality management system diagram).
- b) Determine the sequence and the interaction of these processes (quality management system diagram).
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- e) Monitor, measure and analyze these processes (internal audit, testing/inspection, etc.).
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

If a manufacturer outsources some of the processes, it defines, in the quality management system, the method and degree of management to be adopted in the outsourced processes to ensure that the outsourced processes will be properly managed.

In operating their quality management systems, manufacturers also grade the degree of application of quality management system requirements according to the importance of products in terms of nuclear safety. An example of basic policy for grading according to the importance of products in terms of nuclear safety is the “Examination Guide for Classification of Importance of Safety Functions for Light Water Nuclear Power Reactor Facilities.” Manufacturers also refer to the “Guide for Design and Instrumentation & Control Equipment with Safety Functions (JEAG4611)” and the “Guide for Grade Classification of Electric and Mechanical Equipment with Safety Functions (JEAG4612).”

2. Control of Documents and Records

(1) Control of Documents

In operating their quality management systems, manufacturers define the method for controlling documents required for the quality management systems, in other words, documents required for their operations.

Each manufacturer, as an organization, lists the documents required for the quality management system by judging what and how to control based on its own need and responsibility, and establishes a controlling method that can flexibly respond to changes in practical business.

Specifically, each manufacturer establishes practical execution rules of documentation considering the following points, documents the rules, and control documents according to the rules.

- a) When a document is prepared, a person responsible for review and approval is appointed for each document, and the person approves the document from the viewpoint of whether it contains necessary and sufficient information.
- b) Documents shall be periodically inspected in accordance with a rule established beforehand [reviewing]. If the content of a document becomes inconsistent with reality or unnecessary, revise or abolish the document as necessary [updating]. If a document is of external origin, replace it with the latest version as necessary. When revising a document, the organization or responsible person who initially prepared the document shall closely examine the content and re-approve it [re-approval].
- c) When changing a document, make sure that the users of the document can identify the change [identification of document change]. Indicate the revision number and date so that the current revision status can reliably be identified [identification of current revision status].
- d) Keep documents accessible so that the document users can view the latest version at any time (including prevention of old versions from being mistakenly used). Use the latest version of each document in principle (control documents so that their old versions will not be mistakenly used). In cases where an old version is used in response to a request from the customer, etc., control its use reliably [use of appropriate documents].
- e) Control documents so that they remain accessible. It is therefore necessary to take care in handling them. Give titles and control numbers to documents so that they can be easily identified [legible and identifiable state].
- f) For documents of external origin (contracts with manufacturers, drawings, specifications, applicable laws, codes, etc.), clarify which documents should be controlled and ensure that their distribution and latest versions are controlled [use of external documents].
- g) Remove obsolete documents (including old versions) from places where documents are used in order to prevent them from being mistakenly used. If it is necessary to keep them for some purpose, put them in a place other than the place for storing the latest versions, and control identification to prevent them from being mistakenly used by attaching labels such as "old version," "obsolete" and "do not use" [prevention of obsolete documents from being mistakenly used].

(2) Control of Records

ISO9001:2008 defines that “records shall be prepared and maintained in order to provide evidence of conformity with the requirements and effective operation of the quality management system.” The purpose of controlling records is to prepare and maintain them in order to indicate with evidence that the quality management system has been operated as planned as a result of the functioning of the organization's operation mechanism. Manufacturers control records by defining and documenting control rules appropriate for their organizations.

- a) In defining the scope of preparing records, focus is placed on the aspect of “‘demonstration’ for giving a sense of trust,” and care is taken so that records will not be excessive. Therefore, it is preferable to define the scope in advance with design specifications, procurement documents, testing/inspection reports, operating instructions, etc. Control methods are established so that prepared records are accurate and easy to read, specific record items can easily be identified (e.g., content, place, date/time), and stored records can easily be found. The environmental condition of storage is considered and the recording medium is selected so that records will not be deteriorated or damaged during the retention time.
- b) Control rules are also defined for the handling of records including the submission, reception, correction, addition, retrieval and viewing of records. The person handling records recognizes the importance of the records and ensures that they are not lost or damaged when submitting or receiving.
- c) Storage of records

It is necessary to clarify the type and retention time of records and define the control method for the storage. The “retention time” here means the period in which evidence of conformity with the requirements and effective operation of the quality management system is required. The retention time is determined using the grading approach as appropriate, taking into account the retention time based on the Rules for the Installation, Operation, etc. of commercial power reactors and the final period in which records are used for verifying the state of nuclear safety achievement.

(Reference 1)

Generally, there are three ways of storing records: storing and controlling original paper records; storing and controlling originals after digitizing them in some form; and storing and controlling originals by using the former two methods simultaneously.

The following describes a typical procedure in which records are stored and controlled in the forms of original paper and digitized data.

The original paper records to be controlled are digitized and registered using a device such as a scanner.

The digitized data is compared with the original to check that it contains no missing pages, leaning, smudge, blur, etc. and can be read correctly.

The originals are provided with identification such as indexes so that they can be promptly retrieved for reference and stored and controlled in a storage place under appropriate temperature, humidity and other conditions for preventing the records from being deteriorated, according to the classification of whether the records are stored permanently or temporarily.

That the digitized data is correctly registered is confirmed by accessing the digitally registered data once again.

From the viewpoint of preventing records from being lost due to disasters, accidents, etc., a dual record storage and control structure is established, such as locating the storage of originals and the storage of digitized data at sufficiently distant places, or storing digitized data in two separate places that are sufficiently distant from each other.

(Reference 2)

Control of quality records related to nuclear power plants has traditionally been conducted by manufacturers under common policies defined by related laws and regulations as well as codes and standards such as those of JEAG.

(Reference 3)

When correcting a record, it is necessary to take sufficient care to prevent the correction from being regarded as falsification. For example, correction using cover-up fluid or scissors and paste is unacceptable. Considerations are made, for example, by using a strike-through mark, adding a reason for correction and providing a signature of the corrector in the margin of a sheet, even though it may compromise the neat appearance of the record.

3. Quality Policy, Quality Objective and Management Review

(1) Quality Policy

“Quality policy” indicates the quality-related objective and direction of each organization. At manufacturers, their top management in the field of nuclear energy has declared “quality policies” as their commitments, on the basis of their corporate philosophy and guidelines for achieving “nuclear safety” and fostering the underlying safety culture.

Reference: JEMA Nuclear Safety Action Guidelines^{*1}

“Quality policy” expresses the intention of top management to comply with the quality requirements and continuously improve the effectiveness of the quality management system. When setting their quality policies, manufacturers refer to the “Eight Quality Management Principles.”^{*2}

^{*1} JEMA Nuclear Safety Action Guidelines (excerpt)

- 1. Maintenance and improvement of nuclear safety awareness
- 2. Review of operations
- 3. Enhancement of audit, and conduction of audit and evaluation by a third party
- 4. Sharing of information between nuclear related companies
- 5. Clarification of countermeasures and support measures in case of emergency

^{*2} ISO9000:2005 Eight Quality Management Principles (excerpt)

- 1. Customer focus
- 2. Leadership
- 3. Involvement of people
- 4. Process approach
- 5. System approach to management
- 6. Continual improvement
- 7. Factual approach to decision making
- 8. Mutually beneficial supplier relationship

(2) Quality Objective

Manufacturers set their “quality objectives” by reflecting quality policies, evaluation results of management reviews, etc., and also set objectives at necessary subordinate organizations or hierarchical layers in order to make their activities more effective. Each manufacturer encourages the organization members to deepen their understanding of the objectives by clarifying the position of the “quality objectives” within the activity objectives of the entire organization, so as to create an environment suitable for the members' activities.

As organizations, manufacturers set indexes for the status of objective achievement, and make consideration so that the indexes allow judgment of the level of achievement by, for example, quantifying target values as much as possible. In addition, when evaluating the achievement status, manufacturers not only evaluate the result but also the levels of effort and commitment toward achieving the objectives, so as to maintain motivation.

(3) Management Review

A management review is a means used by the top management to evaluate the effectiveness of the quality management system in order to respond to changes in the business environment, make necessary changes in “quality policies” and “quality objectives,” and provide an opportunity for improving the quality management system. The top management of each manufacturer expresses, through management reviews, their strong interest in achieving nuclear safety and quality assurance.

Figure III-3-1 shows the overall flow of the above items (1) to (3).

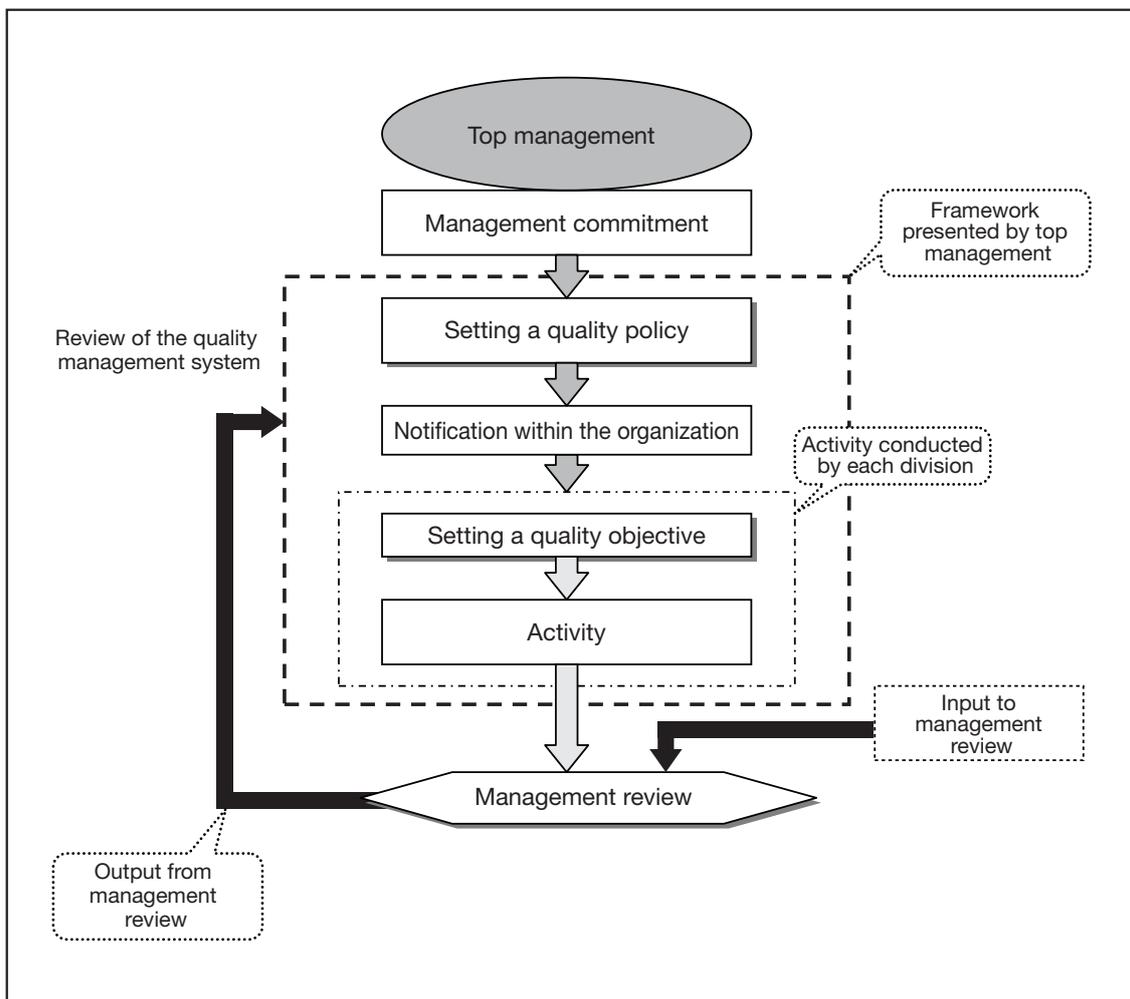


Fig. III-3-1: Flow of quality policy, quality objective and management review

4. Responsibilities, Authorities and Communication

Operations at a manufacturer include various processes involving many divisions.

To ensure that a quality management system effectively functions, it is necessary to clarify the responsibility and authority of each process and notify them throughout the organization. Therefore, the quality manual of each manufacturer contains an organizational chart and the responsibility and authority of each division involved in the QMS process. In addition, the manufacturer prepares and maintains an organizational function chart for each division (department or section) as necessary, making the responsibilities and authorities more detailed and specific.

The top management appoints an appropriate person as the quality management representative, and has him/her lead the organization in improving customer satisfaction and achieving nuclear safety. The head of the quality assurance department or the like who can act for the top management is appointed as the management representative, and he/she has the following responsibilities and authorities.

- a) ensure that processes needed for the QMS are established, implemented and maintained.
- b) report to the top management on the performance of QMS and any points needed for improvement.
- c) ensure the promotion of awareness of the customer requirements and nuclear safety throughout the organization.

An internal communication process in which necessary information is reliably communicated to divisions requiring the information is clarified in order to make the elements of the quality management system function effectively. This internal communication is usually conducted at various meetings such as a “project promotion meeting,” “product planning and development meeting” and “nonconformity study meeting.” Manufacturers implement various measures to improve communication, such as clarifying the purposes and attendants of these meetings, adopting an appropriate way to distribute data and adopting an information technology (IT) system that supports communication.

5. Competence, Education, Training and Awareness

Humans are the most important element of managerial resources not only in manufacturers, but also in other types of companies. To develop an organization, it is essential to establish an education and training structure for enhancing the abilities of individuals and to efficiently pass on skills. Manufacturers intend to maintain and improve the knowledge, experience and technological capabilities required to accomplish their operations by conducting competence management, education and training in a planned and systematic manner for personnel engaged in operations that may affect product quality. In addition, manufacturers manage designers, design reviewers, design verifiers, inspectors, internal auditors, etc. by establishing internal qualifications, certifying those with experience, skill and knowledge above a certain level, and registering them on a list of qualifiers.

Concerning competence evaluation, the administrator at each division manages the proficiency levels of personnel within the division regarding elemental skills required for the operations of the division by preparing a map that quantifies proficiency levels (elemental skills map) in each fiscal year. Using the elemental skills map, the administrator formulates an annual education plan for each person after identifying his or her strengths and weaknesses. Meanwhile, personnel recognize their current skill levels through interviews with the administrator or other means in an effort to cultivate themselves. In addition, the administrator evaluates the effectiveness of personnel education and training from attendance reports and other education records as well as progress in daily duties.

Education and training conducted are organized into such areas as layer-specific education, quality management education, specialty education, qualification education, pre-assignment education, ethical improvement education, re-education/re-training and OJT (on-the-job training). The forms of education include company-wide training, divisional training and external training. The administrator formulates long-term and short-term education and training plans for each person in accordance with the elemental skills map, tracks the status of implementation of the plans, and records and maintains an education and training history for each person. Some characteristics of the field of nuclear energy are described below.

In the field of nuclear energy, nuclear safety is especially important. Manufacturers therefore conduct nuclear safety education and compliance education for thorough understanding of the importance of law compliance and corporate ethics.

As for designers, manufacturers extensively cultivate them as system engineers in addition to having them learn advanced elemental skills through specialized education. As regards technicians, manufacturers certify those who have received education and training on key basic operations such as screw tightening, terminal crimping and soldering. Concerning skills in special processes such as welding, heat treatment and nondestructive inspection, manufacturers provide education and training to workers for skill certification and periodic updating. Those who engage in operations requiring official qualification, such as slinging work and hazardous material handling, are also registered on the list of qualifiers. As for workers engaged in pre-operation, manufacturers intend to improve their technical capabilities by providing simulative operation training or the like at training facilities in addition to ordinary education for deepening their understanding of the entire plant.

Because installation and modification work and periodic inspection on site are extensively performed, manufacturers cultivate highly skilled instructors and dispatch them to the site, and provide education regarding general nuclear, specialties and radiation safety to all workers engaged in site work before they are dispatched to the site. In addition, at the site, manufacturers provide education to workers at the time of their entering the plant, including quality control and radiation control, and before starting their work, and provide daily education through toolbox meetings (TBMs), etc.

6. Customer-Related Processes

This section summarizes the requirements given in “7.2.1 Determination of requirements related to products,” “7.2.2 Review of requirements related to the products,” “7.2.3 Customer communication,” and “8.2.1 Customer satisfaction” in ISO9001:2008, and describes specific customer related processes used by manufacturers.

(1) Preparation of plan

The manufacturer prepares a plan that specifies the project process including the relevant statutes/codes/standards, implementation scheme, implementation items, content, delivery date, schedule and estimate conditions in accordance with the specification of requirements provided by the customer.

In the time schedule attached to the plan, the manufacturer stipulates, for each item, related implementation divisions, hold points set with the customer and designated by the coordinating division, and the like.

(2) Kick-off meeting with the customer (confirming/adjusting the implementation details, schedule, etc. with the customer before starting the work)

The manufacturer holds a kick-off meeting with the customer before commencing the work by using a plan or the like for confirming and coordinating hold points with the customer to check whether the work plan has any problem.

(3) Preparation of work procedures

Before performing the work, the manufacturer prepares work procedures that specify detailed work methods and steps (e.g., input data, work procedure/method, cross-divisional items, work schedule, check procedure, check sheet), and receives confirmation or approval from the customer.

(4) Checking with hold points with the customer

The manufacturer organizes matters requiring approval of the customer using hold points set with the customer in the plan, and receives confirmation or approval from the customer.

(5) Checking the implementation result

In preparing a report, the manufacturer specifies the period for preparing a draft report (including the checking period), internal review period, draft report correction period, report submission deadline, etc.

Before double-checking the implementation result, the manufacturer reconfirms the checking procedure defined in the work procedures. In addition, the manufacturer secures a sufficient period for reviewing prepared documents, and conducts an overall review. The manufacturer checks the checking method and the like based on evidence, validates the check process, and submits a report to the customer.

(6) Evaluation by the customer

To grasp how the customer evaluates the manufacturer, a direct interview with the customer and other methods are being used.

The manufacturer collects evaluation data from the customer by, for example, directly interviewing the customer for opinions and requests, accepts the customer's inputs with sincerity as valuable feedback, and makes use of them in improving future activities.

7. Design and Development

Activities conducted at the design and development stage aim to meet the customer requirements and the applicable statutory and regulatory requirements. Basically, they consist of formulation of design and development plans; control of design and development inputs/outputs; review, verification and validation of design and development; and control of changes in design and development.

In formulating a design and development plan, design and development stages, design interfaces between organizations, reviews appropriate for each stage, and methods and timing of verification and validation must be specified. In doing so, the manufacturer adopts a grading approach according to the complexity of design and development, novelty, importance of equipment and assumed risk.

In particular, if a special material or new technology for which no official standard is defined is adopted, it is required to exchange information between the parties concerned (customer, supplier, etc.) as necessary, in addition to conducting examination, so that the meaning and importance of the material specifications, technical contents, etc. are fully understood. The manufacturer reflects such information in the design and development plan (a lesson learned from the cask issue*).

In a review of design and development, the manufacturer not only confirms that the design and development result meets the requirements, but also makes an evaluation from diversified viewpoints with the participation of specialists in the respective fields.

Verification of design and development is conducted through design and development reviews, alternative calculation, manual calculation, demonstration test, comparison with similar designs, checking of design documents, etc., and it is stipulated that the verification of design and development shall be performed by someone other than the original designer. For analyses concerning collation of construction approval, application for permission, etc., the manufacturer specifies the required verification procedures for control, such as checking collation by a third party, in addition to verifying the computer programs used.

Validation of design and development must be completed before the product is used. It is conducted, for example, in performance tests at the factory, performance tests at the stage of installation at the nuclear power plant, and during pre-operation before the start of operation.

Changes in design and development are made using a design control method equivalent to that used for the original design. In addition to reviewing, verifying and validating the changes, the impact of the changes on the products already delivered is evaluated.

*: Falsification of data on the boron concentration of a neutron shielding material inside a spent fuel cask

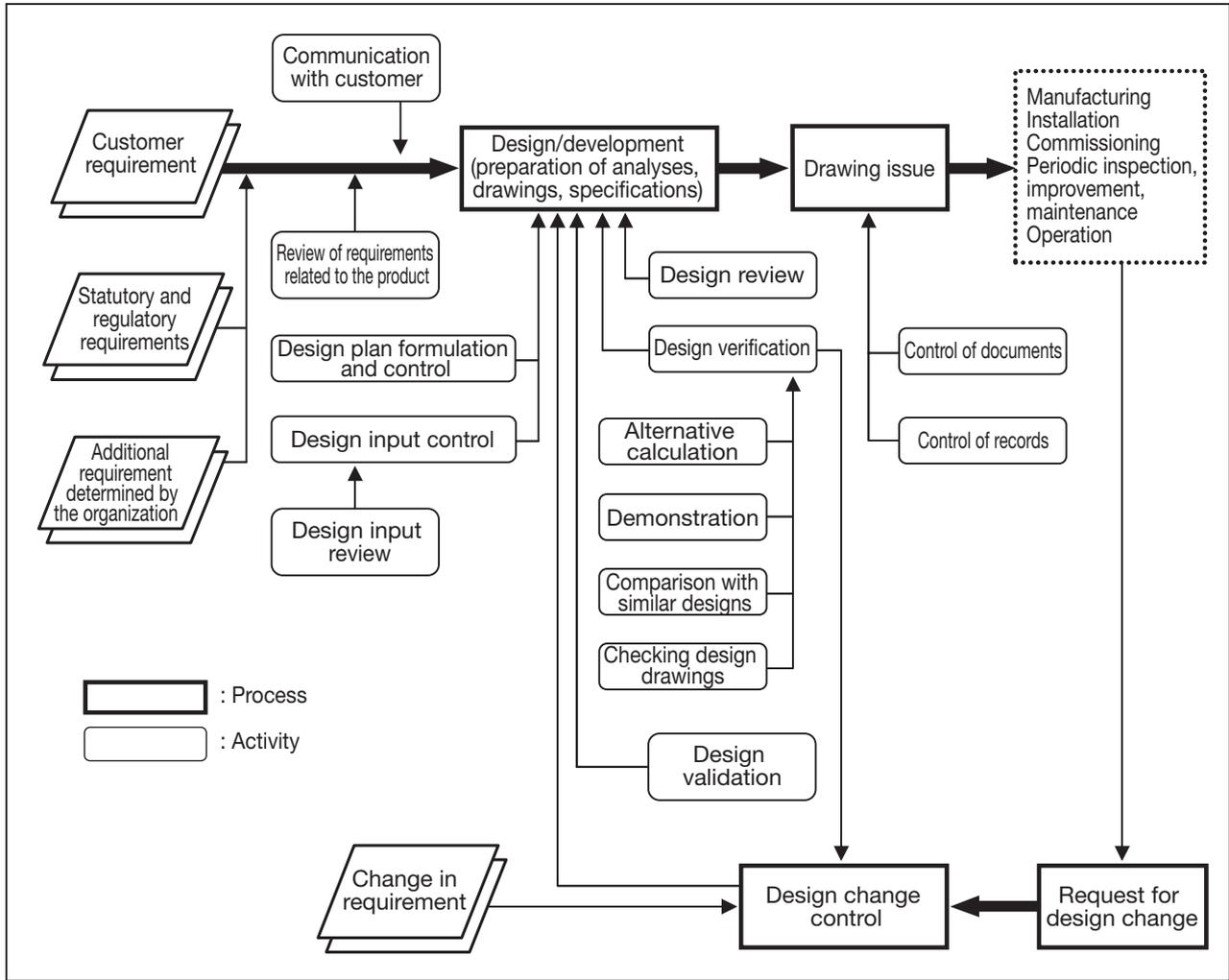


Fig. III-7-1: Flow of design control

8. Procurement Control

Before purchasers procure products for a nuclear power plant, it is important for the manufacturers to:

- clarify quality requirements in the procurement documents,
- evaluate suppliers' abilities to manufacture products and establish a smooth cooperative relationship with the suppliers, and
- establish verification systems for products to be procured.

In light of the lessons learned from the cask issue*, manufacturers (orderers) strive to facilitate liaison and coordination with suppliers (contractors) by, for example, checking whether the procurement schedule is unreasonable and would affect the quality. Figure III-8-1 shows the flow of product procurement operations.

The procurement of products for nuclear power plants entails the following:

- Products important to safety are inspected by the government according to the Electric Utility Industry Law.
- Since complicated products that are completed through a number of processes are difficult to check for conformity to their requirements by inspection at the final product stage only, manufacturing procedures are prepared so that the products can be inspected at predetermined intermediate checkpoints.
- Prior to manufacturing, manufactures review and discuss the design together with suppliers to confirm that any improvements and changes to the preceding plants are taken into consideration and that any problems in domestic and overseas plants are taken into account.
- If manufactures adopt a new design or construction method that is made available through technological development, they should begin discussion with suppliers at an early stage in order to identify possible problems and realize smooth introduction.

When procuring special materials for which no official standard has been defined, manufacturers intend to secure the quality of such special materials by adding requirements for controlling the issuance of a material certificate, checking the original data, etc. in light of lessons learned from the cask issue*.

*: Falsification of data on the boron concentration of a neutron shielding material inside a spent fuel cask

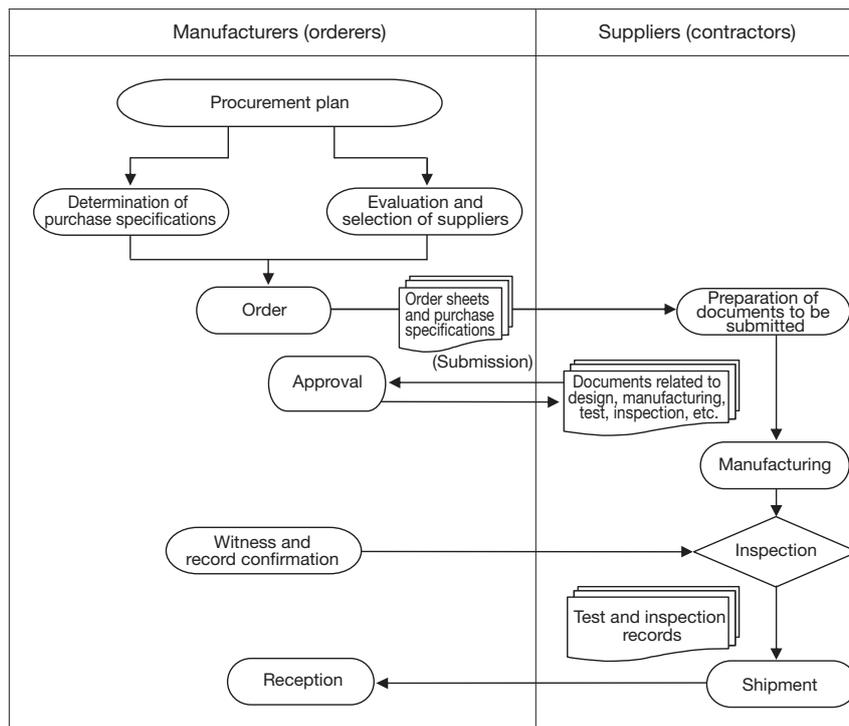


Fig. III-8-1: Flow of product procurement operations

9. Production and Service Provision

(1) Manufacturing Control

The most important aspect of manufacturing control is to ensure quality in the manufacturing process. Therefore, design requirements must first be clearly identified by means of documents, drawings, etc. Manufacturers strictly comply with codes, standards, procedures, instructions, drawings, etc. to fulfill the design quality.

Manufacturers conduct the quality control of manufacturing in the field of nuclear energy as follows.

a) Planning and preparation

Planning is important for manufacturing. Therefore, manufacturers formulate work standards, and organize construction methods and work procedures in the form of instructions. These instructions include a QC process chart or manufacturing procedure drawing where hold points are set. In particular, when adopting an innovative technique, manufacturers carefully study it.

Before starting work, manufacturers hold meetings among the parties involved for confirming the construction method and work procedures.

b) Work environment

Establishment and improvement of the work environment are widely practiced as a “5S” movement. 5S stands for Seiri (orderliness), Seiton (neatness and tidiness), Seiso (cleaning), Seiketsu (cleanliness), and Shitsuke (good manner)

In addition, manufacturers make efforts to improve occupational health and safety such as securing lighting, reducing noise and removing hazardous substances.

In many cases, stainless steel is used for nuclear industry products. To prevent stainless steel from being corroded, manufacturers set work zones, maintain cleanliness, control temperature and humidity, prevent dust and foreign material intrusion, and restrict the components contained in subsidiary materials (permanent markers, tapes, curing sheets, etc.).

In addition, manufacturers control temperature, humidity, etc. as necessary in order to prevent electric parts from being deteriorated.

c) Facilities, devices, jigs/tools, and measuring instruments

Appropriate facilities, devices, jigs/tools, and measuring instruments are used because they significantly affect quality. It is important to maintain and control them in order to secure the prescribed functions and accuracy, and therefore manufacturers conduct pre-work and periodic inspection

d) Identification

Various materials and parts are present at a manufacturing site. To avoid improper use and confusion, manufacturers manage identification of such items.

Identification methods are defined in procedures or the like, and practices such as indicating unique numbers using tags, stamps, etc. are performed. Care is taken to protect these marks from being erased. If a material is divided, its identification will be transferred accordingly.

Concerning the indication of the state of products, manufacturers identify whether the inspection is completed, whether the inspection result is satisfactory, and any nonconforming products.

e) Traceability

If a problem occurs with a product while the customer is using it after being delivered, it may be necessary to trace back the cause to the manufacturing stage and take some measures. Therefore, manufacturers maintain a manufacturing history and use it to enable any nonconformity to be traced back to the time and process where it

occurred. In particular, in cases where there are statutes, rules or customer requirements, manufacturers ensure that the product history can be traced.

At the manufacturing stage, manufacturers record the date/time, workers and manufacturing equipment used in a work report or the like so as to allow their identification. Manufacturers keep a series of manufacturing records to allow parts to be traced.

Materials can be traced in material certificates (Mill sheets) with identification marks.

f) Competence, education and training of workers

Manufacturers improve the skills of workers through education and training. There are operations requiring workers with official qualifications such as crane operation, slinging work and organic solvent handling, and those who have acquired the required qualification engage in such operations.

When necessary, manufacturers limit nut and screw tightening, crimping and soldering operations to in-house qualifiers who have been trained for key basic operations.

g) Implementation of operations

Workers perform operations in accordance with procedures or instructions. Manufacturers strive to secure the safety of workers by routinely holding toolbox meetings, etc., rechecking procedures and conducting risk prediction.

h) Schedule coordination

Manufacturers coordinate schedules at periodic schedule meetings and the like so that the schedules will not adversely affect the achievement of the required quality.i)

Shipping

Manufacturers ship products after completing all work, tests and inspections determined at the manufacturing stage. Before the product is shipped, final checks are performed, and a person responsible for shipping checks the result and issues a shipping permit.

j) Process validation (special process)

If an output at the manufacturing stage cannot be verified by the subsequent monitoring or measurement, it is necessary to demonstrate somehow that the planned result can be achieved. Manufacturers secure the required quality by confirming that the operation is performed with a correct method. In particular, manufacturers regard welding, heat treatment, cleaning, surface treatment, etc. as special processes and validate these processes. In addition, manufacturers validate an innovative technique when adopting it. To secure the reliability of these special processes, manufacturers define in the work procedures the methods for controlling facilities, jigs and tools as well as work procedures based on existing know-how, etc., have well-trained or experienced adept workers do the work, and perform operations in accordance with the procedures. To achieve this, manufacturers check the work procedures in advance, and check the qualification of personnel, facilities used, construction records, etc.

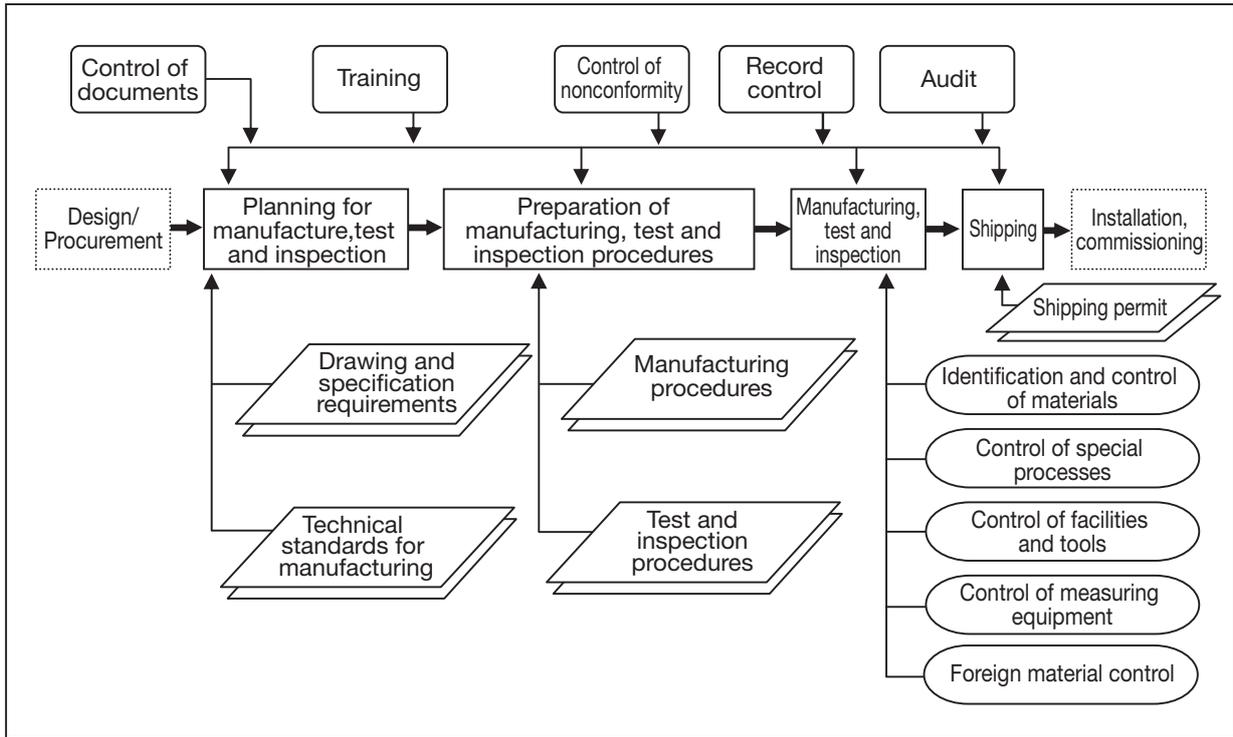


Fig. III-9-1: Flow of manufacturing control

(2) Control of Construction and Installation Work

Manufacturers control construction and installation work using methods similar to those for manufacturing control.

Various organizations and people such as utilities, plant manufacturers, equipment/device manufacturers, and builders are involved in the construction and installation work, and abundant and varied operations are performed concurrently. Therefore, it is necessary to establish a clear structure and ensure close interactions. To reliably achieve this, activities such as the following are conducted within or between organizations.

- QA/QC meeting
- Technical communication meeting
- Schedule coordination meeting
- QA/QC patrol
- Full check of installation
- QA audit

In addition, manufacturers systematically conduct education and training intended for improving the work environment and enhancing workers' safety and skills throughout the construction period in order to secure the required quality and operational safety.

Furthermore, manufacturers strive to streamline construction work by actively working on the improvement of construction methods so as to shorten construction periods, reduce construction costs, and secure quality and operational safety.

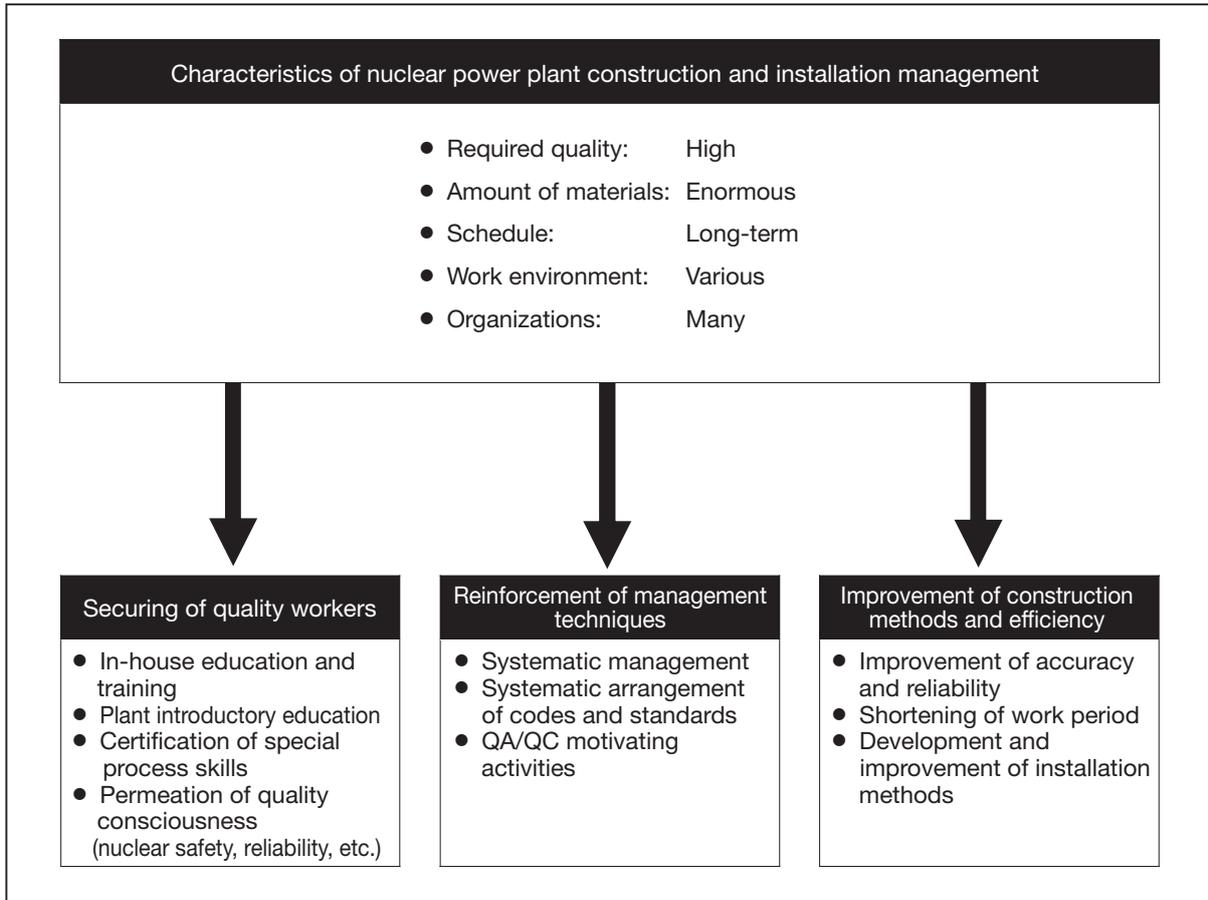


Fig. III-9-2: Key items of quality assurance activity at the installation stage

10. Control of Monitoring and Measuring Equipment

Manufacturers clarify the measurement instruments (calipers, micrometer, etc.) and monitoring equipment (e.g., ammeter used for welding) that must be controlled by specifying them in control manuals, procedures, etc.

To maintain and secure the accuracy of such measuring and monitoring equipment, manufacturers also clarify the following specific steps and methods for each piece of equipment to be controlled, by specifying them in control manuals, procedures, etc.

- a) Identification control using control numbers, etc.
- b) Equipment calibration expiration date and calibration interval
- c) Specific calibration method including technical elements at the time of calibration
- d) Specific action in case of deviation from the equipment calibration criteria
- e) Storage site and environment

Measuring equipment used for assessing inspection or test results is required to be calibrated or verified in accordance with a metering standard traceable to an international or national measurement standard.

Measuring equipment for measuring test conditions, for example, may also be treated as “measuring equipment used for assessing results” if it is judged to be important for the assessment, even if it is not directly used for assessing inspection or test results.

Concerning the “traceability control” of measuring equipment, the manufacturer confirms linkage to the extent that the equipment can be traced to a “traceable metering standard” indicated below.

<Metering standard traceable to an international or national measurement standard*>

- a) A meter owned by a national measurement standard laboratory
- b) A standard that is in accordance with the inspection system for standards under the Measurement Act
- c) A meter that is owned by a registered (certified) business operator in accordance with the registration (certification) system for calibration business operators (JCSS) within the scope of registration (certification) under the Measurement Act; and a meter calibrated within the scope of registration (certification) by a registered (certified) business operator in connection with the former meter
- d) A meter that is owned within the scope of certification by a calibration business operator certified as per ISO/IEC17025 by a certified testing organization that has international mutual recognition (ILAC/APLAC-MRA, etc.); and a meter calibrated within the scope of certification by a certified business operator in connection with the former meter

* Source: “Confirmation of Calibration and Traceability of Measuring Equipment at Nuclear Power Stations” (May 21, 2007, Nuclear and Industrial Safety Agency, Ministry of Economy, Trade and Industry, NISA-161c-07-01)

11. Internal Audit

An internal audit is intended to check and evaluate a quality management system from the viewpoints of conformity and effectiveness and provide an opportunity for improvement. While conducting an internal audit is not itself an objective, manufacturers utilize it as a tool for enhancing their quality management systems.

In selecting auditors and conducting an internal audit, the manufacturer secures objectivity and fairness of the audit process, and the audit team confirms that all necessary improvements and corrective actions are taken against any nonconformity found in the audit.

When formulating an audit program, the manufacturer adopts the “grading” approach, and takes into account the state and importance of the process and area subject to the audit, past audit results, etc. In addition, for follow-ups conducted to check the implementation state of corrective actions, the manufacturer defines the timing and the method according to the importance of nonconformity.

The following are examples of strategies to effectively conduct an internal audit.

- a) The auditing and audited parties mutually confirm the meanings of the matters indicated by the audit (weaknesses of the organization) and the necessity of improvement.
- b) Make recommendations in order to spread good examples into other organizations.
- c) Place focus also on problems found in other organizations and between multiple organizations, leading to improvement.
- d) Specify key audit items for each audit in order to prevent auditing from getting into a rut.
- e) Make efforts (enhancing education and training for auditors) to improve the competence of auditors.
- f) Utilize the result of self assessment by the audited organization as an input to the internal audit.

(Reference)

IAEA's safety standard GS-R-3 (2006) defines “self assessment” by division administrators and “independent assessment” by an organization independent from the subject operation. An internal audit is conducted as an “independent assessment.”

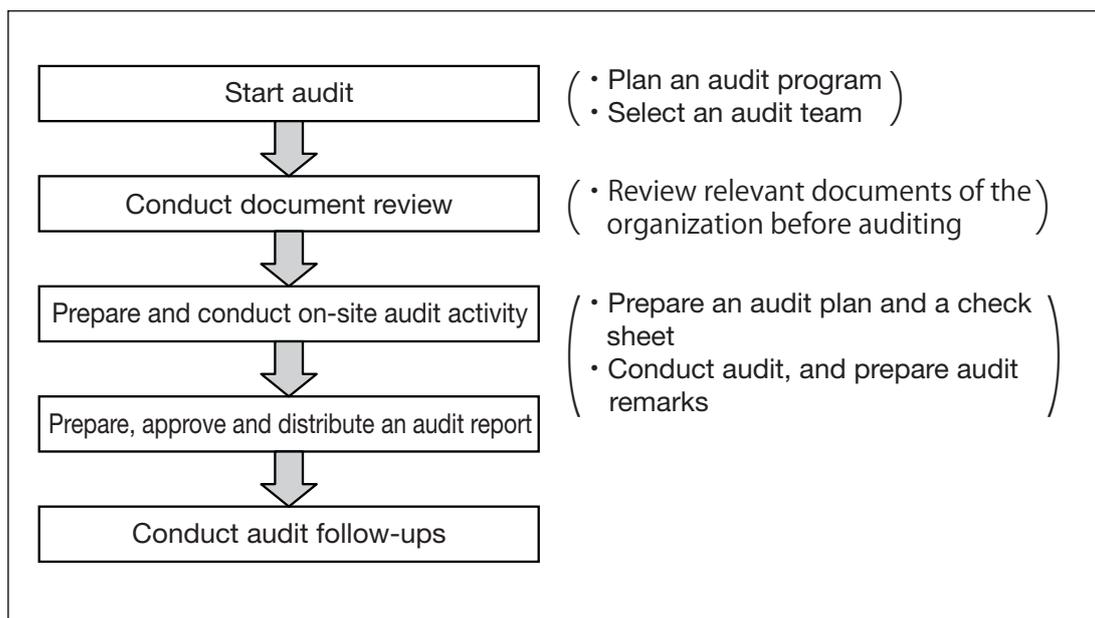


Fig. III-11-1: Overview of audit activity

12. Monitoring and Measurement of Products

For a product delivered to a nuclear power plant, the manufacturer reliably conducts the required inspection and testing as a means to monitor and measure the product in order to ensure its conformity to the quality requirements including nuclear safety.

The inspections and tests conducted at various stages from product design to manufacturing and installation are roughly divided into demonstration testing for verifying the design, inspection and testing at the manufacturing stage at the factory; and inspection, testing and pre-operation at the installation stage at the nuclear power plant.

With regard to the control of inspection and testing at the above-mentioned process stages, there are some critical points that need to be dealt with, such as test and inspection planning, preparation of written procedures, management of inspector and tester qualifications, calibration of monitoring and measuring equipment, and management of its handling, storage and use. In the nuclear power industry, these activities are controlled in the same way as in other industries, except for the fact that control is conducted very strictly and thoroughly to meet the requirements in nuclear power plants. Such activities include, for example, establishment of hold points, verification of effectiveness of the monitoring and measuring equipment, and indication of inspection and test conditions.

The characteristics of product monitoring and measurement at a nuclear power plant include recording the result of acceptance judgment, and defining the degree of independence between the person responsible for the inspection and testing involving result judgment and the person responsible for the manufacturing, operation, etc. with the aim of securing the reliability of the inspection and testing.

For this hold point, there are pressure-resistance and leakage inspections by the utility, welder inspection, characteristic tests, welding safety management review by the government or a third party inspection agency, pre-service inspection, and other inspections.

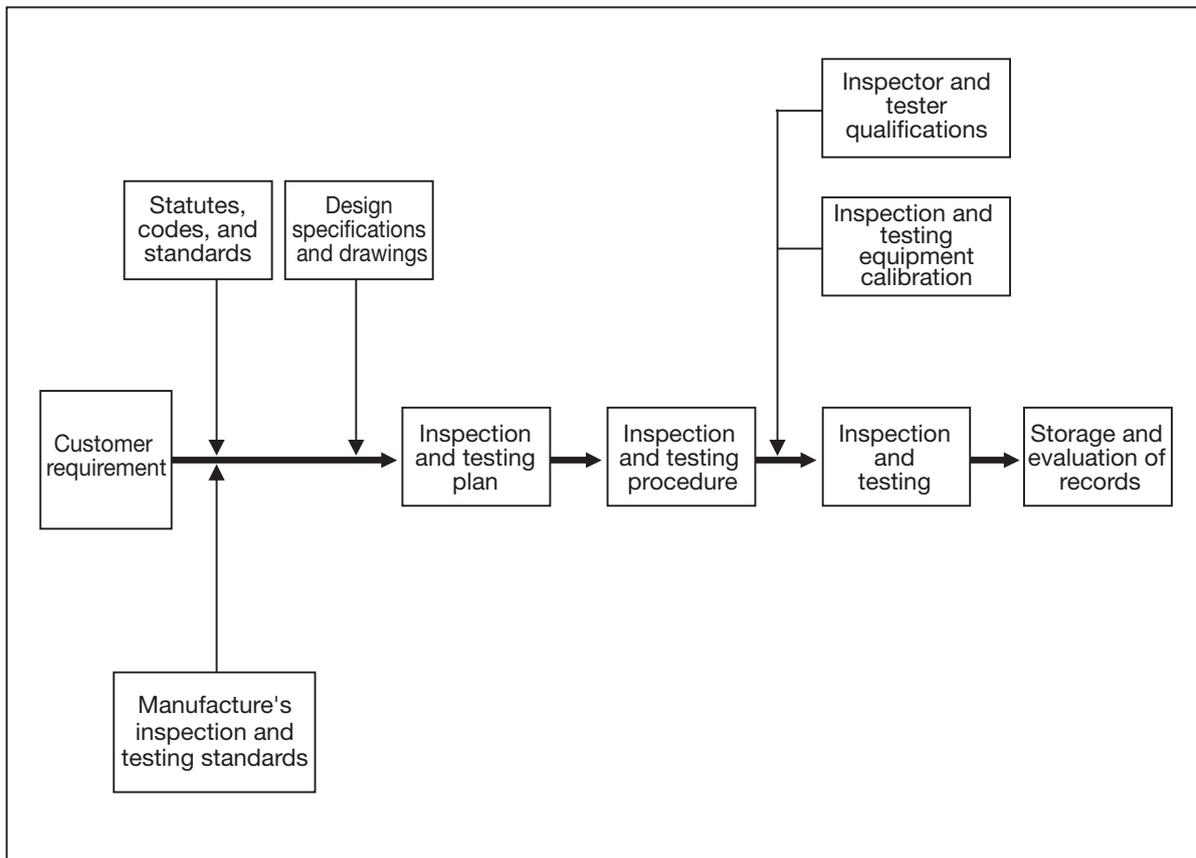


Fig. III-12-1: Flow of Inspection and testing control

13. Control of Nonconforming Products

In quality assurance activities at various stages from design and development to operation and maintenance, the manufacturer manages so that its quality assurance activities are consistent with the requirements in drawings, procedures, instructions, etc., and it proceeds to a next step after verifying, at the prescribed timing, that the requirements are met.

In doing this, the manufacturer regards it nonconforming when the product or service to be delivered is inconsistent with and does not meet the requirements (specification or instruction).

The manufacturer controls nonconformities in accordance with a procedure that defines the following:

- a) Method for reporting any detected nonconformities
- b) Method for treating nonconformities (identification, removal, concession, disposal, etc.)
- c) Method for re-verification in the case of correction of a nonconforming product
- d) Control method for clarifying the causes of nonconformities and establishing and implementing measures to prevent recurrence
- e) Recording method

If nonconformity is detected, the worker in charge discontinues the operation, and promptly reports to the supervisor. In addition, the manufacturer reports the nonconformity to the utility in accordance with an agreement with the utility.

A nonconforming product is provided with an identification that allows the nonconformity to be easily recognized, so as to prevent the product from being improperly used or mistakenly shipped. Methods for this identification include marking and tagging on a nonconforming product.

As treatment of nonconformity, deliberations are conducted by the supervisor at the responsible organization or concerned personnel to adopt an appropriate method. The following are examples of such methods.

- Elimination of detected nonconformity: adjust, repair or correct the nonconforming product so that it meets the requirement.
- Concession: judging that the state of the nonconforming product is acceptable, the customer and the supervisor of the organization give approval and accept it exceptionally, and the product is used as-is without disposal.
- Disposal: identify any nonconforming product in order to prevent it from being used or adopted as originally intended, ensure isolation by such as moving it to another place, and discard it if necessary.

If a nonconforming product is adjusted, repaired or corrected, the manufacturer conducts testing and inspection again to re-verify the product.

Nonconformity is recorded in the form of a nonconformity report that describes the detection status, emergency action status, disposal method, reevaluation result, development of corrective action, etc.

In addition, the manufacturer stores these pieces of information in a database and utilizes it for preventive action.

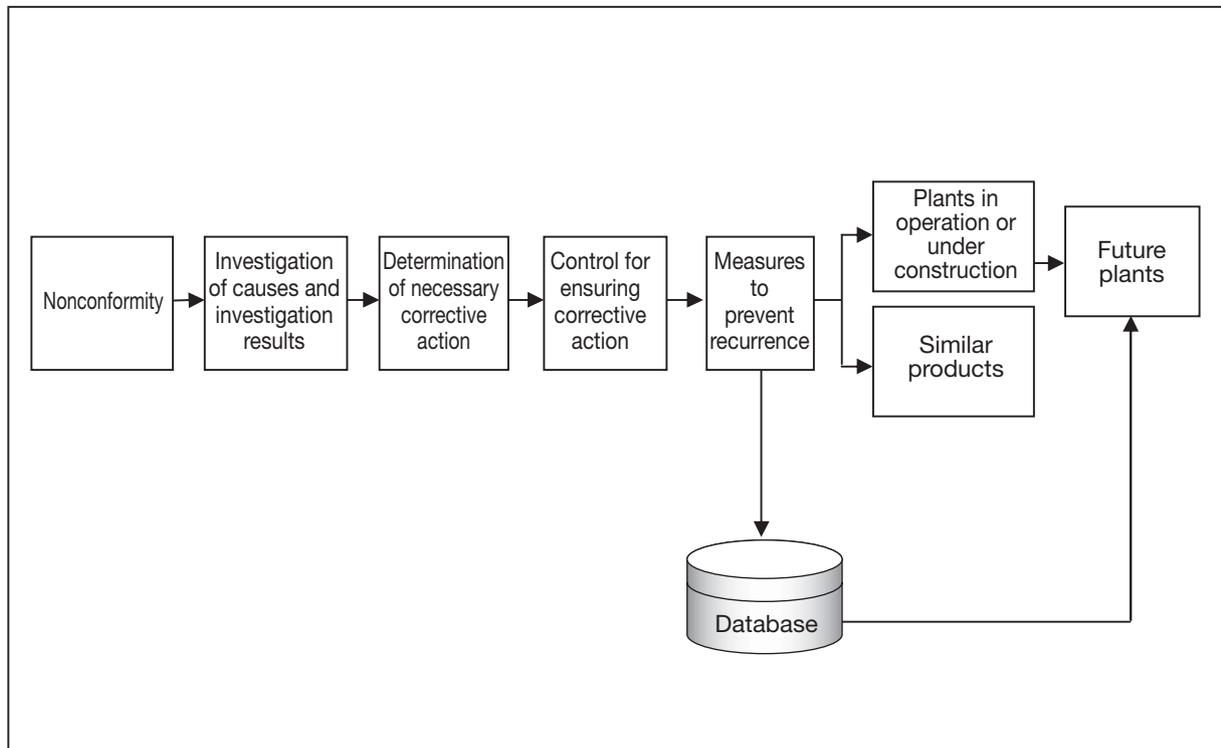


Fig. III-13-1: Flow of control of nonconforming products, corrective action and preventive action

14. Corrective and Preventive Actions

(1) Corrective Action

A corrective action is required not only to handle nonconforming products and prevent the recurrence of nonconformities but also to identify and remove the causes of the nonconformities. In addition, since a corrective action responds to the impact of the detected nonconformities, the manufacturer adopts various causal analysis methods in order to reliably identify the causes of the nonconformities.

To appropriately take a corrective action, the manufacturer documents a procedure that defines the following ISO9001 requirements.

- a) reviewing nonconformities (including customer complaints)
- b) determining the causes of nonconformities
- c) evaluating the need for action to ensure that nonconformities do not recur
- d) determining and implementing action needed
- e) records of the results of the action taken (see “Control of Records”)
- f) reviewing the effectiveness of the corrective action taken

In addition, the manufacturer takes into account the following matters and reflects them in the procedure.

- communicate the corrective action to the relevant divisions as necessary.
- extract quality assurance issues from nonconformity handing slips, nonconformity cases at preceding plants, etc., and take measures to prevent recurrence.
- report the measures to prevent the recurrence of nonconformities in accordance with an agreement with the utility.

(2) Preventive Action

A preventive action is an action determined and taken for removing the causes of possible nonconformities in order to prevent such nonconformities from occurring. A preventive action must respond to the impact of a possible problem. Therefore, the manufacturer conducts causal analysis for nonconformities envisaged from knowledge, experience or information acquired through nonconformity control and corrective actions or for possible occurrence of similar nonconformities expected from various information of external origin, and determines and takes preventive action according to the importance of the matter.

To appropriately implement preventive action, the manufacturer documents a procedure that defines the following ISO9001 requirements.

- a) determining potential nonconformities and their cause,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of the results of the action taken (see “Control of Records”)
- e) reviewing the effectiveness of the preventive action taken

If necessary, the manufacturer reflects the preventive action in the procedure as a matter to be communicated to the nuclear related divisions.