

## CATEGORIES IN THE IAEA SAFETY SERIES

*A hierarchical categorization scheme has been introduced, according to which the publications in the IAEA Safety Series are grouped as follows:*

### **Safety Fundamentals** (silver cover)

Basic objectives, concepts and principles to ensure safety.

### **Safety Standards** (red cover)

Basic requirements which must be satisfied to ensure safety for particular activities or application areas.

### **Safety Guides** (green cover)

Recommendations, on the basis of international experience, relating to the fulfilment of basic requirements.

### **Safety Practices** (blue cover)

Practical examples and detailed methods which can be used for the application of Safety Standards or Safety Guides.

Safety Fundamentals and Safety Standards are issued with the approval of the IAEA Board of Governors; Safety Guides and Safety Practices are issued under the authority of the Director General of the IAEA.

There are other IAEA publications which also contain information important to safety, in particular in the Proceedings Series (papers presented at symposia and conferences), the Technical Reports Series (emphasis on technological aspects) and the IAEA-TECDOC Series (information usually in preliminary form).

QUALITY ASSURANCE  
FOR SAFETY IN  
NUCLEAR POWER PLANTS  
AND OTHER  
NUCLEAR INSTALLATIONS

Code and Safety Guides Q1-Q14

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN	HOLY SEE	PERU
ALBANIA	HUNGARY	PHILIPPINES
ALGERIA	ICELAND	POLAND
ARGENTINA	INDIA	PORTUGAL
ARMENIA	INDONESIA	QATAR
AUSTRALIA	IRAN, ISLAMIC REPUBLIC OF	ROMANIA
AUSTRIA	IRAQ	RUSSIAN FEDERATION
BANGLADESH	IRELAND	SAUDI ARABIA
BELARUS	ISRAEL	SENEGAL
BELGIUM	ITALY	SIERRA LEONE
BOLIVIA	JAMAICA	SINGAPORE
BOSNIA AND HERZEGOVINA	JAPAN	SLOVAKIA
BRAZIL	JORDAN	SLOVENIA
BULGARIA	KAZAKSTAN	SOUTH AFRICA
CAMBODIA	KENYA	SPAIN
CAMEROON	KOREA, REPUBLIC OF	SRI LANKA
CANADA	KUWAIT	SUDAN
CHILE	LEBANON	SWEDEN
CHINA	LIBERIA	SWITZERLAND
COLOMBIA	LIBYAN ARAB JAMAHIRIYA	SYRIAN ARAB REPUBLIC
COSTA RICA	LIECHTENSTEIN	THAILAND
COTE D'IVOIRE	LITHUANIA	THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA
CROATIA	LUXEMBOURG	TUNISIA
CUBA	MADAGASCAR	TURKEY
CYPRUS	MALAYSIA	UGANDA
CZECH REPUBLIC	MALI	UKRAINE
DENMARK	MARSHALL ISLANDS	UNITED ARAB EMIRATES
DOMINICAN REPUBLIC	MAURITIUS	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
ECUADOR	MEXICO	UNITED REPUBLIC OF TANZANIA
EGYPT	MONACO	UNITED STATES OF AMERICA
EL SALVADOR	MONGOLIA	URUGUAY
ESTONIA	MOROCCO	UZBEKISTAN
ETHIOPIA	MYANMAR	VENEZUELA
FINLAND	NAMIBIA	VIET NAM
FRANCE	NETHERLANDS	YEMEN
GABON	NEW ZEALAND	YUGOSLAVIA
GEORGIA	NICARAGUA	ZAIRE
GERMANY	NIGER	ZAMBIA
GHANA	NIGERIA	ZIMBABWE
GREECE	NORWAY	
GUATEMALA	PAKISTAN	
HAITI	PANAMA	
	PARAGUAY	

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

© IAEA, 1996

Permission to reproduce or translate the information contained in this publication may be obtained by writing to the International Atomic Energy Agency, Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria.

Printed by the IAEA in Austria  
September 1996  
STI/PUB/1016

SAFETY SERIES No. 50-C/SG-Q

**QUALITY ASSURANCE  
FOR SAFETY IN  
NUCLEAR POWER PLANTS  
AND OTHER  
NUCLEAR INSTALLATIONS**

**Code and Safety Guides Q1-Q14**

INTERNATIONAL ATOMIC ENERGY AGENCY  
VIENNA, 1996

THIS SAFETY SERIES PUBLICATION IS ALSO ISSUED IN  
FRENCH, RUSSIAN AND SPANISH

**VIC Library Cataloguing in Publication Data**

Quality assurance for safety in nuclear power plants and other nuclear installations : code and safety guides Q1-Q14. — Vienna : International Atomic Energy Agency, 1996.

p. ; 24 cm. — (Safety series, ISSN 0074-1892 ; 50-C/SG-Q. Safety standards and guides)

On cover: A publication within the NUSS Programme.

STI/PUB/1016

ISBN 92-0-103696-5

1. Nuclear power plants — Safety measures. 2. Nuclear power plants — Quality control. I. Nuclear Safety Standards Programme. II. International Atomic Energy Agency. III. Series.

VICL

95-00156





# CONTENTS

GLOSSARY .....	1
CODE .....	3
Quality assurance for safety in nuclear power plants and other nuclear installations .....	3
SAFETY GUIDES .....	25
Q1: Establishing and implementing a quality assurance programme .....	25
Q2: Non-conformance control and corrective actions .....	49
Q3: Document control and records .....	65
Q4: Inspection and testing for acceptance .....	97
Q5: Assessment of the implementation of the quality assurance programme .....	113
Q6: Quality assurance in procurement of items and services .....	135
Q7: Quality assurance in manufacturing .....	153
Q8: Quality assurance in research and development .....	169
Q9: Quality assurance in siting .....	187
Q10: Quality assurance in design .....	219
Q11: Quality assurance in construction .....	237
Q12: Quality assurance in commissioning .....	255
Q13: Quality assurance in operation .....	275
Q14: Quality assurance in decommissioning .....	317
CONTRIBUTORS TO DRAFTING AND REVIEW .....	341
SELECTION OF ASSOCIATED PUBLICATIONS .....	343



## GLOSSARY

*The NUSS documents on quality assurance were developed using common everyday language. No unique quality assurance terminology was used beyond the usual terms defined in existing national and international standards. Only seven definitions on specific terms common to the overall NUSS programme are included below.*

*The terms Siting, Design, Construction, Commissioning, Operation, and Decommissioning are used to delineate the six major stages of the licensing process. Several of the stages may coexist; for example, Construction and Commissioning, or Commissioning and Operation.*

### **Commissioning**

The process during which nuclear power plant components and systems, having been constructed, are made operational and verified to be in accordance with design assumptions and to have met the performance criteria; it includes both non-nuclear and nuclear tests.

### **Construction**

The process of manufacturing and assembling the components of a nuclear power plant, the erection of civil works and structures, the installation of components and equipment, and the performance of associated tests.

### **Decommissioning**

The process by which a nuclear power plant is permanently taken out of operation.

### **Design**

The process and the result of developing the concept, detailed plans, supporting calculations and specifications for a nuclear power plant and its parts.

### **Operation**

All activities performed to achieve the purpose for which the plant was constructed, including maintenance, refuelling, in-service inspection and other associated activities.

## **Nuclear Safety**

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of site personnel, the public and the environment from undue radiation hazards.

## **Siting**

The process of selecting a suitable site for a nuclear power plant, including appropriate assessment and definition of the related design bases.

**Code**

**QUALITY ASSURANCE  
FOR SAFETY IN  
NUCLEAR POWER PLANTS  
AND OTHER  
NUCLEAR INSTALLATIONS**



## CONTENTS

1.	INTRODUCTION .....	7
	Background (101–104) .....	7
	Objective (105) .....	7
	Scope (106-107) .....	8
	Structure (108) .....	8
2.	MANAGEMENT .....	8
	Quality assurance programme (201-205) .....	8
	Training and qualification (206) .....	9
	Non-conformance control and corrective actions (207-208) .....	9
	Document control and records (209-210) .....	10
3.	PERFORMANCE .....	10
	Work (301-303) .....	10
	Design (304-305) .....	11
	Procurement (306-308) .....	11
	Inspection and testing for acceptance (309-310) .....	12
4.	ASSESSMENT .....	12
	Management self-assessment (401) .....	12
	Independent assessment (402-405) .....	12
ANNEX:	SUPPLEMENTARY INFORMATION ON THE BASIC REQUIREMENTS .....	13



# 1. INTRODUCTION

## BACKGROUND

101. This Code is part of the IAEA Nuclear Safety Standards (NUSS) programme. It provides the basic requirements to be adopted for establishing and implementing quality assurance programmes related to the safety of nuclear power plants. These basic requirements apply to the overall quality assurance programme of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate quality assurance programmes in each stage of the life of a nuclear power plant.

102. This Code (Revision of 50-C-QA (Rev. 1)) contains only basic requirements, which must be satisfied to ensure safety. Therefore, the main text of the Code has been significantly condensed and guidance on how to implement the basic requirements is included in the appropriate Safety Guides. The result is a much simpler Code, setting out only requirements. Care was taken to ensure that all the requirements of the previous issue were retained. Certain requirements of the former Code, such as audit and training, were expanded in the new edition to be more comprehensive and to provide better direction.

103. Through the revised Code and related Safety Guides on quality assurance, the point is emphasized that managers, those performing the work and those assessing the work, all contribute in ensuring quality and achieving safety. This performance based approach to quality assurance serves to correct a common misunderstanding that quality assurance consists only of formalistic requirements.

104. The responsible organization has to demonstrate the effective fulfilment of the quality assurance requirements to the satisfaction of the regulatory body. Explicit reference to the regulatory body is avoided in this Code in order to focus on performance and emphasize the full responsibility of those who do the work, such as: designers, constructors, operators, maintenance workers and radiation protection personnel. The main objective is to facilitate, support and ensure safety in nuclear power plant siting, design, construction, commissioning, operation and decommissioning.

## OBJECTIVE

105. The objective of this Code is to establish basic requirements for quality assurance in order to enhance nuclear safety by continuously improving the methods employed to achieve quality. The Code recognizes that all work is a process that can be planned, performed, assessed and improved.

## SCOPE

106. The Code provides the basic requirements for establishing and implementing quality assurance programmes for the stages of siting, design, construction, commissioning, operation and decommissioning of nuclear power plants.<sup>1</sup> These basic requirements apply to all individuals and organizations, including designers, suppliers, constructors, manufacturers and operators.

107. The basic quality assurance requirements presented in this Code also apply, with appropriate modifications, to nuclear installations other than nuclear power plants.

## STRUCTURE

108. The basic requirements defined by this Code constitute the foundation of a comprehensive quality assurance programme. They are divided into three functional categories: Management (Section 2), Performance (Section 3) and Assessment (Section 4). Supplementary information on the basic requirements of the Code is given in the Annex.

## **2. MANAGEMENT**

### QUALITY ASSURANCE PROGRAMME<sup>2</sup>

201. Management shall develop, implement and maintain a quality assurance programme.<sup>3</sup> The quality assurance programme shall include details of how work is to be managed, performed and assessed, consistent with the basic requirements in this Code. The quality assurance programme shall include the organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of work. The quality assurance programme shall address management measures, including planning, scheduling and resource considerations.

---

<sup>1</sup> Typical work to be addressed includes research and development, designing, purchasing, fabricating, manufacturing, handling, storing, cleaning, erecting, installing, testing, inspecting, maintaining, repairing, operation, technical support, refuelling and disassembly.

<sup>2</sup> For further guidance see Safety Guides Q1; and Q8 to Q14 inclusive.

<sup>3</sup> In some Member States the quality assurance programme is referred to as the quality assurance system or the quality system.

202. Management in the entire and constituent areas of work shall provide and demonstrate support for the effective implementation of the quality assurance programme consistent with specified time schedules for accomplishing project activities. The responsible organization shall also be responsible for the establishment and implementation of the overall quality assurance programme. If the responsible organization delegates to other organizations the work of establishing and implementing all or a part of the overall programme, it shall retain responsibility for the effectiveness of the programme in all circumstances.

203. The quality assurance programme shall provide an interdisciplinary approach involving many organizational components and shall not be regarded as the sole domain of any single group. The quality assurance programme shall demonstrate the integration of the following three principles: (1) managers provide planning, direction, resources and support to achieve the organization's objectives; (2) staff performing the work achieve quality; and (3) staff performing assessments evaluate the effectiveness of management processes and work performance. The quality assurance programme shall be binding on everybody.

204. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the quality assurance programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific quality assurance requirements.

205. The quality assurance programme shall include measures, which ensure that documentation is available in language appropriate to the users.

## TRAINING AND QUALIFICATION

206. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS<sup>4</sup>

207. Items, services and processes that do not meet specified requirements shall be identified and the safety impact of the non-conformances assessed and reported to the appropriate level of management. Depending on the results of the assessment,

---

<sup>4</sup> For further guidance see Safety Guide Q2.

the items shall be either accepted, rejected, repaired or reworked, and services and processes accepted or rejected.

208. To ensure improvement, the causes of such non-conformances shall be determined and action taken to prevent their recurrence. Item characteristics (such as reliability), process implementation, experience and other quality related information (including management processes) shall be reviewed and the data analysed to identify improvements.

## DOCUMENT CONTROL AND RECORDS<sup>5</sup>

209. Documents such as procedures, instructions, specifications and drawings, or other media, which describe processes, specify requirements or establish design, shall be prepared, reviewed, approved, issued, distributed, authorized, revised and, as required, validated. All personnel preparing, revising, reviewing or approving documents shall be specifically assigned to this work and be given access to appropriate information upon which to base their input. Personnel using documents shall be aware of and use appropriate and correct documents.

210. Records relating to personnel and records that describe the status, configuration and characteristics of items and services, describe the performance of processes and represent objective evidence of quality shall be specified, prepared, reviewed, approved and maintained. All records shall be legible, complete and identifiable. A records system shall be established to provide for the identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records. Retention times of records and associated test materials and specimens shall be established to be consistent with the type of records, material and specimens involved.

## **3. PERFORMANCE**

### WORK

301. During all stages in the life of the nuclear power plant, work shall be planned and performed in accordance with established codes, standards, specifications, practices and administrative controls. Work shall be performed under controlled

---

<sup>5</sup> For further guidance see Safety Guide Q3.

conditions, using approved current instructions, procedures, drawings or other appropriate means that are periodically reviewed to ensure adequacy and effectiveness.

302. Items and services shall be identified and controlled to ensure their proper use. Items shall be shipped, stored, handled, maintained, operated and used as specified to prevent their damage, loss or deterioration,

303. Equipment used for process monitoring, data collection, and inspections and tests shall be of the proper range, type, accuracy and precision.

## DESIGN

304. Design, including subsequent changes, shall be carried out in accordance with established engineering codes and standards, and shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled.

305. The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification, validation and approval shall be completed before implementation of the design.

## PROCUREMENT<sup>6</sup>

306. Procured items and services shall meet established requirements and perform as specified. Suppliers shall be evaluated and selected on the basis of specified criteria.

307. Requirements necessary to ensure the quality of items and services shall be developed and specified in the procurement documents. Evidence that purchased items and services meet procurement requirements shall be available before they are used.

308. Requirements for reporting deviations from procurement requirements shall be specified in the procurement documents.

---

<sup>6</sup> For further guidance see Safety Guides Q6 and Q7.

## INSPECTION AND TESTING FOR ACCEPTANCE<sup>7</sup>

309. Inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.

310. Administrative controls, such as hold points and status indicators, shall be used to preclude the bypassing of required inspections and tests. Any inadvertent use, installation or operation of items, services and processes, which have not passed the required inspections and tests shall be prevented.

## 4. ASSESSMENT

### MANAGEMENT SELF-ASSESSMENT<sup>8</sup>

401. Management at all levels shall regularly assess the processes for which it is responsible. Management shall determine its effectiveness in establishing, promoting and achieving nuclear safety objectives. Management process weaknesses and barriers that hinder the achievement of the nuclear safety objectives shall be identified and corrected.

### INDEPENDENT ASSESSMENT<sup>8</sup>

402. Independent assessments shall be conducted on behalf of management to measure the effectiveness of management processes and the adequacy of work performance, to monitor item and service quality and to promote improvement. Independent assessments consist of audits, reviews, checks and other methods.

403. An organizational unit shall be established, or an outside agency assigned, with the responsibility to conduct independent assessments. It shall have sufficient authority and organizational freedom to carry out its responsibilities.

404. Persons conducting independent assessment shall not participate directly in the work being assessed.

405. The results of the independent assessments shall be considered by management and, where necessary, actions shall be taken to implement improvements.

---

<sup>7</sup> For further guidance see Safety Guide Q4.

<sup>8</sup> For further guidance see Safety Guide Q5.

## Annex

### **SUPPLEMENTARY INFORMATION ON THE BASIC REQUIREMENTS**

*This Annex provides additional information that might be helpful to the user.*

#### Basic Requirement 1 – QUALITY ASSURANCE PROGRAMME

The quality assurance (QA) programme is an interdisciplinary management tool that provides a means for ensuring that all work is adequately planned, correctly performed and assessed. It provides a systematic approach for accomplishing work with the ultimate goal of doing the job right the first time.

The documentation of the QA programme is a set of documents that describe the overall measures established by an organization to achieve management goals and objectives. These goals and objectives apply to every unit and individual within the organization.

Senior management is responsible and accountable for the planning, development, implementation and success of the QA programme. It is at this level that the success of a QA programme begins, and the responsibility for the effectiveness of that programme cannot and must not be delegated.

As part of the QA programme, senior management is to develop and issue a written QA policy statement that establishes the management's concept and objectives regarding quality. This policy statement must clearly reflect the commitment of senior management to the attainment and continuous improvement of quality.

It is the role of senior management to establish and cultivate principles that integrate quality requirements into daily work, and to provide individuals performing the work with the necessary information tools, support and encouragement to perform their assigned work properly.

The QA programme assigns responsibility to the line organization to carry out the work to achieve the organization's goals and objectives and empowers the individuals in the organization to perform the tasks they have been assigned. Line management is responsible for achieving quality in the items and services provided by the organization. Individual workers are responsible for the quality of their own work.

The QA programme establishes the management's objectives for the nuclear power plant project. The programme sets these broad objectives, assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.

The QA programme is binding on all personnel, including those with responsibility for planning, scheduling and resource considerations. The QA programme

describes or provides reference to the organizational structure, functional responsibilities, levels of authority and interfaces for all segments of the organization. It is the intent of this basic requirement to ensure that the appropriate authorities are established and to enable the organization to carry out its functional responsibilities in management, performance of work, and in the assessment of the adequacy of work.

The QA programme identifies all work delegated to outside organizations, and lines of communication and interfaces between internal and external organizations. The responsibility of each organization, as it relates to the assigned work, is described.

Responsibility and authority to stop unsatisfactory work is assigned in such a manner that planning, scheduling and other considerations do not override safety considerations. The QA programme also requires that reviews be considered prior to restart of work if stopping the work was necessary to bring safety or quality under control.

Management empowers and makes individuals accountable for their work. In this way senior management can encourage improved individual and organization performance. Senior management continues to reinforce a quality culture by being actively involved in achieving quality.

A graded approach based on the relative importance to nuclear safety of each item, service or process is used.

The QA programme provides a common vocabulary consistent with and representative of the work being performed. All key terms used throughout the QA programme are defined and the definitions are an integral part of the training programme to ensure that communications and understanding are consistent throughout the organization.

## Basic Requirement 2 – TRAINING AND QUALIFICATION

This basic requirement recognizes that everyone in the organization contributes to quality and to the success of the organization. Thus, it is a responsibility of management to provide appropriate training for all employees to ensure they are qualified for the tasks they perform.

To achieve quality and maintain safety, personnel have to be capable of performing their assigned tasks. Training emphasizes correct performance of work and, where appropriate, provides an understanding of QA principles and the relevant management procedures; it emphasizes personal accountability and responsibility, describes the main systems and components of the nuclear power plant, and provides an understanding of nuclear power plant operation. This training includes both education in principles and enhancement of skills and practices by on-the-job training and the use of simulators and mock-ups where possible. Training ensures that

everyone understands the processes and tools they are using and provides an understanding of what constitutes acceptable quality for items and services they produce as well as the processes they control. The training programme focuses attention on 'doing it right the first time'.

Management training plans address and stimulate professional development and include professional, managerial, communication and interpersonal skills. Individual personnel training plans are not limited to initial qualification but provide maintenance of proficiency and progressive improvement. This ensures that all employees are continually aware of state of the art technology and processes relative to the work they perform.

Specific qualification requirements are established for critical and unique or uncommon job categories if highly technical, specialized skills are required or if it is necessary to ensure that the individual is competent prior to performing the task. Such categories are determined by the organization, and qualification requirements are established prior to the work being performed.

The qualification training programme for personnel performing work that requires special competency involves a practical and written examination in which each candidate must demonstrate proficiency. Periodical requalifications are required to demonstrate that individuals continue to be capable of performing their tasks.

The training programme is structured in such a way as to ensure that curricula address specific needs of the individuals and the overall organization. This requires that training be planned and carried out using an organized systematic method with established goals clearly defined and sequenced. The training programme also requires that training be presented by qualified instructors knowledgeable in the area of expertise. Because training is crucial to the continued development of personnel, management utilizes technically competent instructors to form the curricula needed to achieve the organization's objectives and enhance the development of personnel.

The training programme is subject to ongoing review to determine programme and instruction effectiveness. On the basis of the results of reviews, the training programme is upgraded whenever necessary improvements or other enhancements are identified.

### Basic Requirement 3 – NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

Management fosters a 'no-blame' culture to encourage employees to identify non-conforming items, services and processes. Management ensures that adequate resources are provided for identifying, resolving and preventing non-conforming conditions. Management is also involved in the resolution of difficult issues and provides a process for resolving professional differences of views and opinions.

Line managers establish and implement measures promptly to identify, document, classify, analyse, correct, eliminate and follow up activities, items, services or processes that do not meet established requirements and goals or do not result in the anticipated quality.

All personnel have the opportunity to identify non-conforming items, services and processes. All personnel are encouraged to identify and suggest improvements via the management system.

Personnel responsible for classifying and analysing non-conformances have an adequate understanding of the area in which they are working and access to pertinent background information concerning the non-conformance. They are also independent from cost and schedule considerations.

Determination of the root cause requires a thorough investigation by technically qualified, experienced personnel. The investigation required includes the participation of the personnel involved, such as craftsmen, operators and those identifying the deficiency, in order to gain complete understanding of the problem. The managers responsible for the determination of the root cause assign sufficient resources to the task.

Non-conforming items are properly controlled to prevent their inadvertent test, installation or use. They are reviewed and either accepted, rejected, repaired or reworked.

Reworked, repaired and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

Performance data and other quality related information are analysed to identify quality trends that adversely affect the achievement of quality and to identify opportunities to improve items, services and processes. In order to identify commonalities, this analysis considers information from external sources and is not limited to one activity, one site or one supplier.

The QA programme requires that all processes be analysed to identify trends that may adversely affect item, service and process quality. This analysis includes information performance data, internal and external failure costs and prevention costs.

The QA programme also requires that levels of performance be established. These levels are directly related to the item or service provided by an organization and based on the goals and objectives set by management. Once the levels have been established, performance is measured against them. These measurements are monitored on a regular basis to ascertain whether or not improvements in item, service or process quality are necessitated. Management plays an integral role in this activity.

Management recognizes that quality problems often have their origins in management systems and that personnel have little or no control over eliminating these problems or improving performance. Management encourages personnel to recognize and contribute to the elimination of problems and thereby promote quality

improvement. Processes are established and implemented with the objective of preventing problems and improving quality.

Each line manager establishes the quality improvement objectives and the measures to be applied to their accomplishment. There may be instances where quality improvement objectives may have an impact on the QA programme. Where this situation arises, the objectives are referred to an appropriate level of management for endorsement and agreement.

In establishing the improvement objectives, each line manager solicits suggestions from supervisors and personnel. A detailed plan for the accomplishment of each of the proposed quality improvement objectives is prepared by the responsible department, with management providing support, co-ordination, resources and training.

All quality improvement objectives are approved by an appropriate level of management. The senior manager ensures that any quality improvement objectives for the nuclear power plant are co-ordinated and complementary, to avoid conflicting objectives between departments.

The quality improvement objectives are subject to ongoing review and monitoring by the respective department managers, and the results are reported periodically.

#### Basic Requirement 4 – DOCUMENT CONTROL AND RECORDS

A system is established and implemented to control the preparation, review, approval, issuance, distribution, use and revision of documents that prescribe processes, specify requirements or establish design.

The scope and functions of the document control systems are defined in each stage related QA programme. Examples of documents requiring control include drawings, data files (including various media), calculations, specifications, computer codes, purchase orders and related documents, vendor supplied documents, procedures, work instructions and data sheets.

Personnel preparing, revising, reviewing or approving documents have access to appropriate information

Revisions to controlled documents are reviewed and approved by a design organization or a qualified and knowledgeable person.

Controlled documents are distributed to and used by the person performing the activity. Obsolete documents are removed from circulation to prevent their inadvertent use.

The distribution of new and revised controlled documents is made in accordance with established guidelines.

A records system is established and implemented to ensure that sufficient records are specified, prepared, reviewed, approved and maintained to reflect

completed work accurately. For example, records of design, procurement, construction, inspection, testing, operation, maintenance, modification, training, and research and development are typically required.

Records that require special processing and control, such as computer codes and software, and information stored on high density media or optical disks, are maintained and controlled to ensure they are readily retrievable and usable.

The QA programme addresses both permanent and non-permanent records and defines their respective retention times. Storage facilities for records are maintained.

#### Basic Requirement 5 – WORK

Each individual takes responsibility for the quality of the work he or she performs. Personnel are technically competent in using the appropriate tools and measuring devices and have a clear understanding of the work processes.

Line managers are responsible for ensuring that personnel working under their supervision have been provided with the necessary training, resources and directions. These elements are to be provided before any work begins. Where appropriate, statistical process control is established and used to reduce item and process variability and improve quality. Line managers are required to review work and related information on a regular basis to ensure that the expected quality is being achieved and to identify areas needing improvement. They also encourage each individual under their supervision to look for more efficient and effective ways of accomplishing assigned tasks.

All work is planned, authorized and accomplished under suitably controlled conditions. All work is accomplished by technically competent individuals using technical standards, instructions, procedures or other appropriate documents. Documents that govern the work processes and activities are of a detail commensurate with the complexity and importance of the work.

Documents that provide direction for accomplishing work are prepared, reviewed and validated by technically competent individuals. These individuals are intimately familiar with the work being accomplished.

Processes are developed and implemented to identify, control and maintain items to the extent appropriate. This helps prevent the use of incorrect or defective items in the organization's work.

Processes are established to provide the identification, handling, storage, shipping, cleaning, maintenance, operation and preservation of items in accordance with applicable design, procurement and manufacturing documents. Packaging, shipping, handling and storage processes are designed to prevent damage, loss or deterioration. The processes specify any special environmental controls.

Processes are established and implemented to ensure that monitoring and data collection equipment is of the accuracy and type appropriate for its intended use. Equipment in this category is typically used by personnel trained in the maintenance and use of such equipment.

A process is established and implemented to ensure that measuring and test equipment which is used for in-process or final inspection of an item or to control any process parameter which influences the quality of an item's characteristics, is properly calibrated, maintained, accounted for and used. The type, range and required accuracy of measuring and test equipment to be used for each application is specified.

## Basic Requirement 6 – DESIGN

The design process requires the use of sound engineering/scientific principles and appropriate design standards. Design requirements, inputs, processes, outputs, changes, records and organizational interfaces are controlled.

Design inputs are correctly translated to design outputs. Design inputs include all requirements for the design, such as the technical bases for the design (design basis), performance requirements, reliability requirements, and safety and security requirements. The design outputs include specifications, drawings, procedures and instructions.

Design changes are justified and subject to design control measures commensurate with the original design. Design changes include field changes, modifications and non-conforming items designated for use-as-is or repair. Changes are subject to configuration and design control measures and approved by the original design organization or a technically qualified alternate.

Interfaces among all organizations involved in the design are identified, coordinated and controlled. Control of interfaces includes assignment of responsibilities and establishment of procedures among participating internal and external organizations.

Design inputs, processes, outputs and changes are verified. Computer programs used in design are validated through testing or simulation prior to use if not proven through previous use. Individuals or groups performing design verification are qualified to perform the original design. Verification is performed by individuals other than those who performed the design (but who may be from the same organization). The extent of verification is based on the complexity, associated hazards and uniqueness of the design.

Some typical design verification methods include design review, alternate calculation and qualification testing. Previously proven designs do not require verification unless they are intended for different applications or the performance criteria

are different. Tests used to verify or validate design features are conducted under conditions simulating the most adverse operating conditions.

Design verification is usually completed before design output is used by other organizations, or to support other work such as procurement, manufacturing, construction, or research and development. In specially controlled circumstances, installation of unverified portions of design may proceed only to a point where extensive demolition or rework would not be required to replace or modify the design.

Evidence that the design was properly accomplished is supported by design records that include the final design, important design steps such as calculations, analyses and computer programs, and sources of design input that support design output. The design organization also provides records of design changes.

## Basic Requirement 7 – PROCUREMENT

Management implements a procurement ' system that ensures purchased items and services, including those designated as commercial grade, meet established requirements and perform as expected. The system requires that procurement documents include acceptance criteria and invoke applicable technical and administrative requirements. Technical and administrative requirements include specifications, codes, standards, tests and inspection requirements.

The procurement process includes prospective supplier evaluation to provide confidence that only qualified suppliers are selected and used. The performance of suppliers, including subcontractors (as necessary), is monitored periodically to ensure that acceptable items and services continue to be supplied.

The procurement process provides methods for accepting purchased items and services. These methods include, for example, review of manufacturing process control data, source verification, receipt inspection, pre- and post-installation tests, and certificates of conformance. The procurement documents specify any one of these methods, a combination of these methods, or some other proven alternative.

The quality of procured items and services is verified at intervals and to a depth consistent with the graded approach, which takes account of the complexity, associated hazards, quantity and frequency of procurement. All specification, inspection and test requirements are satisfied before items are used or placed in service. Responsibilities for rectifying any quality problems are defined and solutions implemented prior to item installation or use.

Management requires that procurement effectiveness be evaluated by comparison of the actual performance of items with the original performance criteria. Procurement effectiveness can also be measured by review of user group surveys, supplier evaluations, inspection and test results, and performance data.

## Basic Requirement 8 – INSPECTION AND TESTING FOR ACCEPTANCE

Management defines the types of work that require formal inspections. A process is established to specify when and what type of inspection is to be performed for the types of work to be inspected. Inspection types include source, in-process, final, receipt, maintenance and in-service.

Administrative controls and status indicators are incorporated into the inspection process. These controls and indicators are used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item or process.

The inspection process may allow inspections to be performed by the organizational unit responsible for the work, another department or an outside agency independent of the responsible organization. Individuals inspect their own work to ensure they have achieved the desired level of quality; however, personnel performing the work do not inspect their own work for acceptance. Personnel responsible for performing acceptance inspections are technically competent.

Management ensures that inspections are properly planned. Planning addresses such attributes as item characteristics, work processes, inspection techniques, hold and witness points, acceptance criteria, and the organization or individuals responsible for conducting the inspections.

Appropriate tests are conducted to demonstrate that items and processes will perform as intended. The test process includes bench tests, proof tests before installation, pre-operational tests, operational tests, post-modification tests and post-maintenance tests.

Testing is performed either by the organizational unit responsible for the work or by other organizations or agencies.

All testing is conducted using established and proven test requirements and acceptance criteria. The test requirements and acceptance criteria are provided by the original design organization or an alternative design organization technically competent and knowledgeable concerning the item or process being tested.

The testing process includes administrative controls and status indicators to prevent bypassing of the required tests and operation of the item or process before acceptance.

Management requires that test procedures be developed and followed for testing work as appropriate. Test procedures cover prerequisites, technical and safety instructions, completeness and accuracy of test data, use and type of test equipment and data recording devices, calibration data, establishment of applicable hold points, test configuration and acceptance criteria.

## Basic Requirement 9 – MANAGEMENT SELF-ASSESSMENT

The thrust of management self-assessment is to identify, correct and prevent management problems that hinder the achievement of the organization's objectives. This Code establishes the requirement for a routine and continuing assessment of the management system by the organization's managers.

This self-assessment methodology is in addition to the traditional audit/appraisal that determines the adequacy and extent of the QA programme development, documentation and implementation in accordance with specified requirements. This basic requirement improves on the standard stipulation in many QA programmes, which requires that management regularly assess the adequacy of the portion of the programme for which it is responsible and ensure its effective implementation. This standard requirement is typically achieved, on an annual basis, by an independent consultant or group of consultants on behalf of management, and it addresses compliance issues rather than broad categories of management issues. Management self-assessment goes beyond such matters as conformance to regulations, item standards or established procedures. These areas are addressed by Basic Requirement 10.

An effective management self-assessment evaluates issues such as:

- – mission of the organization
- – whether employees understand the mission
- – what is expected of the organization
- – whether the expectations are being met
- – opportunities for improving quality and enhancing safety
- – how to make better use of human resources.

The results of the management self-assessment are documented. Decisions and related actions resulting from the recommendations are promptly followed up to evaluate their effectiveness.

The assessment process involves all levels of management, but the overall responsibility for management self-assessments is retained by senior management. It is essential that senior management directly participate in this process.

## Basic Requirement 10 – INDEPENDENT ASSESSMENT

Management establishes and implements a process of independent assessments. These assessments are conducted by an organizational unit independent of the work and focus on improving the overall performance of items, services and processes.

A system of planned and documented internal and external audits is carried out to assess the adequacy and effectiveness of the QA programme.

Assessment personnel operate as an arm of, and as an advisor to, senior management. The assessments focus on evaluating the performance of work and actions, and include the review and evaluation of QA documents.

Assessment personnel view the organization being assessed as the 'customer', so as to produce meaningful feedback about the organization's performance.

Assessments are conducted by peers who are technically competent to review and evaluate the work and processes being assessed. These individuals do not have direct responsibility in the area being assessed. The allocation of resources for assessments is determined. Assessment schedules are flexible enough to allow additional attention to be given to areas of questionable performance or critical or complex work.

Assessment results are tracked and resolved by management having responsibility for the area assessed. The assessment organization schedules a follow-up review of deficient areas as appropriate. Assessment responses are documented and include, as applicable, actions to correct the deficiency, identification of causes and actions to prevent recurrence, lessons learned and actions to be taken for improvement.



## **Safety Guide Q1**

# **ESTABLISHING AND IMPLEMENTING A QUALITY ASSURANCE PROGRAMME**



## CONTENTS

1.	INTRODUCTION .....	29
	Background (101–105) .....	29
	Objective (106) .....	29
	Scope (107) .....	29
	Structure (108) .....	30
2.	ESTABLISHING THE QUALITY ASSURANCE PROGRAMME ....	31
	General (201–208) .....	31
	Grading (209–211) .....	32
3.	DOCUMENTATION OF THE QUALITY ASSURANCE PROGRAMME .....	33
	Strategy (301–308) .....	33
	Documentation structure (309) .....	34
	Quality assurance programme description (310–313) .....	34
	Management documents (314–316) .....	35
	Detailed working documents (317–319) .....	36
4.	IMPLEMENTING THE QUALITY ASSURANCE PROGRAMME ...	36
	General (401) .....	36
	Planning (402–405) .....	37
	Training (406–410) .....	37
	Assessment, analysis and improvement (411–413) .....	38
	APPENDIX: DOCUMENTATION STRUCTURE OF THE QUALITY ASSURANCE PROGRAMME .....	39
	ANNEX I: QUALITY POLICY .....	40
	ANNEX II: INTERFACE ARRANGEMENTS .....	41
	ANNEX III: JOB DESCRIPTIONS .....	42
	ANNEX IV: MANAGEMENT PROCEDURES .....	43
	ANNEX V: WORK INSTRUCTIONS .....	45



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment on basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

103. This Safety Guide should be used equally by the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, and by other organizations participating in the nuclear power plant project.

104. The quality assurance (QA) programme provides a disciplined approach such that work is performed correctly and problems are prevented. Should problems occur, they are detected and corrected, improvements are made and corrective actions taken to prevent recurrence.

105. Participant organizations other than the responsible organization should implement QA programmes to the extent required by their individual procurement documents. Guidance on specifying QA requirements in procurement are contained in Safety Guide Q6.

## OBJECTIVE

106. This Safety Guide recommends acceptable ways to establish and implement a QA programme that is in accordance with the Code and the details contained in other relevant Safety Guides.

## SCOPE

107. This Safety Guide applies to the establishment and implementation of a QA programme by the responsible organization as well as to the establishment and

implementation of other separate programmes at all stages of a nuclear power plant project. It covers items, services and processes important to nuclear safety. It may, with appropriate modifications, also be usefully applied to items, services and processes at nuclear installations other than nuclear power plants. The extent to which a QA programme is applied shall be determined by a graded approach, with nuclear safety as the fundamental consideration.

## STRUCTURE

108. This Safety Guide is arranged into four sections, one appendix and five annexes:

- Section 2 provides guidance on how an organization establishes a QA programme, taking into account the work that it performs for the nuclear power plant project.
- Section 3 provides guidance and a recommended structure for QA programme documentation, including the form and content of individual documents.
- Section 4 provides guidance on how to implement a QA programme.
- Appendix provides an example of a structure of the documentation of the QA programme.
- Annex I provides an example of the key points of the quality policy.
- Annex II describes the content of interface arrangements.
- Annex III describes the content of job descriptions.
- Annex IV describes the content of management procedures.
- Annex V describes the content of work instructions.

## 2. ESTABLISHING THE QUALITY ASSURANCE PROGRAMME

### GENERAL

201. The responsible organization and the organizations involved in the nuclear power plant project shall establish the QA programme<sup>1</sup> as an integral part of their management system.

202. To establish a QA programme, an organization should:

- (a) Identify the activities that have to be carried out.
- (b) Review the applicable regulations and standards and the responsible organization's management and technical practices to determine whether the work activities are adequately addressed.
- (c) Review the Code, the QA Safety Guides and other relevant NUSS Codes and Guides to identify shortcomings and assign priorities to those areas requiring improvement or development.
- (d) Establish time-scales within which the required changes should be implemented.

203. The responsible organization shall develop QA programmes for all nuclear power plant stages (siting, design, construction, commissioning, operation and decommissioning) at a time consistent with the schedule for accomplishing stage related activities.

204. Guidance on details to be addressed in the QA programmes for the different stages of the nuclear power plant project are given in the stage related and basic requirement related QA Safety Guides. The basic requirement related QA Safety Guides are generic to all stages.

205. The person in the most senior management position within the organization is responsible for establishing the QA programme.

206. The QA programme shall be binding on everybody.

207. Since the success of an organization's QA programme is determined by management support and actions, it is essential that management of the organization

---

<sup>1</sup> In some Member States the quality assurance programme is referred to as the quality assurance system or the quality system

express, in issued statements of policy, their commitment to quality and safety and to the implementation of the QA programme as the method of achievement. The quality policy should be reviewed periodically to ensure that it accurately reflects current organizational objectives and priorities.

208. Management should demonstrate its commitment to the quality policy through its actions and provide firm and unambiguous support for its implementation. The actions should foster a corresponding commitment to high levels of performance by all personnel, who in turn should be expected to demonstrate their commitment to the policy. Annex I provides an example of the key points of the quality policy.

## GRADING

209. Whilst the QA principles remain the same, the extent to which the QA requirements are to be applied shall be consistent with the importance to nuclear safety of the item, service or process. A graded approach which can satisfy the necessary requirements and ensure the required quality and safety shall be used.

210. In general, the highest grade should require the most stringent application of the QA requirements; the lowest grade the least stringent. The following are examples of topic areas where grading should be applied:

- Type and content of training,
- Amount of detail and degree of review and approval of instructions,
- Need for and detail of inspection plans,
- Degree of in-process reviews and controls,
- Requirements for material traceability,
- Type of assessment,
- Records to be generated and retained.

211. When items, processes or services are modified, the assigned grade of QA requirements could become more stringent or less stringent depending on whether a change in nuclear safety significance has occurred.

### **3. DOCUMENTATION OF THE QUALITY ASSURANCE PROGRAMME**

#### **STRATEGY**

301. The documentation of the QA programme consists of the QA programme description, the management documents and detailed working documents necessary to ensure that work is properly performed.

302. Documentation of the QA programme should be structured so that it is appropriate to the organization and the work it performs, and is readily understood by users. Its structure and format should also be flexible enough to accommodate changes in policy, strategic aims, quality standards, regulatory requirements and other statutes, as well as feedback from implementation and lessons learned from other plants and facilities.

303. The QA programme should adopt a vocabulary that is coherent, makes managerial sense and is clear, unambiguous and readily understandable. To this end, it is necessary to write each document in a manner appropriate to the level of expertise of the persons using it and in a user-friendly manner that reflects the normal ways of working.

304. The QA programme shall include measures which ensure that documentation is available in a language appropriate to the user. Management shall state the languages to be used for the work instructions and procedures and specify measures to ensure that personnel understand what they are being asked to do. Translations of documentation should be reviewed by competent persons to ensure they are accurate.

305. The content of documents should be determined with the participation of people who will use them to do their work, and other people who are affected by them. Such individuals should also have an input into subsequent revisions. In the case of detailed working documents, trial use and validation using mock-ups, simulators and walk-throughs, or pre-production runs and testing are ways of determining the accuracy of the documents.

306. Some organizations own and operate nuclear power plants and other fuel cycle facilities. In these cases, one QA programme for the whole organization should be established to co-ordinate and integrate the common objectives, missions and work of the organization's nuclear facilities. To complement such QA programmes, specific programmes are necessary to address work that is unique to one or more of the organization's facilities. Maximum use should be made of existing policies and procedures.

307. The QA programmes should take account of the details contained in the corresponding Safety Guides and should also recognize that:

- time-scales for implementing the stage related QA programmes overlap significantly;
- there are significant transfers of responsibility and of hardware and software between the organizations responsible for the consecutive stage (Annex II provides guidance on interface arrangements);
- the planning and development of the later stage QA programmes commences during the early stages of a project, for example design review requires consideration of inspectability, constructability, operability, maintainability and ALARA requirements before finalization of the design. To do this effectively, the advice of constructors and operators should be sought early in the design stage.

308. The requirements and needs of the QA programme for a particular stage should be considered during earlier stages so that they are fully established prior to the commencement of the stage. For example, establishing the QA programme for operations includes: providing fully documented detailed working documents; having a trained and qualified workforce; and ensuring that workshops, facilities, tools and suitable working environments are in place.

## DOCUMENTATION STRUCTURE

309. A three-level system of documentation is recommended as it promotes clarity and avoids repetition by establishing the amount of information and detail contained in each type of document and by using cross-references between specific documents at the different levels. What follows is the description of a typical three-level system, shown in the Appendix, which consists of:

- (1) QA programme description
- (2) Management documents
- (3) Detailed working documents.

## QUALITY ASSURANCE PROGRAMME DESCRIPTION

310. The QA programme description defines the programme established to meet the basic requirements of the Code. The QA programme description shall address those requirements of the Code that apply to the organization's work.

311. The QA programme description should be management's primary means of communicating to personnel its expectations and strategy for success and methods for achieving them.

312. The following should be included in the QA programme description:

- Management's quality policy statement;
- The mission and objective of the organization;
- The organizational structure and outline of the management procedures;
- The level of authority and the responsibilities and accountabilities of persons and organizational units;
- The lines of internal and external communications and interface arrangements;
- The responsibilities of each organization involved in the work;
- Requirements for training, facilities and working environment;
- Requirements for the development of detailed working documents for the performance and assessment of work;
- The arrangements for establishing a graded approach to nuclear safety;
- The arrangements for measuring effectiveness and management self-assessment of the QA programme.

313. The person in the most senior management position in the organization shall approve the QA programme description, ensure it is distributed to staff for implementation of its requirements, and ensure its effective implementation.

## MANAGEMENT DOCUMENTS

314. Management documents identify the controls which expand on the policies and objectives presented in the QA programme description by providing specific detail on how activities are to be performed. These documents should:

- (a) Detail the functions, authority, responsibilities and accountabilities of units and individuals within the organization. For individuals this should be in the form of job descriptions and for units in the form of departmental manuals.
- (b) Define the responsibilities and lines of communication internal and external to the organization in each area of activity, for example management procedures and interface arrangements.
- (c) Specify which activities are to be carried out and controlled, and who is responsible and accountable and, where appropriate, refer to detailed working documents.
- (d) Identify and plan activities to ensure work is dealt with in a systematic and expeditious manner.

315. Management procedures are used to define the processes which are identified in the QA programme description and which usually involve more than one organizational unit. Such procedures describe what is to be done to manage a specific process by identifying inputs, key activities, outputs, records and associated responsibilities and are used as inputs to the development of interface arrangements and job descriptions (see Annexes II, III). To avoid unnecessary detail, cross-reference should be made to working instructions. Annex IV describes a typical format for management procedures.

316. Management procedures should not be used to define how technical tasks are to be performed by an individual or a discrete team.

#### DETAILED WORKING DOCUMENTS

317. Detailed working documents consist of a wide range of documents developed by the line organizations to prescribe the specific details for the performance of tasks by individuals, or by small functional groups or teams. In an operational nuclear power plant, they include work instructions and technical instructions and typically cover components and systems operation, components and systems maintenance and tests, modifications, calibrations, radiation protection and chemistry activities.

318. The type and format of working documents can vary considerably depending on the application involved. Annex V describes an example of the format of a working instruction.

319. The primary consideration should be to ensure that the documents are suitable for use by the appropriate personnel and that the contents are clear, concise and unambiguous, whatever the format.

## **4. IMPLEMENTING THE QUALITY ASSURANCE PROGRAMME**

### GENERAL

401. The person in the most senior management position in the organization shall be responsible for ensuring that the QA programme is implemented. Implementing the QA programme requires the collaborative effort of management, those performing the work and those assessing the work. Satisfactory implementation requires good

planning and the deployment of adequate resources. All participants need to be trained to achieve proficiency and to ensure they understand the management processes which apply to the performance of their work. QA programme effectiveness shall be assessed and reviewed at all stages of implementation. The information gained from assessments should be used to achieve continuing improvements in work performance.

## PLANNING

402. Management should prepare a plan to achieve full implementation of the QA programme. The implementation plan should be approved and monitored by the appropriate management level.

403. Staffing plans should include provisions for selecting, training and assigning adequate numbers of personnel consistent with schedules for implementation and work loading. Consideration should be given to the need for special skills and training.

404. Work plans, schedules, instructions, technical instructions and drawings which are needed to define the specific actions to perform work should be developed and used to accord with the management processes described in the QA programme description. Their preparation should be planned and scheduled, so that performance personnel have clear instructions on how to correctly perform and sequence the work.

405. Plans for assessing the effectiveness of instructions and their implementation relative to the performance of work and the results achieved with respect to quality and safety should be specified and implementation should commence as soon as possible. Frequent early assessments may be necessary to ensure the adequacy of instructions and to prevent the endorsement of poor practices.

## TRAINING

406. The organization's overall objectives regarding item quality, personnel and public safety and their direct relation to the quality policy and the QA programme shall be explained in the initial and continuing training of all personnel who are managing, performing and assessing work.

407. The success of the QA programme in bringing about continuous quality improvement depends on universal acceptance within the organization. Senior

managers, line managers, supervisors, designers and engineers, technicians, craftsmen and administrative personnel should be informed about the importance of their roles.

408. The correct completion of work should be emphasized, focusing on 'doing it right the first time' and on the safety consequences of improper, inadequate or incorrect work.

409. Training in the application of work instructions or major instruction revisions should be given by the department responsible for the work to those who have to apply the procedure to do the work. This is an opportunity for management to explain the importance of adherence to instructions. Feedback on their application should be sought and revisions made to correct identified difficulties.

410. The importance of stimulating professional development should be recognized. Training shall provide for the progressive improvement of personnel, and should not be limited to initial job qualification and proficiency.

#### ASSESSMENT, ANALYSIS AND IMPROVEMENT

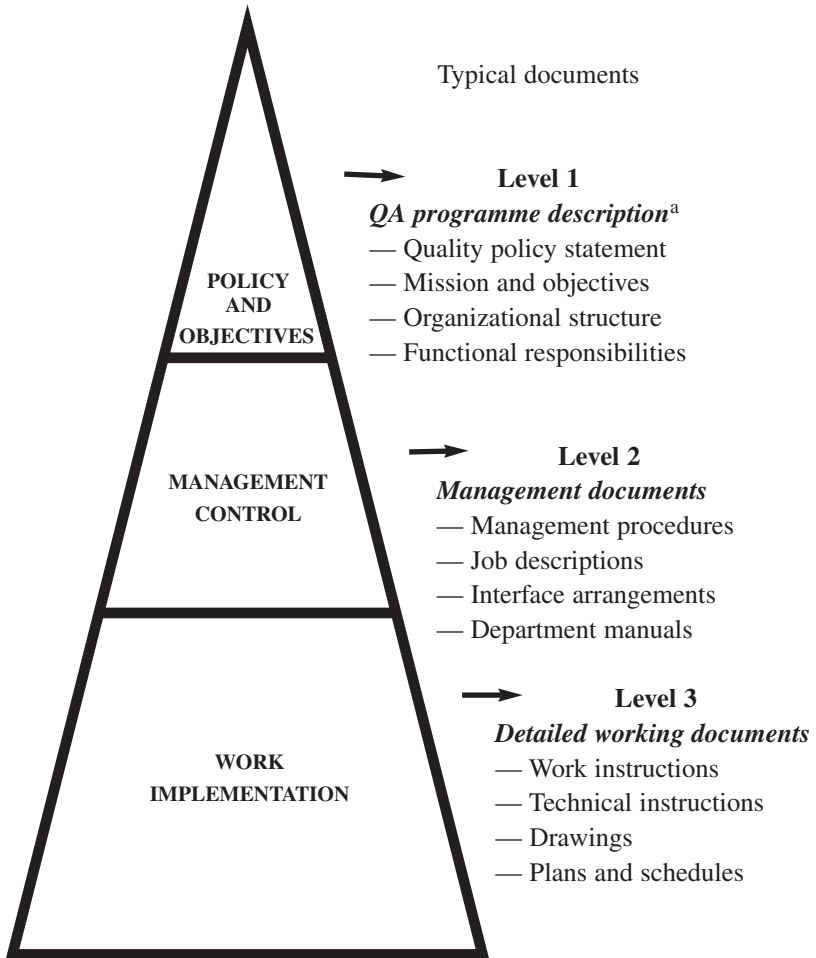
411. Managers should assess and analyse performance. They should consider, for example, failures and breakdowns, rework and frequency, delays, errors, lost time, work backlog trends, compliance with requirements and improvements. Use of performance indicators and other appropriate methods should be developed. For further guidance on performance indicators see Safety Guides Q5 and Q13.

412. When the assessment identifies the need to change management processes, such changes should be formally proposed, agreed and introduced. It may be necessary to refer recommendations for change to a more senior level of management.

413. Target dates for the implementation and completion of improvements arising from these assessments should be assigned. Progress should be tracked to completion.

## Appendix

### DOCUMENTATION STRUCTURE OF THE QUALITY ASSURANCE PROGRAMME



<sup>a</sup> In some Member States this document is termed a quality assurance manual.

## Annex I

### QUALITY POLICY

The quality policy should, for example:

- (1) Specify the organization's mission and objectives.
- (2) Set management's expectations for organizational and individual employee performance.
- (3) Express management's support of each employee in carrying out his/her assigned work.
- (4) Promote an attitude of continuous improvement.
- (5) Create an environment that promotes quality and the improvement of quality throughout the entire organization.
- (6) Ensure employees have the necessary responsibility and authority to carry out their work as it has the greatest effect on item, service and process quality.
- (7) State a commitment that items, services and processes should be of the highest quality, resulting in protection of the health and safety of the workers and the public.
- (8) Establish management's responsibility for ensuring that employees understand and accept their respective roles and obligations in carrying out the quality policy.
- (9) Define the key documents which govern the levels of performance, such as:
  - Responsible organization's policy statements,
  - Statutes and regulations,
  - QA programme description,
  - National codes and standards.

## Annex II

### INTERFACE ARRANGEMENTS

There needs to be a clear understanding of the division of responsibilities between all organizational units participating in a QA programme. These include centralized corporate and technical departments providing support to architect/engineering firms, company safety committees and public services providing support.

Consistent methods of defining relative responsibilities and lines of communication should be implemented whenever two or more significant organizational units contribute to an activity that affects quality.

Interface agreements, sometimes referred to as ‘memoranda of understanding’, or equivalent documents should be developed to satisfy these needs. An interface agreement is a formal agreement which defines the interface. Its acceptance by the senior managers of the interfacing organizations is obtained in writing. It should be distributed to all participants.

In the preparation of these interface documents the following points should be addressed:

- (a) The participating units should be identified and included on the circulation/control list.
- (b) The prime responsibilities, authority and accountability for the activity should be clear.
- (c) Responsibilities for review and comment, approval of technical issues, implementation, reporting, verification and audit, where appropriate, should be defined.
- (d) Key positions within each unit to act as focal points for communication should be identified.
- (e) The contents of the formal documents required to implement the procedure or convey technical information across the interface (typically programmes, plans, specifications, procedures, instructions, drawings and records) should be defined.
- (f) The flow of documents among the organizational interfaces and time-scales for requisite action by the interfacing units/groups should be prescribed.

## **Annex III**

### **JOB DESCRIPTIONS**

The Code requires that QA programmes describe the organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of work. At the individual employee level, one of the primary ways this information is communicated is through a job description.

Job descriptions should be developed for different categories or types of work. They should define the total scope of an employee's job. Job descriptions can be used effectively to establish baselines for identifying training needs. While job descriptions are usually only mandated down to supervisory levels, descriptions are an excellent way for management to communicate responsibilities, authority and interfaces to all employees.

A typical job description should contain the following information:

- (1) Job title
- (2) Purpose of job
- (3) Organization
  - Organizational structure for that post
  - Position in the organization
  - Lines of reporting
- (4) Duties
  - Key tasks and responsibilities
  - Authority
  - Accountability
- (5) Qualifications
  - Knowledge and expertise
  - Education
  - Training
  - Experience
  - Medical fitness

## Annex IV

### MANAGEMENT PROCEDURES

Management procedures, sometimes referred to as programmatic or management control procedures, provide administrative direction to management personnel. The procedures outline the actions management must take to implement the organization's management system. Management procedures are not used to provide the details of how technical tasks are to be performed. Technical tasks are addressed in working level documents (see Annex V). The following provides guidance regarding the content of sections typically contained in a management procedure:

- (1) **Purpose.** What is the objective of the management procedure? State clearly and concisely the specific objectives of the management procedure and answer the question "why does the document exist?"
- (2) **Scope.** What management actions are addressed by the management procedure and who is supposed to use it? Define the type of work and situations to which the management procedure applies. State the boundaries of application of the management procedure.
- (3) **Responsibilities.** Who in management is primarily responsible for the work defined in the management procedure? Identify the persons by title and define their responsibilities.
- (4) **Definitions.** What words are used in the management procedure that are not commonly understood? Define those words that may cause confusion.
- (5) **References.** Would other documents be of use to managers who use the management procedure? If so, list the specifications, standards or other documents that are referenced in the text and which may possibly provide additional information to users. If documents are referenced in part, state the page and paragraph numbers.
- (6) **Details.** How is the work that is the subject matter of the management procedure conducted? Detail the actions required to accomplish the purpose and scope of the management procedure. Include all information that is critical to planning, scheduling and performing the work outlined in the management procedure. Write the text simply and directly. Approved numbering and nomenclature for job titles and documents should be used. The details section of a management procedure describes what is to be done by providing the following typical information:
  - Planning and scheduling considerations to ensure work is dealt with systematically and expeditiously
  - Administrative and technical information

- Work steps to be carried out
  - Responsibilities and authorities
  - Interfaces
  - Lines of communication both within and outside the organization
  - Cross-references between the management procedure and supporting sections of the QA programme description, other management procedures and working level documents.
- (7) Documents and records. Which documents and records are necessary to do the work and which ones need to be retained after the work is complete? Identify the documents that provide the applicable policies and work requirements. Identify the records required to show that the tasks required in the management procedure have been accomplished.
- (8) Appendices (where applicable). Is additional information required? If so, provide it.

## Annex V

### WORK INSTRUCTIONS

Work instructions are used to describe specific work processes and convey administrative and technical information to personnel performing work. Work instructions include technical instructions and drawings. In an operating nuclear power plant, work instructions include, for example, instructions for equipment operations, equipment maintenance and testing, calibrations, health physics processes, chemistry control and welding. The following provides guidance regarding the content of sections typically contained in work instructions.

- (1) **Purpose.** Why is the document necessary? Give a clear, concise statement explaining the specific aim(s) of the document and answer the question “why does the document exist?”.
- (2) **Scope.** What is covered by the document? Define the type of work and places where the document applies, and delineate the boundaries of the functions, systems and areas treated in the document.

*Note:* The above two headings (Purpose and Scope) need not be used if the title adequately covers the content.

- (3) **Responsibilities.** Which persons are responsible for the particular activities defined in the document? Define the duties of the persons implementing the document. Identify the persons (by title) and their responsibilities and specify when a required action is needed.
- (4) **Definitions.** Define those words and terms used in the document that might cause confusion and thus require clarification.
- (5) **References.** Give a bibliography of specifications, standards and other documents referenced in the document. If documents are referenced in part, state the page and paragraph numbers. (This can include reference to other work instructions.) Reference documents could include applicable design or other source documents such as vendors’ literature, engineering drawings or plant specifications.
- (6) **Prerequisites.** What independent actions need to be performed and by whom, prior to the use of the procedure or instruction? State any spare parts, special tools or instrumentation which are necessary (scaffolding, services, etc.) and the required state of the plant if relevant, plus any special conditions to be used to simulate normal or abnormal operating conditions.
- (7) **Precautions.** What precautions are necessary to protect equipment, personnel and the public or to avoid an abnormal or emergency situation? Identify these

in the relevant steps of the procedure or instruction or highlight them in a separate section.

- (8) **Limitations.** Are there any limitations on the parameters being controlled? Identify corrective measures to restore them to the normal control limits.
- (9) **Actions.** Include a step by step description of the function or task to be performed. Give sufficient detail so that a qualified individual can perform the function or task without direct supervision. Wherever possible, a step should consist of one action.
- (10) **Verification.** Identify any work activity which requires verification or independent verification. Highlight these points at the relevant step in the procedure.
- (11) **Acceptance criteria.** Include criteria so that satisfactory completion of the task or function can be determined. If tolerances in prescribed limits are allowable, they should be identified together with any requisite actions (reporting, etc.). Identify the method of verification to be used. This can be included within the procedure or on checksheets. Reference documents could be used as a source of acceptance criteria details.
- (12) **Restoration** (normally used when plant is taken out of normal operation for routine tests). Include step by step requirements for restoring the component or system to the required operational condition following completion of the tasks or function (if relevant to the particular task).
- (13) **Records/checksheets.** Which documents/forms are used and retained? Checksheets are recommended when complex procedures or instructions are used. Enumerate, by title, the list of reports and documents required to certify or provide that the tasks required in the document have been accomplished and verified and attach examples of the documents/forms. Identify records as permanent or non-permanent in accordance with the criteria defined in Safety Guide Q3, together with the retention time for non-permanent records. Mark sample attached forms 'Specimen', record the date and the identification of those performing the work and, where appropriate, the 'as found' condition, corrective action performed and the 'as left' condition.

*Note.* The following paragraphs apply to the event based instructions such as emergency procedures or receipt of alarms and should be included in the procedure when appropriate.

- (14) **Symptoms.** Include a list of symptoms such as alarms, operating conditions and probable magnitude of parameter changes to aid the identification of an abnormal situation. Where applicable, identify those parameters which are not expected to change.
- (15) **Automatic actions.** Identify the probable automatic actions to occur during an abnormal situation.

- (16) **Immediate operator actions.** Specify the immediate operator actions required or confirmation of automatic actions which will stop the degradation of conditions or mitigate their consequences.
- (17) **Subsequent operator actions.** Include steps that need to be taken to return the plant to normal conditions or that are needed to shut down the plant safely under abnormal or emergency conditions.



## **Safety Guide Q2**

### **NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS**



# CONTENTS

1.	INTRODUCTION .....	53
	Background (101–102) .....	53
	Objective (103) .....	53
	Scope (104) .....	53
	Structure (105) .....	53
2.	GENERAL CONSIDERATIONS .....	54
	Management responsibilities (201–204) .....	54
	Grading (205–206) .....	54
3.	NON-CONFORMANCE CONTROL .....	55
	Non-conformance identification (301–303) .....	55
	Reporting (304) .....	56
	Initial actions (305) .....	56
	Labelling and identification (306) .....	56
	Segregation (307) .....	57
	Review of non-conformances (308–313) .....	57
4.	CORRECTIVE ACTIONS .....	58
	Disposition (401) .....	58
	Completion of corrective actions (402–403) .....	59
	Preventive actions (404–406) .....	59
ANNEX I:	EXAMPLES OF GRADING IN NON-CONFORMANCE CONTROL .....	61
ANNEX II:	NON-CONFORMANCE REPORT — TYPICAL CONTENT .....	63



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the basic requirement of the Code on non-conformance control and corrective actions.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e the organization having overall responsibility for the nuclear power plant, as well as to any separate programmes in each stage of a nuclear power plant project, and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into four sections and two annexes:

- Section 2 describes general considerations on management responsibilities and grading.
- Section 3 describes processes and measures for control of non-conformances.
- Section 4 provides guidance on investigation of root causes and determination of corrective actions.

- Annex I provides examples of grading in non-conformance control.
- Annex II provides examples of the typical content of a non-conformance report.

## **2. GENERAL CONSIDERATIONS**

### MANAGEMENT RESPONSIBILITIES

201. Management shall establish and maintain a process or processes that provide for identifying, reporting, reviewing and physically controlling items, services or processes that do not conform to specified requirements. It is possible to develop several different processes to control non-conforming items, services or processes such as work defects, event reporting, operating rule breaches, technical specification violations, assessment findings, etc. Each process should make provisions to prevent the inadvertent use or installation of items, services or processes that do not conform and ensure that effective corrective action is taken. Non-conformances should be regarded as opportunities for improvement and as such should be used as an input to the quality improvement process. Management should assign sufficient resources for this purpose.

202. Management should ensure that those performing work are aware of and use the process for prompt notification and reporting of non-conformances.

203. Management at all levels should encourage personnel to discover and report non-conformances.

204. Management should allocate responsibilities so that the handling of non-conformances is monitored from the time they are identified to verified completion of the agreed corrective action, including providing feedback to those personnel who discovered the non-conformance.

### GRADING

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach, based on the relative importance to nuclear safety of each item, service or process, should be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

206. Annex I provides an example of the application of the graded approach in the non-conformance process. For further guidance on grading see Safety Guide Q1.

### 3. NON-CONFORMANCE CONTROL

#### NON-CONFORMANCE IDENTIFICATION

301. Any person who finds items<sup>1</sup>, services or processes which do not meet specified requirements, or who observes abnormal behaviour, should be required to notify and formally report the matter to the management using the appropriate process.

302. Conditions and events to be handled by the non-conformance control process could include:

- Physical characteristics outside specified limits, such as dimensional and/or material parameters, installation errors and item/system performance deficiencies.
- Deviations from approved process parameters or procedures.
- Failure of personnel to implement work, inspection or test instructions.
- Inadequate documentation, containing incorrect or incomplete information.
- Inadequate training of personnel to perform safety related tasks for which they have been given responsibility.
- Incidents, malfunctions and failures.

303. Non-conformances may be discovered during:

- Performance of work;
- Inspection and testing for acceptance;
- Surveillance, including process monitoring;
- Procurement;
- Assessments (for example audits);
- Regulatory inspections (see Safety Series No. 50-C-G (Rev. 1)).

---

<sup>1</sup> Reference to non conforming items should be considered to also include non-conforming documents.

## REPORTING

304. A formal report of a non-conformance should, for example:

- Identify who is reporting the non-conformance, when it was found and to whom it was reported;
- Identify the non-conforming item, service or process and state the location, the method used to physically mark, label, segregate or otherwise control the item and the service or process to prevent its inadvertent use;
- Include a description of the non-conformance;
- Describe the immediate action taken by the originator, or known to be taken by others, to minimize adverse effects of the non-conformance.

The non-conformances should be reported in sufficient detail to allow proper review. Unique identification should be given to each report to allow effective tracking. Two examples of information which could be included in a non-conformance report are shown in Annex II.

## INITIAL ACTIONS

305. On being advised of a non-conformance, the line management should promptly:

- Ensure that a report has been raised, verify the details contained in it and acknowledge notification;
- Initiate immediate, necessary action to minimize the effect of the non-conformance;
- Confirm that the item, service or process has been identified (i.e. physically marked, labelled, segregated or otherwise controlled) as non-conforming;
- Determine what restrictions on further use of the item, service or process should be put in place;
- Arrange for a more detailed review of the non-conformance, taking into account the guidance in para. 308;
- Inform the regulatory body and other nuclear power plants if necessary.

## LABELLING AND IDENTIFICATION

306. As soon as an item, service or process is recognized as being non-conforming it should be physically marked, labelled, segregated or otherwise controlled. The labelling and identification system should include arrangements to ensure that:

- Marking, labelling and other information is consistent with the content of the non-conformance report (see para. 304);
- The inspection, test or operational status of the item, service or process is clear;
- The non-conforming status is clear, both on the item and at any remote operation or indication points connected to it;
- It is clear who is authorized to change the status of an item, service or process;
- Any restrictions on the use of an item or service are identified.

## SEGREGATION

307. Consideration should be given to physically segregating a non-conforming item or process to ensure that it is not used before any agreed and approved corrective action has been taken. Segregation may be achieved by removal to a secure area, placing behind barriers, isolating the non-conforming item, or stopping the service or process, or by administrative control.

## REVIEW OF NON-CONFORMANCES

308. Non-conformances should be reviewed as soon as practicable by appropriate personnel who should be selected by taking the following into account:

- The QA grade or classification of the affected item, service or process;
- The need for the safety implications of the non-conformance to be independently reviewed;
- The need to involve the design organization or other persons who have access to the original design information, including any subsequent modifications;
- The need to involve the operating organization;
- The need to involve the original supplier;
- The need to involve the regulatory body.

309. The review should determine:

- (1) The cause of the identified non-conformance, which could include failures, malfunctions, incorrect materials, tools, equipment, procedures, information, training, or human error. Root cause analysis techniques should be utilized.
- (2) Any safety implications of the non-conformance.
- (3) The corrective actions (see Section 4) to be agreed and approved to correct the non-conformance and prevent repetition of similar non-conformances which may also include:

- Search for other affected items,
- Reinspection or retesting,
- The amendment of any established documentation,
- Any restrictions or requirements for the corrective action implementation.

310. The results of the review should refer to the non-conformance report.

311. During the review additional information about the nature of the non-conformance and restrictions to be imposed on further processing or operation should be made available to involved organizations, including the regulatory body and other nuclear power plants if required.

312. Information about the non-conformance, and its implications to safety, should then be used to determine the impact on affected activities until the agreed and approved corrective action is verified as having been satisfactorily completed. The following are typical effects that should be considered:

- Requirements to carry out additional inspection or testing, in order to obtain higher levels of confidence in items,
- Restrictions on further processing of items or services during manufacture or construction,
- Restriction on the use of other components from the same supplier,
- Restriction on documents use,
- Restrictions on operation regimes through changes in operating limits and conditions or amendments to maintenance schedules,
- Stoppage of the work if it is determined that its continuation would lead to an unsafe condition,
- Retraining of personnel.

313. Relevant information on the status of non-conformances should be reported to management and the regulatory body, where required.

## **4. CORRECTIVE ACTIONS**

### **DISPOSITION**

401. Following review, non-conformances could be designated in one of the following ways:

- (1) *Reject* (also sometimes referred to as Scrap). The non-conforming item, service or process is not fit for the intended use. Such non-conformances should be marked and segregated as soon as the action is agreed and approved.
- (2) *Repair*. The non-conforming item, when repaired (or in the case of documents revised) is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification. Temporary repair should have a prescribed period of validity.
- (3) *Rework*. The item is capable of being fully restored to the original specification requirements, i.e. some additional rework carried out under suitable conditions will correct the non-conformance.
- (4) *Accept with conditions*. In this instance it is likely that the non-conformance item, service or process will be fit for use under special, specified conditions.
- (5) *Accept without modification* (also sometimes referred to as Use-as-is). In this instance it is likely that the non-conforming item, service or process deviates marginally from specified requirements but is still declared fit for use.

## COMPLETION OF CORRECTIVE ACTIONS

402. Corrective actions should not be considered complete until all affected documents have been amended, modifications implemented and evidence of verification of completion obtained.

403. Management should allocate responsibilities for monitoring non-conformances, from the reporting stage to verified completion of the agreed corrective action, including feedback to those personnel who discovered the non-conformance.

## PREVENTIVE ACTIONS

404. The purpose of preventive actions is to preclude the repetition of similar non-conformances from occurring and to improve plant safety and performance. Preventive actions may include, but need not be limited, to the following:

- Changes to designs, specifications, procedures, etc.
- Enforcement of the requirements of procedures, work instructions, etc.
- Modification of current procedures or issue of new procedures.
- Withdrawal of defective equipment for maintenance or calibration.
- Retraining and requalification of personnel involved.
- Improvement to the QA programme.

405. Management should periodically analyse available information, such as non-conformance reports, audit reports, maintenance reports, operating logs, significant event registers, plant safety reviews, etc. This analysis should seek out trends in order to identify problem areas requiring root cause analysis, to confirm that appropriate actions have been taken to prevent repetition of the non-conformances and to enhance plant safety and performance. Information on incidents, events or quality related problems available from other nuclear power plants/organizations (operational experience feedback) should be assessed in order that suitable preventive measures can be developed and implemented.

406. Implementation of preventive actions may proceed in stages. In such cases each stage should be clearly defined and specify the means of verification that assures that the actions have been effective. Prior to implementation, all proposed actions should have been agreed, documented and authorized by appropriate personnel and the regulatory body if required.

## Annex I

### EXAMPLES OF GRADING IN NON-CONFORMANCE CONTROL<sup>1</sup>

The following text provides an example of what the requirements for each grade could be.

#### Grade 1 (highest level)

- Identify and hold non-conformances for evaluation.
- Report non-conformances to senior management and the regulatory body if required.
- Define the responsibilities and authority of those assigned to the disposition of non-conforming items, services and processes.
- Provide for a review of the non-conformance involving representatives from all relevant organizational units, including the assessment (or quality assurance) unit.
- Record each non-conformance.
- Obtain concurrence of all responsible parties for agreed corrective actions.
- Identify all non-conforming items, services or processes, mark them and place them in a segregated holding area when feasible.
- Ensure that reworked and repaired items are reinspected and retested according to the original or approved modified requirements.
- Verify that the agreed and approved corrective action has been properly implemented.
- Maintain records on all non-conformances, agreed corrective actions, results of reinspection and retests.

#### Grade 2

- Identify and hold non-conformances for evaluation.
- Contact those individuals assigned to the disposition of non-conforming items, services and processes.
- Identify and record each non-conformance and agreed and approved corrective action.
- Verify that the agreed and approved corrective action has been properly implemented.

---

<sup>1</sup> The categorization of non-conformances should be performed by experienced personnel to the procedure appropriate to the type of non-conformance.

### **Grade 3**

- Identify and hold non-conformances for evaluation.
- Contact those individuals assigned to implement the agreed corrective action.
- Identify all non-conforming items.
- Release non-conformances for agreed and approved corrective actions when instructed.

### **Grade 4**

- Identify and correct non-conformances as they occur.
- Record non-conformance data for trend analysis.

## Annex II

### NON-CONFORMANCE REPORT — TYPICAL CONTENT

The following list of headings for a non-conformance report may be considered, but it is not necessarily a full list. On the other hand, not all its headings are applicable for every non-conformance. Responsible management should consider their own activities, the stage of the nuclear power plant in which the work is being undertaken and the importance of any item to safety. From those considerations they should then develop their own reporting requirements.

#### Example 1

Non-conformance reporting content for items (*Note*: These points may be included in separate parts of the document.):

- Unique number
- Description of non-conformance
- Plant item and location of non-conformance
- When discovered (time/date)
- By whom discovered (name/department/organization)
- How discovered
- Immediate action taken
- To whom the report is addressed
- Reported at (time/date) (*Note*: Important items may be initially reported by telephone or radio and then confirmed in writing. Both actions should be documented in the report.)
- Signature to record acceptance of the form.

The status of the item under corrective action should be recorded with respect to the following:

- To whom reported (name/position/organization)
- Verification of non-conformance details
- Initial assessment of implication with regard to safety
- Notification to management/other affected personnel and, as appropriate, to the regulatory body
- Physical marks, labels or other controls implemented on other items or systems potentially affected by the non-conformance
- Root cause
- Agreed corrective action

- Agreement of principal designer
- Restrictions to be applied during the implementation of the agreed corrective action and if necessary in the longer term
- Documentation requiring to be changed
- Related instructions for implementation of the agreed actions
- Verification of completion (name/date/time).

## **Example 2**

Non-conformance reporting content for processes:

- Report No.
- Plant
- Location or installation
- Title of occurrence of non-conforming (unusual) event
- Date and time of occurrence
- Status of plant/installation
- Category of unusual event (if relevant)
- Date of prompt notification and means thereof
- Description
- Safety assessment
- Root cause
- Corrective actions
- Lessons learned
- Additional useful information for assessment
- Status of installation (power, start-up, shutdown, testing, etc., to be ticked off)
- Affected system components
- Radiological information
- Cause of occurrence
- Consequences of occurrence
- Effect on site personnel (injuries, radiation exposures)
- Conditions in installation after occurrence
- List of supporting documents annexed
- Signatures such as: prepared by, countersigned by, approved by.

## **Safety Guide Q3**

### **DOCUMENT CONTROL AND RECORDS**



# CONTENTS

1.	INTRODUCTION .....	69
	Background (101–102) .....	69
	Objective (103) .....	69
	Scope (104) .....	69
	Structure (105) .....	69
2.	GENERAL CONSIDERATIONS .....	70
	General (201–204) .....	70
	Grading (205–206) .....	70
3.	DOCUMENT CONTROL .....	71
	Preparation of documents (301–305) .....	71
	Review of documents and confirmation of acceptability (306–311) .....	72
	Approval of documents (312–313) .....	72
	Issue and distribution of documents (314–319) .....	72
	Temporary documents (320–321) .....	73
	Document modification control (322–324) .....	73
	Suspension or cancellation of a document (325–327) .....	74
	Documents external to the responsible organization (328–330) .....	74
	Document archives (331–332) .....	74
4.	ESTABLISHMENT OF A RECORDS SYSTEM .....	75
	General (401–403) .....	75
	Categorization of records (404–406) .....	75
	Records administration (407–412) .....	76
	Receipt of records (413–414) .....	77
	Retrieval and accessibility (415–417) .....	77
	Storage requirements (418–424) .....	78
	Disposal (425–427) .....	79
ANNEX I:	STORAGE MEDIA FOR RECORDS .....	80
ANNEX II:	DOCUMENT AND RECORD STORAGE FACILITIES .....	82
ANNEX III:	EXAMPLES OF RECORDS AND THEIR RETENTION CATEGORIES .....	87
ANNEX IV:	A TYPICAL PROCESS FOR ALLOCATING RETENTION TIMES OF RECORDS .....	94



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the basic requirements of the Code on document control and records.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate programmes in each stage of a nuclear power plant project, and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into four sections and four annexes:

Section 2 provides general considerations relating to document control and records including information on grading.

Section 3 describes the controls applicable to preparing and issuing documents. It also addresses temporary instructions, external documents and archives.

Section 4 describes the requirements for the establishment of a records system.

- Annex I describes the storage media for records.
- Annex II describes document and record storage facility features.
- Annex III gives examples of records and their retention categories.
- Annex IV provides an example of the process for allocating retention times of records.

## **2. GENERAL CONSIDERATIONS**

### **GENERAL**

201. For each nuclear power plant, a document control system should be established and should provide for the preparation, review, approval, issuance, distribution, revision and validation (where appropriate) of documents essential to the management, performance and verification of work.

202. In the document control system the responsibilities for each participating organization or individual should be defined in writing.

203. The types of document include, but are not limited to, documents comprising the QA programme, safety requirements, maintenance and operating procedures, inspection instructions, inspection and test reports, assessment reports, drawings, data files, calculations, specifications, computer codes, purchase orders and related documents, vendor supplied documents and work instructions.

204. Management should identify the need for documents and should provide guidance to the organizations and people preparing them. The guidance should cover status, scope and contents and the policies, standards and codes which apply. It should also explain the need for feedback of experience. Plant modification or the results of assessments could also give rise to the need for a new document.

### **GRADING**

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach, based on the relative importance to nuclear safety of each item, service or

process, shall be used. The graded approach shall reflect a planned and recognize difference in the applications of specific QA requirements.

206. Aspects of document control and records management that could be graded include:

- The need to apply controls to the preparation of documents and records,
- The need and extent of validation,
- The degree of review and the persons involved,
- The level of approval,
- The need for distribution lists,
- The types of document which can be supplemented by temporary documents,
- The need to archive superseded documents,
- The need to categorize, register, index, retrieve and store document records,
- The retention time of records,
- The responsibilities for the disposal of records,
- The types of storage media.

For further guidance on grading see Safety Guide Q1.

### **3. DOCUMENT CONTROL**

#### **PREPARATION OF DOCUMENTS**

301. When documents are in their preparatory phase, they should be marked and controlled so that their draft status clearly distinguishes them from issued documents.

302. An appropriate document identification system should be established. Each document should be uniquely identified.

303. Standard forms should be identified and controlled, whether these stand alone or are part of another document.

304. The need for traceability of a document to related hardware or software should be determined.

305. During preparation, activities described by the documents should be assessed using the grading system, so that the appropriate controls are chosen and included.

## REVIEW OF DOCUMENTS AND CONFIRMATION OF ACCEPTABILITY

306. Documents shall be reviewed before issue. The review should comprise a critical examination of the adequacy of and the need for the document, against prescribed requirements, guidelines and relevant modifications taking into account the safety significance of the document

307. The document review system should identify the organizations or individuals responsible for reviewing the documents.

308. The reviewing organization or individuals shall have access to the relevant information upon which to base an effective review and to ensure that safety considerations are adequately addressed.

309. The reviewing organization or individuals shall be competent in the specific topic they are being asked to review.

310. A record of review shall be prepared showing the date of the review, the reviewer(s) and the outcome.

311. One aspect of review involves validating the implementation of the document through simulation, mock-up, walk-throughs or the like. This validating process is usually applied to significant working level instructions and procedures.

## APPROVAL OF DOCUMENTS

312. Documents shall be approved according to a prescribed method before they are issued for use. The responsibilities for approval should be clearly defined by management.

313. Where acceptance by, or approval of, a regulatory body (see Safety Series No. 50-C-G (Rev. 1)) is required, this should be obtained before the document is issued for use.

## ISSUE AND DISTRIBUTION OF DOCUMENTS

314. A document issue and distribution system should be established, utilizing up to date distribution lists. Those participating in an activity shall be aware of, have access to, and use the documents which have been approved for performing the

activity. The system shall ensure that changes to documents are relayed to all affected persons and organizations. Copies subject to revision update (controlled copies) should be identifiable.

315. The issued documents should be marked so that their use becomes clear, especially if their use is restricted to a certain purpose. Examples of marking include the indication that the document is approved for use in engineering procurement, manufacturing, construction or operation.

316. The system for storing and issuing documents should be secure.

317. To preclude the use of non-applicable documents and to ensure control of current documents, the distributor may employ a written acknowledgement system. This would require the recipient to indicate receipt of the document and to return or dispose of the previous issue.

318. Master copies of documents should be retained until they are superseded or withdrawn. The need to archive master copies of documents should be considered.

319. Uncontrolled copies of documents may be supplied, provided they clearly indicate they are not subject to document revision. In these circumstances it is the responsibility of those using the information contained in the documents to check before use that they are still current.

## TEMPORARY DOCUMENTS

320. Under certain circumstances, a temporary document may be required to cover an activity for a limited period. This will be necessary when an immediate amendment to an existing document cannot be justified.

321. Temporary documents should be subject to the same controls as permanent documents. Temporary documents should have a defined period of validity. When this period expires the document should be withdrawn or integrated into an appropriate document or the temporary period of validity should be renewed.

## DOCUMENT MODIFICATION CONTROL

322. Modifications to documents shall be subject to the same level of review and approval as the originals.

323. A modification to one document may affect other documents. Affected documents should be revised accordingly.

324. Where practicable, modifications to documents should be highlighted in the documents by the use of sidelining or other suitable means.

#### SUSPENSION OR CANCELLATION OF A DOCUMENT

325. When a document is to be suspended or cancelled, it should be removed from use.

326. Suspension and cancellation notices should uniquely identify the reference and issue numbers of the document to which they apply and give their effective date of application and reasons for suspension/cancellation. In the case of suspension notices, the duration of suspension should also be provided.

327. Suspensions and cancellation notices should be distributed to all controlled copy holders, to preclude the use of suspended or cancelled documents.

#### DOCUMENTS EXTERNAL TO THE RESPONSIBLE ORGANIZATION

328. A registration system should be established and maintained to record and control the receipt and amendment of documents which are generated and controlled externally.

329. The system should, as a minimum, register the receipt date of the document, its reference number, title, date of issue and/or issue status and the person or persons to whom it was passed for distribution or, if appropriate, assessment.

330. Documents from external sources should be reviewed to ensure their suitability before acceptance and use.

#### DOCUMENT ARCHIVES

331. When documents which were subjected to the formal issue process are withdrawn from use, the master copies should be archived as records, following the guidance of Section 4.

332. An appropriate storage system should be established and maintained (see Annexes I, II).

## **4. ESTABLISHMENT OF A RECORDS SYSTEM**

### GENERAL

401. An appropriate records system shall be established and implemented by the responsible organization. The records system should ensure that records are specified, prepared, authenticated and maintained, as required by applicable codes, standards and specifications. Examples are: records of siting, design, construction, commissioning, operation and decommissioning. The records should include: the results of inspections, tests, reviews, assessments, monitoring of work performance and material analysis; test materials and specimens; plant operation logs and related data such as training and qualifications and other appropriate data.

402. The responsibilities for maintaining and operating the records system should be clearly defined and documented.

403. The records system should ensure that records are:

- categorized;
- registered upon receipt;
- readily retrievable;
- indexed and placed in their proper location within the record facility files with the retention time clearly identified;
- stored in a controlled environment;
- corrected or supplemented to reflect the actual plant status.

### CATEGORIZATION OF RECORDS

404. Records should be categorized as permanent or non-permanent according to their importance to safety. An example of a system used for categorization is provided in Annex III.

405. Records which meet one or more of the following might be considered as permanent:

- Recording the as-manufactured condition of items accepted for use in the installation;
- Recording the as-built condition of the installation;
- Providing evidence that the nuclear installation has been tested and commissioned in accordance with the design intent;
- Providing required baseline data for in-service inspection;
- Demonstrating capability for safe operation;
- Demonstrating that staff are competent to perform their work;
- Demonstrating that the plant is being operated, tested and inspected in accordance with design requirements and approved instructions;
- Demonstrating that the plant is being maintained in accordance with design requirements and the approved maintenance programme and instructions;
- Confirming design reliability assessment by plant performance history;
- Demonstrating compliance with statutory and regulatory requirements;
- Providing information for maintenance, rework, repair, replacement or modification of an item;
- Demonstrating that the quality of originally installed or replacement items meets the specified requirements;
- Providing information for decommissioning;
- Recording the investigation of an accident, malfunction or non-conformance.

406. Records such as QA programme documentation, procedures and assessment reports should be considered as non-permanent.

## RECORDS ADMINISTRATION

407. The applicable design specifications, procurement documents, construction procedures, test procedures, operational procedures or other documents should specify the records to be generated by, supplied to, or held for the responsible organization. Such records should be considered valid only if dated, stamped, initialled, signed or otherwise authenticated by authorized personnel. They may be originals or reproduced copies. The copying of records from one medium to another may result in the records not being legally admissible. The records system should therefore ensure that records are kept in the appropriate medium and that copying to maintain image quality during the storage time is adequately controlled. All records should be legible, complete, identifiable to the item, service or process involved and made of appropriate material to resist deterioration for the required retention time.

408. Records should be listed in an index which indicates:

- The title or unique identification of the record and the item, service or process it is related to
- The organization or person generating the record
- The retention time of the record
- The location of the record in the storage location
- Revision dates and the persons approving the revisions.

The method of indexing should be established before receipt of the record. The index should provide sufficient information to identify both the item and the relevant record.

409. The responsible organization should specify retention times for all records. Annex IV describes a process for the allocation of retention times.

410. Guidance is given in Annex I on the choice of storage media for the different record retention times.

411. When records are to be corrected or supplemented, the organization originating the records should review the correction for approval. When this is not possible, another authorized person or organization should be assigned.

412. The correction or supplement should include the date and the identification of the person making the correction or supplement.

## RECEIPT OF RECORDS

413. Management should ensure that records are available at the required time and should prepare a plan to cover the receipt of records .

414. The receipt control of records should ensure that the records are complete, legible and in a form suitable for storage.

## RETRIEVAL AND ACCESSIBILITY

415. Records shall be indexed, filed, stored and maintained in facilities which allow retrieval when required.

416. At all times during the specified retention time, the records should be accessible. Access to retention locations should be controlled.

417. Consideration should be given to the off-site storage and/or access to documents that would be required in emergency conditions.

## STORAGE REQUIREMENTS

418. The responsible organization should establish storage and location requirements for the maintenance, preservation and protection of records and associated test materials and specimens from the time of receipt until their disposal. A record storage system should include the following:

- Description of the document or record storage facility. Examples of storage facilities are given in Annex II;
- Description of the filing system to be used;
- A method for verifying that the records received are in agreement with the transmittal document and that the records are in good condition;
- A method for verifying that the records agree with the records index;
- Rules governing access to, and control of, the files;
- A method for maintaining control of and accountability for records removed from the storage facility;
- A method for filing corrected or supplemental information and voiding or disposing of records that have been superseded;
- Periodic checking to ensure that the records are not damaged, deteriorating or missing.

419. Continued ability to read the data must be assured, taking into account any technological changes that may occur.

420. Records shall be stored in such a manner as to prevent deterioration. Examples of storage methods for different storage media are given in Annex II.

421. Paper records should be firmly attached in binders, or placed in folders or envelopes for storage on shelves or in containers. Steel file cabinets or safes are preferred.

422. Records which are processed by special methods should be packaged and stored as recommended by the manufacturers' instructions, in line with applicable standards. Examples are: radiographs, photographs, microfilm, magnetic tapes, microdiskettes, laser discs and those records which might be sensitive to light, pressure, humidity, magnetic fields, dust and temperature. Special requirements for the packaging and storage of test materials and specimens should be taken into account.

423. Record storage facilities should protect the contents from possible damage or destruction by such causes as fire, flooding, insects and rodents and from possible deterioration by adverse environmental conditions such as light, temperature and humidity.

424. Amongst others, the following features should be considered in the construction of a storage facility:

- Location and security
- Type of construction, including structural features and internal surface treatment
- Pipework layout and drainage
- Ventilation, temperature and humidity control
- Fire prevention, detection and fighting
- Electromagnetic protection.

Where it is not practicable to provide suitable storage conditions, consideration should be given to the provision of a duplicate set of records stored in a separate facility. In that case, the location and construction features of both facilities should be such that the probability of simultaneous destruction, loss or deterioration of records is sufficiently low.

## DISPOSAL

425 The responsible organization should identify who is responsible for transferring or disposing of records.

426. Upon transfer of the records, the responsible organization or its designee should acknowledge their receipt and process them. Access to records accumulated at locations not under the control of the responsible organization should be agreed.

427. Records categorized in accordance with paras 404–406 should be retained for the minimum period specified by the responsible organization. After this period these records may be disposed of by, or with the agreement of, the responsible organization.

## Annex I

### STORAGE MEDIA FOR RECORDS

Examples of media which may be used to store records are:

- Paper with an acidity level of pH between 6 and 9
- 35 mm roll film
- Silver–gelatin type microfilm or X ray film
- Microfiche
- Magnetic tape or disc
- Optical laser disc
- Hardware such as graphite samples, weld samples or other materials which have been or are able to be subjected to qualification testing
- Electronic firmware (computer or component) such as thermal luminescent dosimeters (short term only).

Records that require special processing and control, such as computer codes and software and information stored on high density media or optical disks, should be maintained and controlled to ensure they are readily retrievable and usable.

#### RECORD STORAGE MEDIA AND THEIR RECOMMENDED RETENTION TIME

The following media are considered to be acceptable for records with retention periods of up to 30 years:

- Hard paper copy retained in a controlled environment with an indexing system to allow retrieval in a reasonable time, for example, one working day;
- Microfilm or other microforms prepared appropriately and stored in adequate conditions;
- Punched paper tape or cards where the information is stored as physical artifacts on a paper/card medium. The storage should be in equivalent environmental conditions to hard paper copy;
- Magnetic media stored and maintained appropriately, such as disc packs, storage modules, disk cartridges and magnetic tape on open spool.

The following media are considered to be acceptable for records with retention times of up to five years:

- Any of those media with retention times of up to 30 years, plus optical discs. Records using optical disc media may be held for periods beyond five years provided that periodic checks are made to check for any deterioration in image quality. The record should be copied onto a new optical disc if any deterioration of image quality is found. This may be before the manufacturer's certified lifetime of the original disc is exceeded.

The following media are considered to be acceptable for records with retention times of up to three years:

- Any of those media with retention times of five years or 30 years, plus flexible disk cartridges (floppy disks) and magnetic tape cartridges stored and maintained appropriately.

The preparation and storage requirements for the different media should reflect the manufacturer's guidance.

## Annex II

### DOCUMENT AND RECORD STORAGE FACILITIES

All quality documents and records should be securely stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.

The type of storage facilities required depends on factors such as the records media, environmental conditions (including insect or fungal infestation), safety significance (duplication of copies in diverse locations), duration of retention, security, and both active and inactive records.

Records should be retained in facilities appropriate to the media. Care should be taken to ensure that record media requiring different storage environments are not stored in the same area. In particular, cellulose nitrate film should be stored in a separate facility.

Unsuitable environments can cause more damage to records than any other single factor. A dry or polluted atmosphere may lead to embrittlement of documents; dampness and poor ventilation may cause the growth of mould; excess heat may accelerate chemical damage. All three conditions can lead to irreparable damage to records. Careful control and observation of temperature, humidity and ventilation within the records facility is therefore essential. In general, low temperatures with adequate air movement are preferable.

Fire precautions, including limitations on the distance to travel to reach means of escape and the physical dimensions of the storage facility, are the subject of national legislation and local by-laws. The fire precautions adopted, however, should be designed to protect the contents and structure of the facility from damage caused by fire fighting operations, as well as to ensure the safety of staff and limit the fire to its source. The possibility of fires or explosions in adjacent facilities and the proposed type of fire fighting chemicals to be employed to counter such events should be taken into account when the facility is chosen.

Loose material should not be permitted and smoking should be prohibited at all times in the storage facility.

Precautions should be taken during the storage and handling of records to avoid fingermarks, dust or scratching on microfilm records (by the provision of suitable hand covering), unnecessary bending or cracking of paper (by the suitable positioning on adequately designed shelving) and failure of components due to static discharge (by the provision of static handling precautions).

Records entering the record archive facility should be registered. To protect the integrity of the records, the facility should be secure, and wherever possible copies of

archived records should be used for reference purposes rather than permitting the removal of the master record.

## MICROFILM STORAGE FACILITIES FOR UP TO TEN YEARS

The following storage conditions are considered suitable for the storage of microfilm records for a time not longer than that sufficient for general business purposes. Such a time might be ten years, but could vary depending on specific conditions.

### **Relative humidity and temperature requirements for the storage of microfilm**

The relative humidity of the storage facility should not exceed 60% and the temperature should not rise above 25°C. Rapid changes of humidity and temperature should be avoided.

### **Protection of microfilms against fire and water**

Microfilms using safety film are difficult to ignite and combustion speed is low. To provide effective protection of microfilms against fire, as much attention should be paid to the presence of steam as to high temperatures. The protection available in a given room should take into consideration conditions special to that room and also the following general conditions.

Microfilm stored at 40% relative humidity can withstand a dry heat of 120°C for a time of 24 h without appreciable loss of legibility and printability. At a dry heat of 150°C some distortion may take place after 6 h but individual microfilms of texts or figures are still printable. The action of dry heat of 180°C for at least 6 h causes deformation of microfilms and reproduction generally becomes impossible.

In the presence of water vapour, temperatures of 90–110°C produce serious distortions and cause adhesion of coils or surfaces in contact; prolonged action or condensation will make the emulsion melt. Fireproof cabinets and safes thermally insulated by water vapour production are therefore not suitable for storing microcopies unless they have an inner moisture-proof chamber or the films are placed inside suitably sealed airtight containers. To obtain complete protection from fire, safes or cabinets should be placed in premises which are themselves fireproof. Microfilms should be protected from the action of water resulting from leaks, fire sprinklers or flooding, by being stored above basement levels on shelves at least 150 mm from the ground. If films are immersed in water, allowing them to dry, even partially, will cause the layers to stick together. The films should be placed in water filled containers until they can be washed and dried properly.

## **Chemical contamination**

Various noxious emanations can cause slow deterioration and a gradual fading of the image on film. Danger is presented by peroxides which may originate from bleaching agents, glues, varnishes and other products used in manufacturing storage cabinets for film containers. Hydrogen sulphide, ozone, sulphur dioxide, sulphur trioxide, ammonia and oxides of nitrogen are the most common, but not the only, atmospheric gases which harm film. Such fumes should be eliminated or an alternative store found.

Chemical products in the immediate vicinity of the films may also cause the presence of other impurities in the atmosphere. If dust and liquid particles suspended in the air are deposited on the microfilm they may impair its legibility and cause permanent scratching. Microcopies on silver image film should be kept neither with other photographic records which do not conform to these recommendations, nor with those films explicitly excluded, such as microfilm on a nitrate film base. Cross-contamination between microcopies can occur by the transfer of free thiosulphate to sodium (or ammonium) thiosulphate free film if they are stored with the emulsion sides in contact. Radiographs and other photographic media should be stored in chemically benign envelopes. Multiple films stored in envelopes should be separated by benign sleeves or separators.

## **ADDITIONAL RECOMMENDATIONS FOR ARCHIVAL OF MICROFILMS IN EXCESS OF TEN YEARS**

### **Air purification**

Air should be filtered to remove dust, purified of noxious gases and circulated by means of forced draught.

### *Relative humidity*

If sealed airtight containers are not used, the air in the archival storage facility should be conditioned to maintain the relative humidity at a level between 20 and 40%. If air conditioning is used, dehumidifiers using calcium chloride or other chemical desiccants should not be used. An electrical dehumidifier is recommended. If dehumidifiers are used, they should be of a type that does not produce rapid changes in the relative humidity.

## **Temperature of the archival premises**

The temperature in the archival storage area should be maintained between 15 and 25°C, but preferably should not exceed 20°C. If film which has been stored at a low temperature is handled in a room where the temperature or relative humidity is comparatively high, condensation will occur on the cold film surfaces. In these circumstances the film should not be removed from its closed container or the place where it is stored until the storage temperature has been brought up to the approximate temperature of the room where the film is to be handled.

## **Containers**

The following two types of container are recommended:

- (1) The closed non-airtight container.
- (2) The sealed airtight container.

If the recommendations for relative humidity and temperature of the archives are observed, containers for storage of microfilm can be of the closed non-airtight type. Sealed airtight containers should be used if there are no other means of protection against the danger of an ambient atmosphere of which the relative humidity or temperature goes beyond the limits recommended in this annex or which contains chemical impurities or dust. The containers used should be made from materials meeting the requirements below. These containers may be placed in boxes of paper or board, but such boxes should not be used alone.

## **General precautions for the long term protection of microfilm records**

The use of non-corroding materials for containers is recommended but whatever the materials used for the containers, their corrosion resistance coating and their airtight seals should not melt, ignite, decompose, develop fumes, distort or be subject to excessive dimensional changes when subjected to a temperature of 150°C for 4 h.

Care should be taken to avoid the deterioration or damage which may result from the rust, rubber joints, rubber bands and gum on certain types of envelope, and of lignin and other peroxide forming substances contained in certain wooden materials.

Microcopies stored in roll form may be mounted either on reels or on cores. Rolls more than 30 mm long wound on cores should be laid flat unless the core itself is carried on a horizontal spindle which prevents the lower part of the film from supporting the load of the core and its contents.

## ADDITIONAL PRECAUTIONS FOR SEALED AIRTIGHT FILM CONTAINERS

### **Fire**

The container should be of a type which will prevent steam reaching the film in the event of fire. Containers with a high resistance to corrosion are recommended. The container and its airtight seal should withstand an excess pressure inside the container of 70 kPa without rupture of the seal or other injurious effects.

### **Relative humidity**

The relative humidity inside a sealed airtight container should be within 20 to 40% at the storage temperature. Relative humidity exceeding 60% encourages the formation of mould which, in time, can completely destroy the image. Below 15% the film tends to curl and become more brittle as the relative humidity decreases.

## STORAGE FACILITIES FOR PAPER

### **Relative humidity and temperature requirements for the storage of paper**

The relative humidity of the storage facility for paper should be within the range 55 to 65% and the temperature should be within the range 13 to 18°C. However, if the paper is in bound volumes and is little used, it may be stored at a relative humidity of 40%.

## STORAGE FACILITIES FOR MAGNETIC TAPE OR DISC — OPTICAL LASER DISC — HARDWARE — ELECTRONIC FIRMWARE

Magnetic tapes or discs, optical laser discs, electronic firmware and general hardware records should be archived in accordance with the manufacturer's requirements or the component media. The retention requirements should be consistent with the life expectancy of the media and should provide for rejuvenation and backup.

## Annex III

### EXAMPLES OF RECORDS AND THEIR RETENTION CATEGORIES

This annex indicates examples of types and retention categories of records of safety related items and activities. It is recognized that the nomenclature and type of records may vary from organization to organization and alternative categories may be chosen at the discretion of the responsible organization. In general, procedures are classified as non-permanent and results are classified as permanent, on the basis that the recorded results can be interpreted without recourse to the procedures. However, where interpretation of the results depends on a knowledge of the procedure, both should be classified as permanent.

Retention times should be standardized to the following:

- (a) greater than 30 years (permanent)
- (b) 30 years (permanent)
- (c) 5 years (non-permanent)
- (d) 3 years (non-permanent)

#### TYPE OF RECORD

1. Design records	Permanent	Non-permanent
As-constructed drawing	*	
Codes and standards in design	*	
Design calculations and records of checks	*	
Design change requests		*
Design deviations	*	
Design drawings	*	
Design procedures and manuals		*
Design reports	*	
Design review reports		*
Drawing control procedures		*
Purchase and design specifications and amendments	*	
QA audit reports		*
Reports of engineering surveillance of field activity		*
Safety analysis report	*	

	<b>Permanent</b>	<b>Non-permanent</b>
Stress reports	*	
System descriptions	*	
Systems process and instrumentation diagrams	*	
Technical analysis, evaluations and reports	*	
 <b>2. Procurement records</b>		
Procurement procedures		*
Procurement specification	*	
Purchaser order including amendments		*
Purchaser's pre-awarded QA survey		*
QA audit reports		*
Receiving records		*
Supplier's QA programme manual		*
 <b>3. Manufacturing records</b>		
As-built drawings	*	
Certificate of inspection and test personnel qualification		*
Certificates of compliance	*	
Cleaning procedures		*
Code data reports	*	
Eddy current examination procedure		*
Eddy current examination final results	*	
Electronic control verification test results		*
Ferrite test procedure		*
Ferrite test results	*	
Forming and bending procedure qualifications		*
Heat treatment procedures		*
Heat treatment records	*	
Hot bending procedure		*
Measuring and test instrumentation and tooling calibration procedures and records		*
Liquid penetrant examination procedure		*
Liquid penetrant examination final results	*	
Location of weld filler material	*	
Magnetic particle examination procedure		*

	Permanent	Non-permanent
Magnetic particle examination final results	*	
Major defect repair records	*	
Material properties records	*	
Non-conformance reports	*	
Packaging, receiving, storage procedures		*
Performance test procedure and test result records	*	
Pipe and fitting location report	*	
Pressure test procedure		*
Pressure test results	*	
Product equipment calibration procedure		*
Product equipment calibration records		*
QA audit reports		*
QA manuals, procedures and instructions		*
Radiographic procedures		*
Radiographic review forms and radiographs	*	
Ultrasonic examination procedures		*
Ultrasonic examination final results	*	
Welding materials control procedures		*
Welding personnel qualification		*
Welding procedure qualification and data reports		*
Work processing and sequencing documents		*

#### **4. Installation/construction records**

##### *4.1. Receiving and storage*

Inspection reports for stored items		*
Non-conformance reports	*	
Receiving inspection reports on items		*
Receiving, storage and inspection procedures		*
Storage inventory and insurance records		*
Vendor QA releases		*

##### *4.2. Civil*

Aggregate test reports		*
Batch plant operation reports		*
Cement grab sample reports		*
Check-off sheets for tendon installation	*	

	<b>Permanent</b>	<b>Non-permanent</b>
Concrete cylinder test reports and charts	*	
Concrete design mix reports	*	
Concrete placement records	*	
Inspection reports for channel pressure tests	*	
Material property reports on containment liner and accessories	*	
Material property reports on metal containment shell and accessories	*	
Material property reports on reinforcing steel	*	
Material property reports on reinforcing steel splice sleeve material	*	
Material property reports on steel embedments in concrete	*	
Material property reports on steel piling		*
Material property reports on structural steel and bolting	*	
Material property reports on tendon fabrication material	*	
Mix water analysis		*
Pile drive log	*	
Pile loading test reports	*	
Procedure for containment vessel pressure proof test and leak rate tests and results	*	
Reinforcing steel splice		*
Operator qualification reports		*
Release to place concrete		*
Reports for periodic tendon inspection	*	
Reports of high strength		*
Bolt torque testing		*
Slump test results		*
Soil compaction test reports	*	
User's tensile test reports on reinforcing steel		*
User's tensile test reports on reinforcing steel splices		*
 <i>4.3. Welding</i>		
Ferrite test procedures		*
Ferrite test results	*	

	<b>Permanent</b>	<b>Non-permanent</b>
Heat treatment procedures		*
Heat treatment records	*	
Liquid penetrant test procedures		*
Liquid penetrant test final results	*	
Magnetic particle test procedures		*
Magnetic particle test final results	*	
Major weld repair procedures and results	*	
Radiographic test procedures		*
Radiographic test final results	*	
Ultrasonic test procedures		*
Ultrasonic test final results		*
Weld fit-up reports		*
Weld location diagrams		*
Weld procedures	*	
Weld procedures qualifications and results		*
Welding filler metal material reports	*	
Welding materials control procedures		*
Welding personnel qualifications		*

#### *4.4. Mechanical*

Chemical composition user's test (grab samples) for thermal insulation		*
Chemical tests of water used for mixing insulation cement		*
Cleaning procedures and results		*
Code data reports	*	
Construction lifting and handling equipment test procedures, inspection and test data	*	
Data sheets or logs on equipment, installation, inspection and alignment		*
Documentation of systems check-off (logs or data sheets)		*
Erection procedures for mechanical components	*	
Hydro-test procedures and results	*	
Installed lifting and handling equipment procedures, inspection and test data	*	
Lubrication procedures	*	
Lubrication records		*

	<b>Permanent</b>	<b>Non-permanent</b>
Material property records	*	
Material property test reports for thermal insulation	*	
Pipe and fitting location reports	*	
Pipe and fittings material property reports	*	
Pipe hanger and restraint data	*	
Safety valve response test procedures	*	
Safety valve response test results		*
 <i>4.5. Electrical and instrumentation and control</i>		
Cable pulling procedures		*
Cable separation checklists		*
Cable splicing procedures	*	
Cable terminating procedures	*	
Certified cable test reports	*	
Documentation of testing performed after installation and before system conditional acceptance		*
Field workmanship checklist or equivalent logs		*
Instrument calibration results		*
Relay test procedures and results	*	
Reports of pre-installation tests		*
Voltage breakdown tests on liquid insulation	*	
 <i>4.6. General</i>		
As-built drawings	*	
Calibration of measuring and test equipment and instruments procedures and reports		*
Certificate of inspection and test personnel qualification		*
Field audit reports		*
Field QA manuals		*
Final inspection reports and releases	*	
Non-conformance reports	*	
Special tool calibration records		*
Specification and drawings	*	

**Permanent    Non-permanent**

**5. Pre-operational and startup test records**

Automatic emergency power source transfer procedures and results	*	
Instrument AC systems inverters test procedures and reports	*	
Main and auxiliary power transformer test procedures and results	*	
Off-site power source energizing procedures and test reports	*	
On-site emergency power source energizing procedures and test reports	*	
Plant load ramp change data	*	
Plant load step change data	*	
Power transmission substation test procedure and results	*	
Pre-operational test procedure and results	*	
Primary and secondary auxiliary power test procedure and results	*	
Reactor protection system tests and results	*	
Startup logs	*	
Startup problems and resolutions		*
Startup test procedures and results	*	
Station battery and DC power distribution test procedures and reports	*	
System lubricating oil flushing procedures		*
Water chemistry reports	*	

## Annex IV

### A TYPICAL PROCESS FOR ALLOCATING RETENTION TIMES OF RECORDS

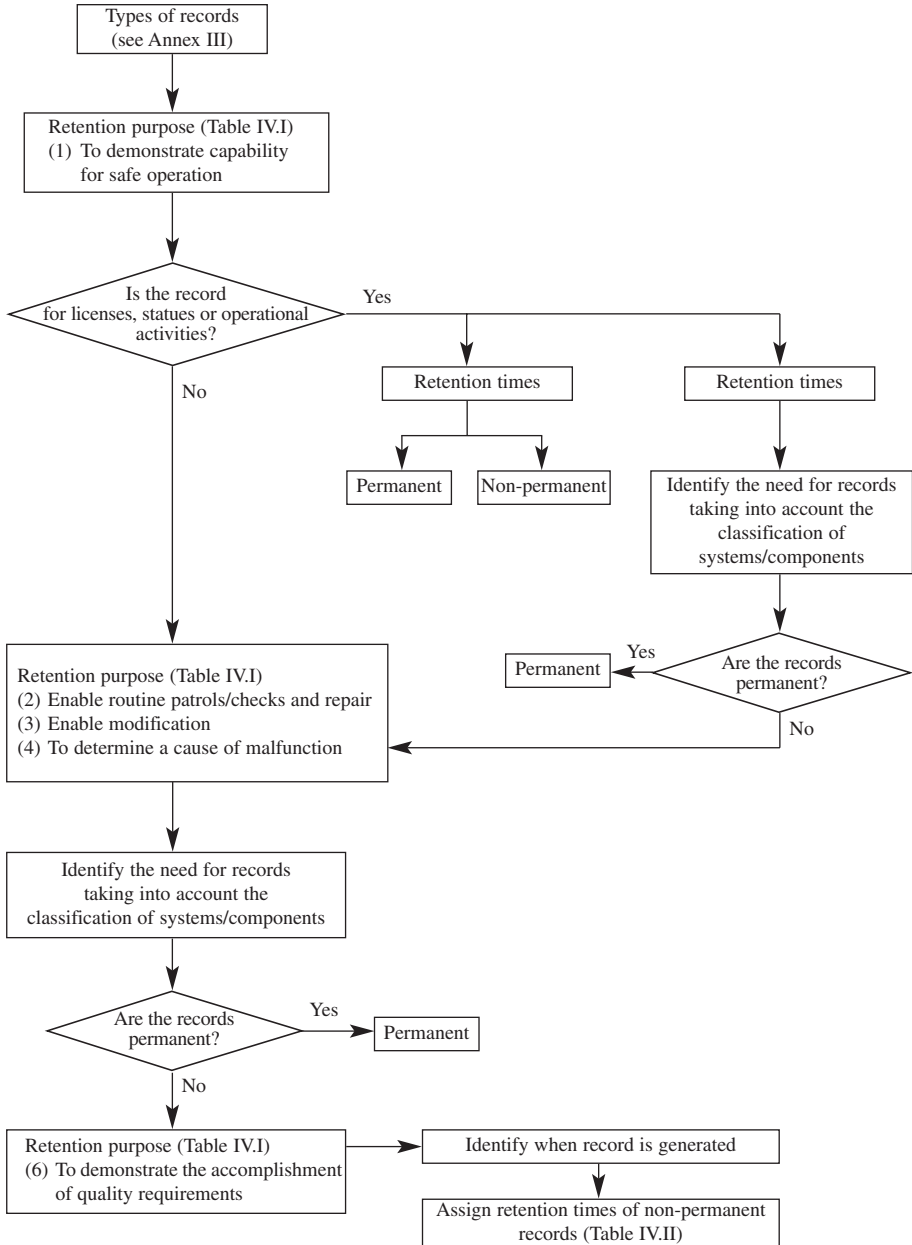


TABLE IV.I. RETENTION PURPOSES OF QUALITY RECORDS

Retention purpose	Subjected records
To demonstrate capability for safe operation at nuclear power plant	Necessary quality records at each stage of construction and operation of nuclear power plant. For endorsing licences, permits and operation/maintenance. When required to report, certify, explain and audit/review safe operation by requirement of law, regulation and others.
To enable routine patrols/checks, periodic inspection and repair of an item	Necessary quality records during operation stage of nuclear power plant, for routine patrols/checks, periodic inspection and repair (including replacement) that maintain safety and stable supplies of electric power and prevent malfunction.
To enable modification of an item	Necessary quality records during operation stage of nuclear power plant, for modifications which achieve functional improvement of power plant, reflect past experience and preclude recurrence of malfunction.
To determine the cause of an item's malfunction	Necessary quality records during operation stage of nuclear power plant, to resolve the cause of a malfunction and dispose of it.
To provide required baseline data for in-service inspections	Necessary quality records during operation stage of nuclear power plant to evaluate degeneration of components.
To demonstrate the accomplishment of QA requirements	Additional quality records from those identified above at each stage of construction or operation of nuclear power plant, to prove that the QA activities have been performed as planned and the requirements have been accomplished. These records may support or endorse information contained in reports on the areas covered above.

TABLE IV.II. RETENTION TIME OF NON-PERMANENT RECORDS

Classification	Retention time	Remarks
A	Up to start of operation	Up to start of commercial operation (if in operation stage, up to start of operation after completing periodic inspection)
B	Up to completion of first periodic inspection	(1) Completion of first periodic inspection of component. In cases such as turbines for which partial periodic inspection is applied, or those with long intervals for inspection, up to start of operation after completing first major periodic inspection.  (2) In operation stages, (1) above is applied at the start of operation after completion of periodic inspection as a starting point.
C	Up to expiry of guarantee	Period guaranteed by contract
D	Up to completion of in-service inspection cycle	Inspection period specified in inspection programme
E	Up to period specified by law/regulation	
F	Others (specific periods)	(1) Revision: up to next revision (2) Renewal: up to next renewal (3) Calibration/check: up to completion of next calibration/check (4) Audit: up to next audit (5) Work: up to completion of next work (6) Others: periods specified by each organization

## **Safety Guide Q4**

### **INSPECTION AND TESTING FOR ACCEPTANCE**



# CONTENTS

1.	INTRODUCTION .....	101
	Background (101–102) .....	101
	Objective (103) .....	101
	Scope (104) .....	101
	Structure (105) .....	101
2.	GENERAL CONSIDERATIONS .....	102
	Procedures and instructions (201) .....	102
	Grading (202–203) .....	102
	Training and qualification (204–207) .....	102
	Non-conformance control and corrective actions (208) .....	103
3.	INSPECTION AND TESTING .....	103
	Inspection and testing stages (301–310) .....	103
	Inspection and testing plans (311–313) .....	104
	Measuring and test equipment (314–316) .....	105
	Inspection and testing status (317–318) .....	106
	Testing (319–323) .....	107
4.	ACCEPTANCE OF ITEMS AND SERVICES FROM SUPPLIERS ....	108
	Prerequisites (401–402) .....	108
	Methods of acceptance (403–404) .....	109
	Acceptance by source verification (405–407) .....	109
	Acceptance by receiving inspection (408–410) .....	110
5.	PLANT INSPECTIONS AND TESTING .....	110
	Pre-operational inspection and testing (501–507) .....	110
	In-service inspection and testing (508–514) .....	112



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment on basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the basic requirement of the Code on inspection and testing for acceptance.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate programmes in each stage of a nuclear power plant project, and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into five sections:

Section 2 describes general considerations on procedures and instructions, grading, training and qualification, and non-conformance control and corrective actions.

Section 3 describes generic features of inspection and testing.

Section 4 focuses on the relevance of inspection and testing in procurement, including the acceptance of items or services from suppliers.

Section 5 is concerned with inspection and testing at the nuclear power plant both before and during operation.

## 2. GENERAL CONSIDERATIONS

### PROCEDURES AND INSTRUCTIONS

201. Inspection and testing procedures and instructions should be developed with particular attention being paid to acceptance criteria, methods to be used, equipment requirements, record requirements and independent verification requirements. For further guidance on procedures and instructions see Safety Guide Q1.

### GRADING

202. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA inspection and testing requirements.

203. Inspection and testing activities that can be graded include the following:

- The need to verify inspection and testing activities,
- The training and qualification of personnel carrying out inspection and testing,
- The need for inspection and testing plans,
- The level and detail of information in inspection and testing procedures,
- The responsibilities for review and approval of inspection and testing documentation,
- The review of non-conformances,
- The requirements for record production and retention.

For further guidance on grading see Safety Guide Q1.

### TRAINING AND QUALIFICATION

204. Personnel shall be trained and qualified so that they are competent to perform their assigned work and so they understand the safety consequences of their activities.

205. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work.

206 The training for inspection and testing personnel should include on-the-job participation and should emphasize inspection and testing experience.

207. Where certification of qualification and requalification is required, it should be in writing and in an appropriate format. For further guidance on training see Safety Guide Q1.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

208. If inspection and testing have not been performed as required or have indicated that a feature or characteristic does not conform to specified requirements, this is considered as a non-conformance. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

# 3. INSPECTION AND TESTING

## INSPECTION AND TESTING STAGES

301. Inspection and testing, whether performed by the responsible organization or by a supplier, take place at three identifiable stages. These are:

- (1) Receiving inspection and testing, prior to commencement of work.
- (2) In-process inspection/monitoring, during performance of the work.
- (3) Final inspection and acceptance testing, upon completion of the work.

### **Receiving inspection and testing**

302. Items and services, including input material to be processed, should not be used, nor processing commenced, until they have been checked for conformance to specified requirements. Such checks should be in accordance with inspection and testing plans or procedures. Receiving inspection and/or testing activities should be carried out in conjunction with a review of the corresponding documents.

### **In-process inspection/monitoring**

303. Items and services should be identified, inspected and tested as required by the inspection and testing plan or procedures as the work proceeds.

304. The items and services should be checked for conformance by appropriate process monitoring and control methods.

305. Arrangements should be established to hold the item or stop further work until the required inspections and tests have been completed and the corresponding reports have been received and verified by designated personnel.

306. It may be necessary to validate each stage of a process in order to confirm its capability.

307. Appropriate statistical techniques may be used for sampling or for determining process capability. These techniques should be based on well established principles.

### **Final inspection and testing for acceptance**

308. Final inspection and testing for acceptance should require confirmation that all previous inspections and tests have been carried out and that specified requirements have been met.

309. In accordance with the inspection and testing plan, final inspection and testing should prove conformance of the finished item to the specified requirements.

310. Items and services should not be dispatched or brought into service until all the activities specified in the inspection and testing plan have been satisfactorily completed. The associated documents and records should be available and approved as specified.

## **INSPECTION AND TESTING PLANS**

311. An inspection and testing plan should be prepared and used in order to control verification activities and provide a record of their satisfactory execution.

312. Inspection and testing plans should identify the sequential inspection and testing elements necessary to demonstrate conformance with requirements, the means by which they are to be verified and the relevant acceptance criteria.

313. The following information should be included in an inspection and testing plan:

- General information such as the facility name, item or system reference, procurement document reference, document reference number and status, associated procedures and drawings;
- A sequential listing of all inspection and testing activities; all items and services to be inspected and tested should be identified and referenced in the plan;
- The procedure, work instruction, specification or standard (or specific section, if appropriate) which should be followed in respect of each operation, inspection or test;
- Reference to relevant acceptance criteria;
- The identification of who is to perform each inspection and test, and provision for recording that each has been performed satisfactorily;
- The identification of hold points beyond which work should not proceed without recorded approval of designated individuals or organizations;
- Requirements for independent inspection and testing or independent witnessing at hold points;
- The type of records to be prepared for each inspection or test;
- The number of items and services to be inspected or tested when multiple items or repeat operations are involved;
- The persons or organizations having authority for final acceptance.

## MEASURING AND TEST EQUIPMENT

314. Tools, gauges, instruments and other measuring and test equipment (including test software and devices) used in determining item status and verifying the acceptability of items and services shall be of the proper range, type, accuracy and precision.

315. The selection, identification, use, calibration requirements and calibration frequency of all measuring and test equipment used for the determination of item quality or operational status should be specified. The responsibility for measuring and test equipment controls should be defined. Arrangements should include:

- Identification of the measurements to be made, the accuracy required and the selection of the appropriate measuring and test equipment;
- Identification, calibration and adjustment of all measuring and test equipment and devices that can affect item quality at prescribed intervals, or prior to use, against certified equipment having a known and valid relationship to nationally or internationally recognized standards. If such standards do not exist, the basis used for calibration should be documented;

- Establishment, documentation and maintenance of calibration procedures which include details of equipment type, unique identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;
- Ensuring that the measuring and test equipment is capable of the accuracy and precision necessary;
- Identification of measuring and test equipment with a suitable indicator or approved identification record to show its calibration status;
- Maintenance of calibration records for measuring and test equipment;
- Review and documenting of the validity of previous measurements, when measuring and test equipment is found to be out of calibration;
- Controls to ensure that environmental conditions are suitable for the calibrations, measurements and tests being carried out;
- Controls to ensure that the handling, preservation, storage and use of calibrated equipment is such that its accuracy and fitness for use is maintained;
- Protecting measuring and test equipment from adjustments which may invalidate its accuracy;
- Methods for adding and removing measuring and test equipment to and from the calibration programme, including the means to ensure that new or repaired items are calibrated prior to their use;
- System to control the issue of measuring and test equipment to qualified and authorized personnel.

316. Testing hardware, such as jigs, fixtures, templates or patterns, and/or test software used for inspection, should be checked prior to use in production and installation and rechecked at prescribed intervals. The extent and frequency of such checks should be established and records maintained as evidence of control. Such approved testing hardware should be properly identified.

## INSPECTION AND TESTING STATUS

317. The inspection and testing status of items should be identified to ensure that only acceptable items are used, installed or operated. The method of achieving this will vary according to the form of the item and its grading and can include: markings, stamps, tags, labels, routing cards, annotated inspection and testing plans, inspection records, testing software, physical location and colour coding. Whichever method is chosen, it should be possible to establish the status of items quickly and clearly and, in particular, to identify those items which do not conform to specified requirements.

318. Inspection and testing records should identify the inspection organization or the individual responsible for verifying conformance to specification at whatever point in the process the inspection and testing has taken place.

## TESTING

319. Test requirements, including frequency and acceptance criteria, should be provided. Unless otherwise designated, they should be approved by the organization responsible for the specification of the item or system to be tested. Required tests should be controlled. Tests may include:

- prototype qualification tests
- production tests
- proof tests prior to installation
- construction tests
- pre-operational tests
- operational tests.

Testing requirements and acceptance criteria should be based on the applicable design or other pertinent documents. Testing should demonstrate that the safety function of an item or service has been maintained.

320. Appropriate testing of computer software is essential before operational reliance is placed upon it.

321. Testing procedures should define the test objectives and make provisions for ensuring that prerequisites for the given test have been met, that adequate equipment is available and being used, that necessary monitoring is performed and that suitable environmental conditions are maintained. Testing procedures should also take into account the following where applicable:

- Appropriately calibrated measuring and test equipment,
- Availability of trained personnel,
- Condition of test equipment and the item to be tested,
- Suitable environmental conditions,
- Data acquisition system,
- Required tests and testing sequence,
- Required range of input parameters,
- Identification of the stages at which testing is required,
- Criteria for establishing test cases,
- Requirements for testing software logic,

- Requirements for hardware and software integration tests,
- Software validation and its performance criteria,
- Anticipated output values,
- Acceptance criteria,
- Reports, records and their agreed formats,
- Actions taken when results are unacceptable,
- Process conditions when required (initial condition included),
- Precautions and limitations during each test,
- References to applicable documents.

322. Test results should be documented and evaluated to ensure that testing requirements have been satisfied.

323. Test records should identify:

- Test procedure or test plan reference;
- Item tested, and stage of testing;
- Date and time of the test;
- Testing equipment and its calibration status, where applicable;
- Person(s) performing the test and recording the data;
- Type of observation;
- Results and their acceptability;
- Action taken in connection with any non-conformances noted;
- Person(s) evaluating the test results.

## **4. ACCEPTANCE OF ITEMS AND SERVICES FROM SUPPLIERS**

### **PREREQUISITES**

401. The purchaser of an item or service should establish the method of acceptance and the criteria for acceptability in the procurement documents. The purchaser should clearly define responsibilities and require documentary evidence that the acceptance criteria have been met.

402. Before offering an item or service for acceptance, the supplier should verify that all defined procurement requirements have been satisfied. Acceptance by the purchaser should not absolve the supplier from responsibility to provide items and services fit for the given purpose nor should it preclude subsequent rejection.

## METHODS OF ACCEPTANCE

403. The method used by the purchaser to accept an item or service may include inspection and testing on receipt, or source inspection prior to authorizing release for delivery. The latter should involve surveillance, requiring process monitoring and participation with in-process inspection and/or final inspection and testing. Demonstration of complete acceptability may not be possible until installation and commissioning have taken place (see para. 502).

404. Records showing that the purchased item or service conforms to procurement requirements shall be available before installation or use. The records should contain: details of the verifications performed; how, when and by whom they were conducted; the results achieved; the associated certificates; and the final inspection records indicating that all requirements have been satisfactorily met. Whatever form the documentary evidence takes, there should be means available to verify its validity.

## ACCEPTANCE BY SOURCE VERIFICATION

405. Verification at source should be considered, for example, when:

- the item or service is significant in terms of nuclear safety;
- the item or service is such that some design characteristics are difficult to verify after delivery, assembly or installation;
- the item or service is complex in terms of design, manufacture or testing.

406. Verification activities at source should confirm, where relevant, that:

- the documents providing evidence of approvals, material used, and applicable inspections and tests have been submitted as required;
- processes and procedures have been approved and have been complied with;
- the applicable qualification testing of items, procedures, qualification of personnel, process records and certifications are available;
- items and services have been inspected, examined and tested as required and the applicable inspection, test and certification records are available;
- non-conformances have been resolved;
- items have been cleaned, preserved, packed and identified in accordance with specified requirements.

407. When the purchaser has accepted an item by source verification, documentary evidence should be provided.

## ACCEPTANCE BY RECEIVING INSPECTION

408. Acceptance by receiving inspection alone could be considered when:

- Items are relatively simple and standard in terms of design, manufacture and testing;
- The item is adaptable to standard or automated inspection and/or testing after delivery to verify quality characteristics;
- Receiving inspection does not require operations that could adversely affect the integrity, function or cleanliness of the item;
- Items are susceptible to damage during transit.

409. Incoming items should not be used or processed until conformance to specified requirements has been verified. The verification should be in accordance with the quality plan or procedures.

410. Receiving inspection should be co-ordinated with a review of the supplied documents when procurement documents require these to accompany the item or to be furnished before receiving inspection takes place. Such supplied documents may include:

- material analysis certificates
- type test certificates
- specific test results
- specified inspection data
- calibration certificates
- supplier declaration of compliance with specified requirements
- release certification
- non-conformance reports.

## 5. PLANT INSPECTIONS AND TESTING

### PRE-OPERATIONAL INSPECTION AND TESTING

501. Systematic inspection and testing following installation of major plant systems is an essential element during the commissioning stage.

502. There may be circumstances when final acceptance of a supplied item is only possible after it has been installed. Examples are:

- When it is difficult to verify all the quality characteristics of the item without installing and operating or using it;
- When the item requires an integrated system check-out or testing with other items and services to verify its design characteristics and functionality;
- When the ability of the item to perform its intended function cannot be fully demonstrated except when the item is in use (for example when radioactive material is to be processed within an item of the plant).

503. Pre-operational inspection and testing requirements and the associated acceptance documents should be specified in procurement and commissioning documents and specific responsibilities clearly defined.

504. Performance testing should be carried out to demonstrate that items will function as specified. A performance testing programme should be established, authorized and documented. The programme should identify the arrangements to enable instructions for the operation of the installation to be validated.

505. The testing programme should cover all the required tests and should include the following where appropriate:

- personnel qualification requirements
- procedure and equipment qualification tests
- prototype qualification tests
- proof tests prior to installation
- pre-operational and startup tests
- operational tests
- tests to demonstrate satisfactory performance following plant maintenance.

506. Testing as described in the testing programme should be performed in accordance with specified procedures. These procedures should incorporate the requirements and acceptance limits specified in design documents. Provisions should be made for ensuring that prerequisites for a given test have been met and that the testing is performed by trained personnel using calibrated instrumentation.

507. Inspection and testing results should be recorded and evaluated to ensure that the specified requirements have been satisfied before an item or system is released for operational service. For further guidance on QA during the commissioning stage see Safety Guide Q12. Safety Guide 50-SG-O4 provides guidance on commissioning procedures.

## IN-SERVICE INSPECTION AND TESTING

508. In-service inspection and testing should be an integral part of preventive maintenance aimed at the early detection of the potential failure of items. It also provides data on which to base judgements related to the continued operation and life extension of the plant.

509. In-service inspection and testing should be concentrated on items that may affect safety to ensure that operation has not resulted in an unacceptable degradation or deviation from the design intent.

510. In-service inspection and testing during operation will comprise both routine checks and periodic examinations which may require the plant to be shut down. Both activities should be defined.

511. Routine in-service inspection and testing activities should confirm the availability and reliability of systems and should indicate the current plant status.

512. For evaluation purposes, the results of in-service inspections and tests during plant shutdown should be recorded using appropriate media such as photographs, videos, instrumentation printouts and computer records.

513. Results of in-service inspections and tests should be promptly reviewed and evaluated. Non-conformances should be investigated to determine their root cause. The resulting data should be analysed for trends using statistical methods.

514. Plant management should be periodically appraised of all in-service inspection and testing performed on the operating plant. Plant management should also be provided with summary reviews of the results. Issues requiring attention, such as problems that could jeopardize the safe operation of the plant, should be highlighted. For further guidance on in-service inspection and testing in operation see Safety Guide Q13, the Code 50-C-O (Rev. 1) and particularly Safety Guide 50-SG-O2.

**Safety Guide Q5**

**ASSESSMENT OF THE IMPLEMENTATION OF THE  
QUALITY ASSURANCE PROGRAMME**



## CONTENTS

1.	INTRODUCTION .....	117
	Background (101–102) .....	117
	Objective (103) .....	117
	Scope (104) .....	117
	Structure (105) .....	117
2.	GENERAL CONSIDERATIONS .....	118
	General (201–205) .....	118
	Grading (206–207) .....	119
	Performance indicators (208–210) .....	119
	Training and qualification (211–214) .....	119
3.	RESPONSIBILITIES .....	120
	Responsible organization (301) .....	120
	Management responsibilities (302–305) .....	121
	Assessment unit (306–315) .....	121
4.	PERFORMANCE OF ASSESSMENTS .....	123
	General (401–403) .....	123
	Planning (404–408) .....	123
	Conduct (409–415) .....	124
	Evaluation (416–418) .....	125
	Reporting (419) .....	125
	Follow-up activities (420–423) .....	125
5.	MANAGEMENT SELF-ASSESSMENT .....	126
	General (501–506) .....	126
	Self-assessment criteria (507) .....	127
	Subjects (508) .....	127
	Reporting (509) .....	128
6.	INDEPENDENT ASSESSMENT .....	128
	General (601) .....	128
	Internal audits (602–605) .....	128
	External audits (606–607) .....	129
	Surveillance (608–612) .....	129
	Peer evaluation (613–616) .....	130
	Technical review (617–620) .....	131

ANNEX I: INTERRELATION BETWEEN MANAGEMENT  
SELF-ASSESSMENT AND INDEPENDENT  
ASSESSMENT ..... 132

ANNEX II: EXAMPLE OF A HIERARCHY OF MANAGEMENT  
SELF-ASSESSMENT ..... 133

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment on basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirement of the Code other than those set out in the Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the basic requirements of the Code on management self-assessment and independent assessment.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate programmes in each stage of a nuclear power plant project, and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into six sections and two annexes:

Section 2 describes general considerations on management self-assessment and independent assessment and requirements for training and qualification.

Section 3 describes the responsibilities of the responsible organization, the management and the assessment unit.

- Section 4 provides guidance on how to perform assessments.
- Section 5 gives guidance on management self-assessment.
- Section 6 gives guidance on the various types of independent assessment.
- Annex I provides an overview of the interrelation between management self-assessment and independent assessment.
- Annex II provides an example of a hierarchy of management self-assessment.

## 2. GENERAL CONSIDERATIONS

### GENERAL

201. Assessments are carried out to determine that requirements are met and that processes are adequate and effective, and to encourage managers to implement improvements, including safety improvements.

202. The assessment activity falls into two broad categories:

- (1) Management self-assessment, which is an on-going process conducted by management in order to evaluate the effectiveness of performance in all areas of their responsibility.
- (2) Independent assessment, which is usually conducted by an independent organizational unit in order to determine the effectiveness of management processes, the adequacy of work performance and the quality of items and services.

203. Both categories of assessment are interrelated in that the output from independent assessment assists management in their task of self-assessment. Annex I shows these interrelationships.

204. Management at all levels shall conduct self-assessments on those key management processes for which they are responsible. Managers shall determine the effectiveness of their performance in achieving and improving nuclear safety objectives. Weaknesses in the management process and organizational barriers that hinder the achievement of nuclear safety objectives and good performance shall be identified and corrected.

205. Independent assessment shall be conducted for and on behalf of senior management by an organizational unit or an assigned outside agency which is

independent of the work to be assessed. Managers should not regard the independent assessment as an opportunity to avoid carrying out their self-assessment. The assessment unit should devote itself to assisting management to improve effectiveness and work performance.

## GRADING

206. Nuclear safety shall be the fundamental consideration in determining to what extent the QA requirements are to be applied. A graded approach, reflecting a planned and recognized difference in specific QA requirements for each identified item, service or process, shall be used.

207. The graded approach should take account of the safety significance and other factors, such as those dealing with important or complex work, to determine the extent and degree of assessment. The allocation of resources for assessment should be flexible and allow for re-allocation of priorities to areas of questionable performance. For further guidance on grading see Safety Guide Q1.

## PERFORMANCE INDICATORS

208. Performance indicators should be developed to measure whether performance is satisfactory or not, with particular emphasis on safety.

209. Performance indicators should be monitored so that changes can be recorded and trends determined.

210. Trends in performance indicators should be analysed to identify both beneficial and adverse factors. Beneficial factors should be used to encourage improvement. The causes of adverse factors should be determined and eliminated. For further guidance on performance indicators see Safety Guides Q1 and Q13.

## TRAINING AND QUALIFICATION

211. Managers should make arrangements to ensure that all personnel performing assessment activities, including themselves, have appropriate qualification, training and experience.

212. Personnel performing assessment<sup>1</sup> activities should be trained in:

- QA principles,
- methodology of assessment.

213. Criteria for qualification of assessment personnel should be established and include technical knowledge, professional competence and experience. The assessment personnel should also have the ability to effectively observe, evaluate and report. Communication skills, integrity and the ability to maintain confidentiality and objectivity are desirable attributes, which should be taken into account.

214. The assessment personnel should maintain their proficiency and technical knowledge by, for example:

- regular participation in assessments;
- study of codes, standards, procedures, practices and other related documents;
- participation in training courses and seminars;
- spending an appropriate amount of time in the field.

Experienced technical personnel and managers should be assigned to the assessment unit as part of career development on a rotational basis. For further guidance on training see Safety Guide Q1.

### **3. RESPONSIBILITIES**

#### **RESPONSIBLE ORGANIZATION**

301. The responsible organization shall be responsible for assessment of the effectiveness of the overall QA programme. The responsible organization may delegate to other organizations the work of assessing all or a part of the programme, but shall retain responsibility for the effectiveness of the assessment. The responsible organization should define and document the extent to which the assessment activities are delegated.

---

<sup>1</sup> For some types of assessment there are accredited courses available in some Member States.

## MANAGEMENT RESPONSIBILITIES

302. Management has a responsibility for setting performance expectations and for ensuring that they are met.

303. Senior management should have the overall responsibility for management self-assessment at all levels. It is essential that senior management directly participate in the process of management self-assessment.

304. Senior management should establish an organizational unit, or appoint an outside agency when appropriate, to conduct independent assessments in order to inform line management of the degree that performance expectations are being met. The assessment unit should be given sufficient authority and organizational freedom to carry out its responsibilities.

305. Line management of the organization to be assessed should make arrangements for:

- Appointing a responsible person to contact and accompany assessors;
- Informing affected employees on the objectives and scope of assessment;
- Providing access for assessors to relevant facilities, documents and personnel for assessment to be carried out;
- Co-operating with the assessment team to achieve the objectives of the assessment;
- Reviewing and discussing the results of the assessment and communicating those to relevant staff;
- Implementing corrective actions and/or an improvement plan that address the root causes;
- Verifying the effectiveness of the corrective actions or the improvement plan.

## ASSESSMENT UNIT

306. The assessment unit should be responsible for monitoring and evaluating the effectiveness of management at all levels in implementing the QA arrangements.

307. The assessment unit should be responsible for assessing as a minimum whether activities are being performed in accordance with specified requirements and should, where possible, identify improvement opportunities. The assessment unit, for example:

- Defines the assessment techniques;
- Identifies the resources needed to achieve an effective assessment;

- Obtains access by assessment teams to levels of management having the responsibility and authority to ensure corrective actions;
- Makes arrangements for temporary assignment of specialists to assessment teams;
- Defines the methods and schedules for initiating, conducting and reporting assessments;
- Determines the distribution list for the assessment reports;
- Makes provisions for follow-up activities.

308. In order to properly focus their assessment on performance, the assessment unit should be well informed as to daily work schedules and long term planning. They should also have access to information such as:

- Whether safety and performance standards are being met;
- What and where the major safety and performance concerns are;
- Whether deficiencies are increasing or decreasing;
- Whether preventive measures are adequate.

309. The independent assessment need not necessarily be carried out always by the assessment unit. It may be beneficial for independent assessment to be carried out by other staff brought together for a specific assessment or by a joint team, including members of the assessment unit.

310. The assessment unit could be supplemented by persons from other departments on short-term secondments, either for the duration of the assessment or for career development purposes. Such persons should have an understanding of the work area being assessed and be conversant with the type of assessment.

311. Personnel conducting independent assessment should not have responsibility for the work performance being assessed. Assessment personnel should exercise objectivity in examining evidence and in forming conclusions.

312. A team leader should be appointed to manage all phases of an individual assessment. The team leader should be responsible for:

- selection of team members
- planning
- representing the team
- managing the team during the assessment
- preparing and submitting the report
- checking the effectiveness of corrective actions.

313. The team members are subject to the leadership, direction and guidance of the team leader.

314. Inexperienced people on the team should be adequately monitored and supervised until they are considered proficient in the type of assessment being carried out.

315. The attitude of assessors can also have an impact on the value of the assessment. Assessors should be capable of looking for improvement opportunities and providing recommendations to management. Problems should be reported in a way that will help management understand what actions are needed.

## **4. PERFORMANCE OF ASSESSMENTS**

### **GENERAL**

401. Assessment activities can include reviewing, checking, inspecting, testing, surveillance and auditing.

402. Some types of assessment, such as checking, inspecting and testing, are usually objective. Results will be verified in accordance with written criteria. Similarly, surveillance and audits can be objectively evaluated against standards and/or specified requirements.

403. Other types of assessment such as peer evaluation are more subjective, based on comparison with good practices and judgements against expert opinions. The results of such activities should be evaluated by senior management before proposed actions are adopted.

### **PLANNING**

404. An assessment plan should be established, taking into account the organization's activities affecting safety and the frequency and results of previous assessments. Assessments may be conducted on a limited scope of activity across a number of organizational units, or on all activities in a single organizational unit, or a combination of these.

405. Planning for an assessment should begin with the selection of areas, activities and requirements to be assessed. Assessment activities should be conducted in a manner so as to not impact plant safety. The assessment activities should be planned to have minimal impact on normal plant activities.

406. The assessor should maximize the effectiveness of the planning by using all available information and resources.

407. A plan for each assessment should be established to identify the topics and grade their priority. Such a plan is not intended to be a procedure or checklist, but an aid to the assessor in keeping the assessment objectives clearly in mind. Assessment plans should be agreed with the organization's management.

408. The assessment schedule should allow adequate time for preparation, conduct of the assessment, evaluation of identified concerns and reporting of results. Extra time may be needed to gain familiarity with the areas to be assessed.

## CONDUCT

409. Assessment should concentrate on observation of activities actually being performed. Many activities can only be properly evaluated after a thorough in-process observation has taken place. Assessors should also interview personnel and examine completed work activities. Where activities are not being performed at the time of assessment, a decision should be made on whether they should be observed at a later date.

410. When assessing an activity, the assessor should observe the sequence of operations and investigate in more detail if a problem is suspected.

411. If, during the course of the assessment, a deficiency is found, the assessor should observe other similar activities to determine the nature and extent of the problem (for example whether it exists throughout the organization).

412. In an assessment, information on equipment, personnel qualification and training should be examined. The assessor may need to ask personnel specific questions to determine, for example, their experience or knowledge of procedures. The assessor may also check the conformance with, and the adequacy of, the procedures.

413. Although the planning and conduct of an assessment may follow an organized plan, circumstances may arise that require flexibility. The assessor should pursue any questionable area after consultation with the team leader. This consultation will ensure that the investigation is worthwhile.

414. When potential non-conformances are encountered, the assessor should check to determine if these have already been identified by management and if actions are being

implemented to correct them. Conditions found during the assessment which require prompt attention should be immediately brought to the attention of management.

415. When potential non-conformances are detected, they should be discussed with the responsible persons to avoid misunderstandings.

## EVALUATION

416. The assessor should analyse and consider the cause of potential non-conformances in order to evaluate the proposed corrective actions.

417. Findings should describe the non-conformance and not just provide an indication of the non-conformance. The assessor should also highlight good performance and identify any areas where improvement could be made.

418. Findings should be discussed among the assessment team members so that they can be sure of the applicability, improve consistency and look for generic problems.

## REPORTING

419. Assessment results should be reported clearly and promptly. The assessment report should communicate findings in a way that makes their significance readily apparent. For reports to be effective, they must be submitted in their final form as quickly as possible, emphasizing particular items if necessary. The report should include:

- A list of findings,
- A list of personnel contacted and procedures reviewed,
- A description of assessment methods adopted by the assessors,
- References to the assessment plan which indicate what areas were assessed and why they are important,
- A summary statement on whether the activities assessed were satisfactory or not,
- Opportunities for improvement.

## FOLLOW-UP ACTIVITIES

420. The assessed organization should review and investigate assessment findings to determine corrective actions, and prepare an implementation schedule and a written

response to the report within a given time. The corrective actions and implementation schedule should be discussed between management and the team leader to help ensure that the corrective actions are adequate.

421. The assessed organization should review and report on the progress achieved in completing corrective actions, so that senior management are aware of the status of corrective actions in their organization.

422. The assessment unit should verify the implementation of the corrective actions.

423. On completion of all corrective actions, the assessment should be closed.

## **5. MANAGEMENT SELF-ASSESSMENT**

### **GENERAL**

501. The purpose of management self-assessment should be to evaluate known performance issues, identify contributing management aspects and make improvements.

502. Management self-assessment should be regarded as an on-going process that determines how well leadership is being provided to meet requirements and expectations.

503. Management at all levels (for example senior, line and supervisory managers) perform these self-assessments with an emphasis on the allocation of human and financial resources to achieve organizational goals and objectives.

504. At the senior management level it is appropriate to perform a self-assessment to determine if the overall performance effectively focuses on meeting strategic goals, including safety goals. Reports from line management, summaries of both categories of assessment and regulatory feedback are useful sources of information on the overall performance of the organization. It also assists the manager in targeting improvement actions.

505. Line management is more likely to rely on surveillance and review of work performance. This would include, but not be limited to, surveillance of items, services and processes, review of design documents and validation, review of procedures and records, observation of independent assessments and regular facility tours.

506. At the supervisory level, direct observation of work supported by inspection and testing should be routinely carried out (see Safety Guide Q4). Annex II gives an example of a hierarchy of management self-assessment.

## SELF-ASSESSMENT CRITERIA

507. The following are examples of the criteria used to perform self-assessments:

- (1) *Leadership*. Senior managements' personal leadership and involvement in: creating and sustaining continuous improvement; setting clear values and expectations; establishing a system that promotes performance excellence; integrating into the QA programme the fulfilment by the responsible organization of its public responsibilities.
- (2) *Information and analysis*. Management and effectiveness of the use of data and information to support performance excellence.
- (3) *Strategic planning*. Setting strategic directions; determining key plan requirements; translation of plan requirements into effective performance.
- (4) *Human resources development and management*. Enabling the workforce to develop and utilize its full potential, aligned with the responsible organization's performance objectives; responsible organization efforts to build and maintain an environment conducive to performance excellence, full participation, and personnel and organizational growth.
- (5) *Process management*. Key aspects of process management are designing, managing and improving key processes to achieve higher performance.
- (6) *Measuring results*. Responsible organization's performance and improvement in the key areas: safety and quality; productivity and operational effectiveness; performance indicators linked to these areas.
- (7) *External focus*. Responsible organization's systems for learning; building and maintaining relationships; levels and trends in key measures of success; service availability and responsiveness to changing requirements.

## SUBJECTS

508. Input to management self-assessment should include information on:

- Safety results/trends and performance indicators;
- Current performance analysis, such as peer evaluation feedback, surveillance and technical review results;
- Adequacy of the QA programme of the responsible organization;
- Effectiveness of management procedures/work instructions;

- Organizational issues, such as levels of authority and responsibility, interfaces, communications, recruitment, training and promotion policies;
- Effect of regulatory and statutory requirements and any changes to them;
- Overall performance including safety, reliability and cost considerations;
- Strategic planning, mission of the organization and nuclear safety objective;
- Feedback from experience.

## REPORTING

509. Management self-assessment should result in an improvement in nuclear safety and should be part of the organization's quality improvement process. Existing reporting mechanisms should be used.

## 6. INDEPENDENT ASSESSMENT

### GENERAL

601. Independent assessment, such as internal audits, external audits, surveillance, peer evaluation and technical review, should be focused on safety aspects and areas where problems have been found. Assessment objectives should be reviewed periodically to reflect current management concerns and performance activities. Appropriate combinations of various types of assessment should be used to provide the best balanced evaluation of performance.

### INTERNAL AUDITS

602. A system for internal audits should be established by the assessment unit and agreed with the management of the organization.

603. Internal audits are conducted on behalf of management by the independent assessment unit to determine whether activities and related results comply with the basic requirements of the Code and whether the established QA programme is adequate and being implemented effectively to achieve nuclear safety objectives.

604. Internal audits should not be conducted with the sole purpose of determining compliance with requirements. They should be conducted to evaluate the needs for

corrective actions, with the emphasis on seeking opportunities for improvement and enhancing safety standards.

605. Internal audits should be conducted on an on-going basis, but they should also be prompted by significant changes in the QA programme or the associated processes, or by performance and nuclear safety weaknesses.

## EXTERNAL AUDITS

606. External audits of suppliers should be managed by the assessment unit on behalf of management, who agree the schedule of audits to be performed. The frequency of audits should be determined by factors such as the importance of items and the performance of the supplier.

607. External audits should be carried out when:

- it is necessary to determine the capability of a supplier and the adequacy of its QA programme before awarding a contract or placing a purchase order;
- after award of a contract, it is necessary to determine whether the supplier is appropriately performing the functions as defined in the QA programme, applicable codes and standards and other contract documents;
- significant changes are made in the supplier's QA programme, such as significant reorganization or significant revisions of procedures;
- it is suspected that the quality of an item or service is in jeopardy owing to a deficiency, either in the requirements or in the QA programme.

## SURVEILLANCE

608. Surveillance of work performance is considered to be the best technique for assessing and reporting on a specific area, or an on-going activity. It is flexible and less formal than audits and can be performed in a relatively short period of time with limited preparation. However, advance notice should usually be given. Surveillance is normally carried out to:

- provide information and data in a specific performance area;
- provide information and data on an individual activity;
- provide immediate feedback of results;
- follow up on previous assessment observations.

609. Surveillance may show product deficiencies or indications of localized weakness in the QA programme. When the work is intellectual, for example design

work, selective analyses and random checks of results are considered to be more appropriate.

610. Surveillance is most suited where:

- flexibility in timing, method, personnel and reporting is desirable;
- additional information is required to develop conclusions regarding previous assessments;
- there is a need to respond to opportunities that arise at short notice.

611. Several surveillance visits are required over a period of time for activities which occur frequently or for determining if trends exist.

612. A single surveillance should not be considered to be sufficient to fully assess the overall effectiveness of the QA programme. In addition to monitoring activities and the observation of work being done, reviews of documentation and interviews are also needed.

## PEER EVALUATION

613. Peer evaluation is a critical examination of specific nuclear safety related subjects by senior staff from one or more other nuclear power plants to seek improvements and to promote good practices. The evaluation team should consist of experts in all areas of evaluation in order to promote the sharing of experience and to develop relationships between the peers and the people at the nuclear power plants.

614. Senior management should consider developing, on the basis of best international practices, a set of performance indicators, objective standards and criteria against which performance can be evaluated. For a nuclear power plant, performance objectives in areas such as operation, maintenance, chemistry, reactor engineering, radiation protection, fire protection and emergency planning should be considered and developed.

615. This type of assessment is both objective, in that it compares against the performance standards and objectives, and subjective, in that it uses the collective knowledge of the peers to identify areas for improvement and good practices.

616. During the evaluation, observation of the work should be done and a judgment made on the basis of the methods used and results achieved. A written report of problems and good practices observed should be presented to management. Management

should develop an action plan to implement any improvement and ensure that information on good practices is made known to others within the organization.

## TECHNICAL REVIEW

617. Senior management may arrange for a review of the technical content of activities and processes, with a view to improving the effectiveness of these activities or processes.

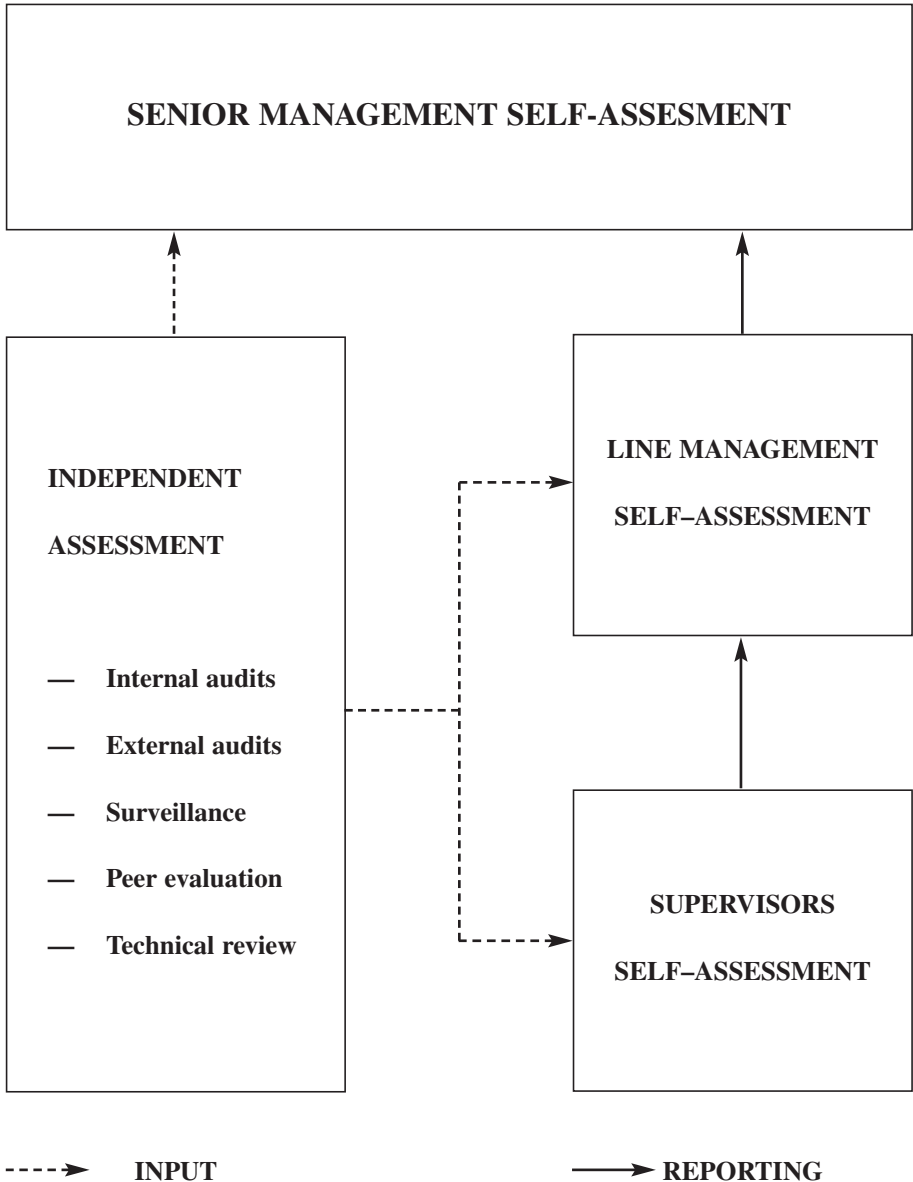
618. Different techniques can be used, such as inspection and testing (see Safety Guide Q4) as well as emergency drills and exercises (see Safety Guides 50-SG-G6 and 50-SG-O6).

619. Senior management should define in clear terms the scope of each technical review, what is expected, when it will be implemented and by whom it will be implemented.

620. Those who are asked to perform a technical review should be demonstrably qualified and competent in the area of work being assessed.

**Annex I**

**INTERRELATION BETWEEN MANAGEMENT SELF-ASSESSMENT AND INDEPENDENT ASSESSMENT**



## Annex II

### EXAMPLE OF A HIERARCHY OF MANAGEMENT SELF-ASSESSMENT

#### REVIEW

<ul style="list-style-type: none"><li>— Middle management reports</li><li>— Management self-assessment reports</li><li>— Summary reports from independent assessment unit</li><li>— Regulatory feedback</li><li>— Strategic review</li><li>— Peer evaluation</li><li>— Technical review</li><li>— Plant walkabout</li></ul>	<b>SENIOR MANAGEMENT</b>
---	--------------------------

#### SURVEILLANCE

<ul style="list-style-type: none"><li>— Surveillance of items, services and processes</li><li>— Review of design documents and validation</li><li>— Review of procedures and records</li><li>— Observation of audits</li><li>— Nuclear power plant tours</li></ul>	<b>LINE MANAGEMENT</b>
--	------------------------

#### DISCRETE CHECK

<ul style="list-style-type: none"><li>— Checking</li><li>— Inspecting</li><li>— Testing</li></ul>	<b>SUPERVISORS</b>
---	--------------------



**Safety Guide Q6**

**QUALITY ASSURANCE IN PROCUREMENT  
OF ITEMS AND SERVICES**



## CONTENTS

1.	INTRODUCTION .....	139
	Background (101–102) .....	139
	Objective (103) .....	139
	Scope (104) .....	139
	Structure (105) .....	139
2.	ARRANGEMENTS FOR PROCUREMENT .....	140
	Responsibilities (201–203) .....	140
	Grading (204–206) .....	141
3.	PREPARATION OF PROCUREMENT REQUIREMENTS .....	142
	General (301–302) .....	142
	Content (303–314) .....	142
	Review, approval and changes of procurement documents (315–316) ...	145
4.	SELECTION OF SUPPLIERS .....	145
	General (401) .....	145
	Selection process (402–404) .....	146
5.	EVALUATION OF QUOTATIONS AND AWARD OF CONTRACT ...	147
	Evaluation (501–502) .....	147
	Award (503) .....	147
6.	EVALUATION OF SUPPLIER PERFORMANCE .....	147
	Responsible organization and supplier co-ordination (601–603) .....	147
	Document submission, review and approval (604) .....	148
	Source inspection and testing (605) .....	148
	Reporting of inspection and testing activities (606) .....	149
	Non-conformance control (607) .....	149
7.	ACCEPTANCE OF ITEMS AND SERVICES .....	149
	Receiving inspection of items (701) .....	149
	Release of items (702) .....	150
	Post-installation testing of items (703) .....	150
	Acceptance of services (704) .....	150

8. COMMERCIAL GRADE ITEMS (801– 802) ..... 150

9. PROCUREMENT OF SPARES (901) ..... 151

ANNEX: EXAMPLE OF A TYPICAL PROCUREMENT  
PROCESS FOR ITEMS AND SERVICES ..... 152

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the basic requirement of the Code on procurement.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate programmes in each stage of a nuclear power plant project, and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into nine sections and one annex:

Section 2 describes the responsibilities involved in procurement and grading.

Section 3 describes the preparation of procurement requirements, including verification activities.

Section 4 describes a process for the selection of suppliers.

- Section 5 describes methods for evaluation of quotations from prospective suppliers and the award of contracts.
- Section 6 describes the evaluation of supplier performance.
- Section 7 describes actions to confirm that items or services meet procurement requirements.
- Section 8 describes actions to be taken when commercial grade items are purchased.
- Section 9 describes factors to be considered in the procurement of spares.
- Annex provides an example of the procurement process for items and services.

## **2. ARRANGEMENTS FOR PROCUREMENT**

### **RESPONSIBILITIES**

201. The responsible organization shall ensure that procured items and services meet established requirements and perform as specified and that selected suppliers continue to provide acceptable items and services during the fulfilment of their procurement obligations. The responsible organization may delegate procurement activities to other organizations, but shall retain the responsibility for the overall effectiveness of these activities.

202. Procurement activities shall conform to the regulatory requirements of the Member State and, as applicable, to the provisions of recognized codes, standards and specifications used in the design, manufacture, installation and operation of items and services.

203. The responsible organization shall establish a procurement process within its QA programme that meets the requirements of the Code. The procurement process should require personnel carrying out procurement activities to:

- Ensure that the information provided to suppliers is clear, concise and unambiguous, fully describes the items and services required and includes the technical and QA requirements;
- Ensure, as a basis for selection, that the supplier is capable of supplying the items and services as specified, including the continuation of any follow-on spare parts;
- Monitor suppliers to confirm that they continue to perform satisfactorily;

- Ensure that the items and services conform with the requirements of procurement documents and perform as expected;
- Ensure that, when required, documentary evidence of conformance is available at the nuclear power plant site before items and processes are installed or used;
- Specify the contact person for all procurement communications with the supplier;
- Ensure, where necessary, that interfaces between the responsible organization and suppliers and between suppliers are defined to ensure that key dates are met.

The Annex provides an example of a typical procurement process for items and services.

## GRADING

204. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

205. This graded approach should be applied throughout the supply chain.

206. The procurement requirements that could be graded are:

- The requirements for supplier assessment, evaluation and qualification
- The scope and level of detail of the procurement specification
- The need for and scope of supplier quality plans
- The extent of responsible organization inspection, surveillance and audit activities
- The scope of documents to be submitted and approved, and the records to be provided
- The extent of records to be provided or stored and preserved.

For further guidance on grading see Safety Guide Q1.

### 3. PREPARATION OF PROCUREMENT REQUIREMENTS

#### GENERAL

301. Applicable regulatory requirements, design bases, standards, specifications and other requirements necessary to ensure the technical adequacy shall be determined and included or referenced in the documents for procurement of items and services.

302. It is essential that a correct and unambiguous specification of the item or service is available. Therefore all relevant parties within the responsible organization should participate in the process of compiling procurement documents.

#### CONTENT

303. Procurement documents should include the following, where appropriate, together with identification of the associated responsibilities:

- Scope of work
- Technical requirements
- Inspection and testing requirements
- Access to supplier facilities
- Identification of QA standard
- Document requirements
- Record requirements
- Timing of submissions
- Non-conformance reporting
- Subsupplier controls
- Items and services supplied by the responsible organization.

#### **Scope of work**

304. A full description of the work to be undertaken by a supplier, including interfaces with other work, should be provided so that the intent is clearly understood and prospective suppliers can deliver the items or services as specified.

#### **Technical requirements**

305. The technical requirements should be specified by reference to technical documents such as: codes, specifications, regulatory requirements, standards, design

basis, drawings, process requirements and requirements for approval or qualifications of items, procedures or processes. The responsible organization may require supplier personnel to be specifically qualified in order for some technical requirements to be met, for example welding, inspection and testing, and heat treatment. It may also include: requirements for performance; requirements for fabrication, storage, handling, packaging and presentation of materials; requirements for installation; and requirements for operation. Each specified requirement should be achievable and verifiable and when met will render items or services fit for the intended purpose.

### **Inspection and test requirements**

306. When inspection or testing of products is required, it should be specified. For example, there may be a need for qualification type tests such as seismic or harsh environment testing. Specifying testing requirements to the supplier does not relieve the supplier from the responsibility to determine testing requirements necessary to assure item quality. However, on the basis of the intended use of an item, the responsible organization may need to specify additional tests to demonstrate conformance to the codes, standards and specifications previously quoted. The specification should define acceptance criteria for the standards to be applied. At specific stages of production the responsible organization may require hold and witness points. Inspection and testing activities should be detailed by the supplier. For further guidance on inspection and testing see Safety Guide Q4.

### **Access to supplier's facilities**

307. Access to the supplier's premises to carry out inspections, audits, surveillance, etc., should be defined. These activities may be performed by the responsible organization, or by other authorized parties acting on its behalf. Extension of this requirement to sub-suppliers is covered in para. 313.

### **Identification of quality assurance standards**

308. The QA standards to be complied with must be clearly defined. If the responsible organization wishes to quote national or international QA standards, an evaluation should be performed to determine if additional requirements should be specified in order to satisfy the IAEA Safety Standards on Quality Assurance. When international standards are quoted, care should be taken to ensure that optional clauses are adequately addressed.

## **Document requirements**

309. Those documents which the responsible organization requires the supplier to submit for approval or comment should be clearly identified in the procurement documents. Typical documents that may require approval include design documentation, inspection and test reports, manufacturing and testing procedures, maintenance procedures/manuals and the supplier's QA programme description. The following criteria may be considered in determining who should approve documents:

- Which party has design responsibility.
- The capability and responsibility of suppliers and subsuppliers in the supply chain.

## **Records requirements**

310. Requirements regarding records (including material samples) should be identified to the supplier prior to placing the contract. This could best be achieved by providing or requiring a record schedule to be submitted by the supplier detailing all record requirements. Instructions for the retention or transfer of records from the supplier and/or subsuppliers should be specified. These should include those records which are required by the responsible organization to obtain the necessary assurance that the items or services have met or will meet the requirements. Retention periods and responsibilities for the maintenance of records by the supplier should also be specified. For further guidance on the requirements for records see Safety Guide Q3.

## **Timing of submissions**

311. Clear instructions should be given to suppliers regarding the time when the required documents and records should be submitted. The timing should take account of hold points, key events, and document submission and turnaround times.

## **Non-conformance reporting**

312. The supplier should have a clear understanding with regard to the non-conformance control process. Responsibilities for processing non-conformances with the specified procurement requirements should be defined (see para. 607).

## **Subsupplier controls**

313. Unless otherwise specified by the responsible organization, the supplier should be responsible for the control of subsuppliers. Therefore, should

subcontracts be placed, the supplier should be requested to secure from sub-suppliers all rights of access as a contractual obligation. The supplier should be required to impose QA requirements on sub-suppliers consistent with the importance of the subcontracted item or service. This would include, for example, the responsibility to monitor and evaluate the performance of sub-suppliers (see Section 6).

### **Items and services supplied by the responsible organization**

314. The responsible organization should specify storage, inspection and maintenance requirements for items it provides to a supplier.

## **REVIEW, APPROVAL AND CHANGES OF PROCUREMENT DOCUMENTS**

315. The responsibilities for review and approval of procurement documents within the responsible organization should be defined. Procurement documents should be reviewed and approved before issue to ensure that all requirements have been included and are in accordance with the specified requirements, responsible organization procedures and regulatory requirements.

316. Changes to procurement documents should be undertaken in a controlled manner. Before approval, changes should be reviewed to ensure that there are no adverse effects to other structures, systems and components of the plant. The supplier or prospective supplier should be notified of approved changes. Changes to procurement documents should be subjected to the same level of control as the original documents. For further guidance on the requirements for controlling changes to documents see Safety Guide Q3.

## **4. SELECTION OF SUPPLIERS**

### **GENERAL**

401. The selection of suppliers should be based on an evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents.

## SELECTION PROCESS

402. The responsible organization should use specified criteria to evaluate and select suppliers. Responsibilities for determining supplier capability should be identified. This may require involving one or more organizational units of the responsible organization such as engineering, construction, manufacturing, operation and maintenance, purchasing or quality assurance/assessment, depending on the item or service being procured.

403. Methods to be used in evaluating prospective suppliers and the results of evaluations should be documented and should include, for example:

- (a) Evaluating the prospective supplier's history of providing a product which performs satisfactorily in actual use, for example:
  - the experience of users of identical or similar items and services of the prospective supplier;
  - review of records that have been accumulated in connection with previous procurement actions and operating experience with the product;
  - review of historical data relevant to the items or services being procured which are representative of the prospective supplier's current capability. If there has been no recent experience, the prospective supplier should be requested to submit information on an equivalent item or service for evidence of current capabilities.
- (b) Evaluating the prospective supplier's QA programme. This could be carried out by taking into account third party certification relevant to the scope of the work.
- (c) Assessing the capability of the prospective supplier by evaluating facilities and personnel, and the implementation of the QA programme. Safety Guide Q5 provides guidance on assessment.
- (d) Objectively evaluating the prospective supplier's current QA records supported by documented qualitative or quantitative information such as statistical records or other records attesting to the prospective supplier's performance.
- (e) Evaluating the capability of the prospective supplier by investigating samples of current production.

404. After the initial selection of prospective suppliers, procurement documents should be forwarded to them indicating the date for submitting tenders (quotations), and the procedures for resolving questions and seeking clarification (for example by meetings, presentations and/or assessments).

## **5. EVALUATION OF QUOTATIONS AND AWARD OF CONTRACT**

### **EVALUATION**

501. Submitted quotations (bids or tenders) from prospective suppliers should be evaluated in a logical manner to ensure that they conform to the requirements of the procurement documents.

502. The evaluation of quotations carried out by the responsible organization should be a team effort involving the organizational units responsible for the technical and procurement activities. The size of the team undertaking the evaluation should be determined by the size and complexity of the item or service to be purchased.

### **AWARD**

503. The award of the contract should be based on the capability of the supplier to meet the requirements of the procurement documents. All actions arising from the evaluation of quotations should be fully documented and resolved, including the grounds for awarding the contract.

## **6. EVALUATION OF SUPPLIER PERFORMANCE**

### **RESPONSIBLE ORGANIZATION AND SUPPLIER CO-ORDINATION**

601. The responsible organization should monitor, evaluate and verify how the supplier performs against the procurement requirements. This may be done by the responsible organization, its designated representative or other parties authorized by the responsible organization. These activities should provide for:

- Establishing a mutual understanding of the specifications and intent of the procurement documents between the responsible organization and the supplier;
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement requirements;
- Reviewing documents that are generated or processed during activities fulfilling procurement requirements;

- Co-ordinating feedback of experience between the responsible organization and suppliers;
- Identifying and processing changes to information;
- Establishing a method for the exchange of documented information between the responsible organization and the supplier.

Such activities could form the basis for future supplier selection.

602. Depending on the complexity or scope of the items or services, the responsible organization should initiate pre- and post-award activities. These activities may take the form of meetings, or other means of communication, to establish a mutual understanding between the responsible organization and the supplier regarding:

- Procurement document requirements;
- The intent of the responsible organization in monitoring and evaluating the supplier's performance;
- The planning, manufacturing techniques, tests, inspections and processes to be employed by the supplier to meet procurement requirements.

The responsible organization should identify notification points as early as practicable in the procurement process. These should be documented and agreed between the responsible organization and the supplier.

603. The extent and necessity of pre- and post-award communication depends on the uniqueness of the product, its complexity, the procurement frequency with the same supplier and past performance in the supply of similar items or services.

#### DOCUMENT SUBMISSION, REVIEW AND APPROVAL

604. Documents requiring the approval of the responsible organization should be forwarded by the supplier to the responsible organization. They should be reviewed by appropriate staff against the requirements of the procurement documents. After review they should be approved or challenged by the responsible organization's authorized representative(s) and returned to the supplier for action.

#### SOURCE INSPECTION AND TESTING

605. Inspection and testing activities at source (in the supplier's works) should take place in accordance with the requirements of the procurement documents. They

should not absolve the supplier of the responsibility to provide acceptable items or services. When source inspection and testing take place at a subsupplier's works, the responsibility for controlling the subsupplier's activities should remain with the supplier (see para. 313).

## REPORTING OF INSPECTION AND TESTING ACTIVITIES

606. To facilitate the release of products, the results of agreed inspections and tests should be reported to the responsible organization or its representatives for review against the procurement requirements.

## NON-CONFORMANCE CONTROL

607. Non-conformances identified during the procurement process should be handled in accordance with Safety Guide Q2. Non-conformances identified by the responsible organization should be reported to the supplier immediately for processing through the supplier's non-conformance control system.

# 7. ACCEPTANCE OF ITEMS AND SERVICES

## RECEIVING INSPECTION OF ITEMS

701. Items and associated documents, including material certificates where applicable, should be inspected immediately upon receipt in order to verify that they meet specified requirements. Procurement documents should be copied to the goods receipt areas and the procurement department should be notified when items are received. The level of receiving inspection required should be specified and may vary with the complexity of the item, its importance to safety, the level of source verification carried out and the prior performance of the supplier. Any non-conforming items found on receiving inspection should be controlled in accordance with Safety Guide Q2. For further guidance on inspection and testing for acceptance of items and services, see Safety Guide Q4.

## RELEASE OF ITEMS

702. Items should not be released for use or installation at the nuclear power plant until all inspections have been satisfactorily concluded and all specified documentation, for example material certificates, have been received and checked.

## POST-INSTALLATION TESTING OF ITEMS

703. When an item cannot be satisfactorily verified as conforming until it is tested in an installation, appropriate instructions should be given to the installation staff and the requirement included in the procurement documents. The supplier should have the opportunity to carry out the installation tests before offering the item to the responsible organization for acceptance.

## ACCEPTANCE OF SERVICES

704. The criteria for acceptance of services should be specified in the procurement documents and the activities should be monitored. Evidence of conformity should be supplied in the form of, for example, performance measurement activities, inspection and test records. Records of inspection and testing for acceptance should be used for assessing and monitoring the supplier's performance.

# **8. COMMERCIAL GRADE ITEMS**

801. Certain items with a proven record may be available from commercial stock. Procurement documents should provide sufficient information from catalogues and suppliers' specifications to enable the correct item to be supplied. All relevant technical data and trial information should be requested. These items may require confirmatory analysis or testing to demonstrate the adequacy of the item to perform its intended function.

802. When a commercial grade item is proposed for any safety function, a thorough technical evaluation of the complexity of the item and its safety significance should be carried out. The critical characteristics required for that function should be included as acceptance criteria in the procurement documents.

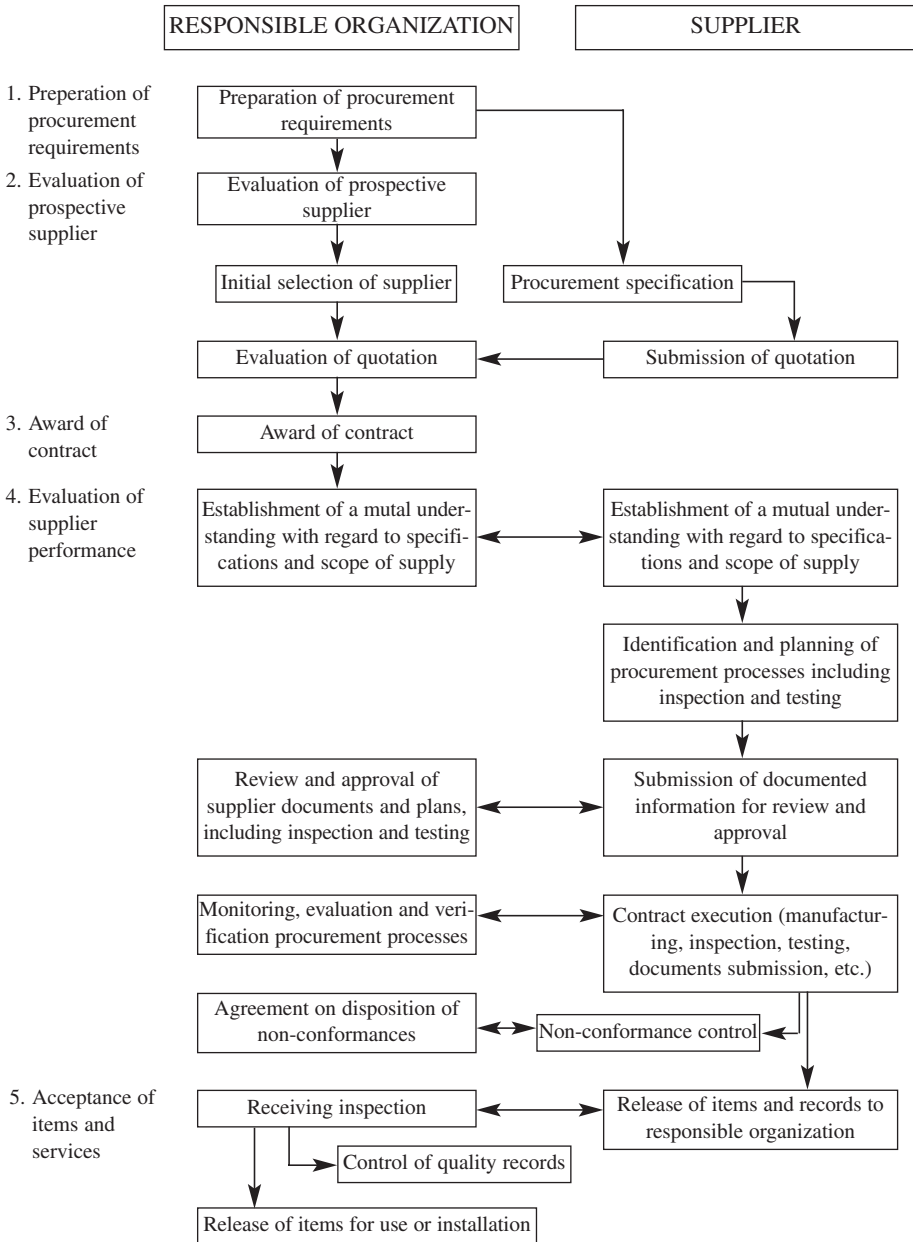
## 9. PROCUREMENT OF SPARES

901. The plant management may arrange to obtain spares of plant items at the time of procurement of the original items. The spares should meet the same QA requirements as the originals, with additional requirements to assure protection during long term storage. The factors to be considered in determining the quantities of spares include the following:

- Numbers and safety significance of items liable to failure,
- Special nature of the manufacturing process which may prevent subsequent manufacture,
- Uncertainties in supply of current spares,
- Anticipated delivery periods and shelf-lives,
- Delays caused by importing spare parts from other countries,
- Isolation from qualified manufacturers.

## Annex

### EXAMPLE OF A TYPICAL PROCUREMENT PROCESS FOR ITEMS AND SERVICES



**Safety Guide Q7**

**QUALITY ASSURANCE IN MANUFACTURING**



## CONTENTS

1.	INTRODUCTION .....	157
	Background (101–102) .....	157
	Objective (103) .....	157
	Scope (104–105) .....	157
	Structure (106) .....	157
2.	GENERAL .....	158
	Responsibilities (201–203) .....	158
	Grading (204–205) .....	158
3.	THE MANUFACTURING PROCESS (301–311) .....	159
4.	IDENTIFICATION AND CONTROL OF ITEMS (401–404) .....	161
5.	CONTROL OF MANUFACTURING EQUIPMENT (501–503) .....	162
6.	HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY (601) .....	162
	Handling (602–603) .....	162
	Storage (604–606) .....	163
	Packaging (607–608) .....	163
	Preservation (609–610) .....	163
	Delivery (611) .....	163
ANNEX:	SOME SPECIAL ASPECTS RELATING TO THE MANUFACTURE OF NUCLEAR FUEL .....	165



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the manufacture of items for nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in each stage of a nuclear power plant project, and covers items impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. The guidance and recommendations given in this Safety Guide should be taken into account in procurement documents in order to clearly communicate specified contractual requirements. Guidance on the procurement of items and services is given in Safety Guide Q6.

## STRUCTURE

106. This Safety Guide is arranged into six sections and one annex:

Section 2 provides guidance on the responsibilities for manufacture and on grading of QA requirements.

- Section 3 provides guidance on the planning of the manufacturing process.
- Section 4 provides guidance on the identification and control of items.
- Section 5 provides guidance on manufacturing equipment control.
- Section 6 provides guidance on handling, storage, packaging, preservation and delivery.
- Annex provides examples of some special aspects relating to the manufacture of nuclear fuel.

## 2. GENERAL

### RESPONSIBILITIES

201. The responsible organization shall ensure that those participating in the manufacture of items important to the safety of nuclear power plants are required, by procurement documents, to establish and implement a QA programme, the level of which shall be commensurate with the safety significance of the manufactured items. For further guidance on procurement see Safety Guide Q6.

202. The responsibility for the effectiveness of the overall QA programme of the nuclear power plant remains with the responsible organization without prejudice to the manufacturer's obligations and the legal requirements imposed on the manufacturer. For further guidance on QA programmes and their content, see Safety Guide Q1.

203. Procedures and work instructions shall be prepared for activities affecting the quality of a manufactured item. These activities include manufacturing processes and their control, inspection and testing, identification, handling, storage, packaging, preservation and delivery.

### GRADING

204. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

205. The manufacturing activities that could be graded are:

- Qualification of any special manufacturing process and of the personnel to carry it out,
- Extent and details of procedures and degree of their review,
- Details and need for inspection and testing plans,
- Degree of in-process controls, witness points, hold points and sample points,
- Requirements for material traceability,
- Records and archive samples.

For further guidance on grading see Safety Guide Q1.

### **3. THE MANUFACTURING PROCESS**

301. The items to be manufactured shall be fully defined by documents, such as specifications and drawings, to the extent necessary before the start of the manufacturing activities.

302. The QA programme for manufacturing activities should provide for the review of procurement documents for the item to be manufactured to determine what regulations, codes, standards and other requirements are applicable during manufacture. Regulatory, technical and other requirements set forth in these documents should be included, as appropriate, in manufacturing drawings, specifications, inspection and test plans, procedures and work instructions.

303. The manufacturer shall be made aware of the requirements of the responsible organization and regulatory body (see the Code 50-C-G (Rev. 1)) for sampling points, hold points and witness points. For further guidance on inspection and test plans and associated inspection activities see Safety Guide Q4.

304. Such functions as purchasing, planning, manufacture and manufacture control, which are performed by the manufacturing organization, should be identified and their relationship with the functions of the responsible organization and the principal designer<sup>1</sup> defined.

---

<sup>1</sup> The principal designer has responsibility for specifying the design requirements and for approving the design output on behalf of the responsible organization. Further explanation of the term 'principal designer' can be found in Safety Guide Q10.

305. During the initial planning phase for manufacture, consideration should be given to such factors as:

- Understanding the manufacturing implications of the design.
- Estimating resource requirements.
- The procurement of critical path and long term delivery items.
- The amount of manufacturing such as forming, heat treating, partial machining or fabricating of subassemblies, to be carried out.
- Clean conditions and other environmental controls to meet requirements and to achieve item quality. These controls may include dust-free or inert atmospheres, humidity controls, temperature controls, and control of the chemical composition of water.
- The assembly of the equipment.
- Handling, storing, packaging and delivery requirements.
- The application of new techniques in manufacturing, inspection and testing.
- The need for inspections and tests specified by the designers and regulatory bodies, and those deemed necessary by the manufacturer to control item quality and to ensure the manufacturing process has been followed.
- The need to develop, qualify and control any new manufacturing processes.
- Processes which are complex or sensitive, or which require extensive set-up, special equipment or special training. Some of those processes which require special consideration in fuel manufacturing are listed in the Annex.

306. The manufacturer's QA programme should include the identification and control of processes which are required to be carried out by qualified personnel or which require continuous monitoring and control of process parameters to ensure that the specified requirements are met. These processes are those where the results cannot be fully verified by subsequent inspection and testing of the item and where, for example, processing non-conformances may become apparent only after the item is in use or operation.

307. The requirements for any qualified processes, including associated equipment and personnel, should have been specified in procurement documents (see Safety Guide Q6).

308. Where required, the manufacturer should establish and maintain clean conditions during manufacture to prevent ingress of extraneous matter and the introduction and use of incompatible materials.

309. Process, inspection and test procedures used during manufacture should be developed and implemented by the manufacturer to ensure conformance with the

necessary requirements. These procedures may require the approval of the responsible organization prior to the commencement of work.

310. Where necessary, inspection and test plans for items should be developed at the earliest time consistent with the schedule for accomplishing the activities. The inspection and test plans should incorporate, as appropriate, a flow chart or sequential narrative listing of all processes, procedures, work instructions, tests and inspections to be performed in the manufacture and acceptance of items. If inspection and test plans are used they should indicate the hold points of the manufacturer, the regulatory body and/or the purchaser; work should not proceed beyond these points until the required action has been taken and the confirmatory documentation generated and accepted. Such plans should also show any optional witness points for which advance notification is required.

311. There are several types of format for an inspection and test plan, for example:

- Flow chart indicating inspection activities and their location in the manufacture cycle;
- Tabulated schedule indicating requirements for manufacture, inspection and test activities, and quality records with provision for noting stage acceptance.

For further guidance on inspection and test plans see Safety Guide Q4.

## **4. IDENTIFICATION AND CONTROL OF ITEMS**

401. The manufacturer should implement suitable means for identifying items at receipt and during all stages of manufacturing, delivery and installation. Special aspects for the identification of fuel assemblies is given in the Annex.

402. Where traceability is required, unique identification of individual items or batches should be made and recorded.

403. Items that deteriorate with age should be clearly marked to indicate shelf-life limits.

404. When parts are stored as subcomponents or subassemblies awaiting final assembly, care should be taken to maintain identification.

## **5. CONTROL OF MANUFACTURING EQUIPMENT**

501. Manufacturing equipment should be maintained as necessary and in accordance with the suppliers' recommendations. The frequency and extent of the periodic maintenance applied to any equipment should be such that the equipment performance characteristics are held within specified limits.

502. Where special equipment such as tooling, jigs, fixtures, unique inspection gauges, computers and computer software are required to aid the manufacturing process, these should be properly qualified or validated for use as required, and their application known to those carrying out the activity.

503. Measuring and test equipment which is used for in-process or final inspection and test of an item, or to control any process parameter, should be controlled in accordance with the guidance given in Safety Guide Q4.

## **6. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY**

601. The responsible organization should ensure that the manufacturer has procedures covering the handling, storage, packaging, preservation and delivery of the item(s).

### **HANDLING**

602. Methods of handling items to prevent damage or deterioration shall be used. Proper care should be taken in handling of items during receipt, manufacture, assembly, inspection, test and delivery, particularly where special precautions are required for reasons such as weight, size, cleanliness, temperature conditions or other environmental conditions. Handling equipment should be inspected and tested periodically. Special aspects concerning the handling of fuel assemblies is given in the Annex.

603. Protective devices (for example cartons, containers), handling equipment (for example hoists, manipulators) and transport vehicles should be considered for use where handling operations are of a nature likely to cause damage.

## STORAGE

604. Designated storage areas or stock rooms should be used to prevent damage or deterioration of items pending use or delivery.
605. Methods of authorizing receipt to and dispatch from such areas should be utilized.
606. The condition of items in storage should be assessed to ensure that items are not deteriorating.

## PACKAGING

607. Packaging and marking should be used to the extent necessary to ensure an item conforms to the specified requirements.
608. Packaging should ensure that an item does not become damaged, lost or deteriorated in transit, upon arrival or when in storage at the nuclear power plant.

## PRESERVATION

609. Preservation methods and segregation of items should be applied where necessary to ensure that items do not deteriorate, become damaged or lost.
610. Preservation and packaging activities should ensure that items do not deteriorate in storage through exposure to air, moisture or other environmental conditions.

## DELIVERY

611. Items being prepared for delivery should be preserved, packaged and identified to prevent damage, deterioration or loss. The manufacturer should be required, before delivery, to check that:
- items to be delivered have met all specified requirements, and the necessary documents such as records, release documents and delivery clearances are available;
  - items have been preserved and packaged in accordance with applicable contractual requirements and specifications;

- items and packaging have been properly identified as to content;
- where specified, devices (such as accelerometers) for recording conditions and events during shipment have been included in the packaging;
- provisions including instructions for handling and storage during transit and after receipt at destination, and for the installation and use of items at the destination, are available as appropriate and their location is indicated.

The Annex provides guidance on some particular aspects that should be considered when shipping fuel assemblies.

## Annex

### SOME SPECIAL ASPECTS RELATING TO THE MANUFACTURE OF NUCLEAR FUEL

#### EXAMPLES OF PROCESSES REQUIRING CONTROL AND QUALIFICATION

##### **Manufacturing**

- Fuel end plug and structural welding
- Heat treatment
- Plating, coating or bonding
- Autoclaving and electropolishing
- Gas filling
- Preservation of fuel pellet integrity, including sintering
- Fuel pellet loading into fuel pin/rod
- Fuel cladding.

##### **Quality verification**

- Ultrasonic testing
- Eddy current testing
- Liquid (dye) penetrant testing
- Radiographic testing
- Helium leak testing
- Gamma or neutron scanning of fuel rods
- Destructive testing of fuel samples, as appropriate
- Special methods for dimensional checking.

#### EXAMPLES OF MANUFACTURING CONTROL AND FUEL ASSEMBLY IDENTIFICATION

The manufacturing, including rework and repair of fuel assemblies, should be done in accordance with approved technical requirements. Special consideration should be given to the following:

## **Control**

- (a) **Fuel processing control**  
Control of fuel material conversion and fuel production with respect to enrichment, homogeneity, chemical composition and contaminants, physical characteristics and dimensions.
- (b) **Nuclear poison control**  
Control of poison materials with regard to their homogeneity and impurities, and control of rod manufacture with regard to physical characteristics and dimensions.
- (c) **Control of fuel cladding and coating**  
Control of fuel cladding and coating manufacture with regard to chemical composition, contaminants, mechanical and metallurgical properties, integrity, dimensions and corrosion characteristics.
- (d) **Control of support structure and associated items**  
Control of support structure and associated items, with regard to chemical composition, contaminants, mechanical and metallurgical properties, dimensions, integrity and corrosion characteristics.
- (e) **Control of fuel rod/element manufacture**  
Control of fuel rod/element manufacture, with regard to fuel stack characteristics, hydrogen content, enrichment, end closure weld integrity, internal pressure, internal gas analysis and dimensions.
- (f) **Fuel assembling control**  
Control during fuel assembling, with regard to fuel rod identification, positioning, dimensions (including the weight of the fuel assembly), weld integrity, cleanliness, surface condition and surface contamination by uranium.

## **Fuel assembly identification**

A system of identification of fuel assemblies and, where specified, individual components and fuel rods should be agreed upon between the purchaser and the manufacturer, for the purposes of traceability, accounting, fuel management and feedback to the design process. Record retention periods should be agreed at the earliest practical time. Measures should be instituted for implementing this identification system during all stages of processing, manufacturing and assembling of fuel.

## **Handling, storage, packaging and delivery**

Packaging requirements should be established, and qualified where required, to ensure adequate protection of fuel assemblies during delivery, handling and storage.

Adequate care needs to be taken in the handling and storage of fuel assemblies during manufacturing, assembling and delivery. Items such as containers, protective devices, hoists, manipulators and transport vehicles should be qualified for their intended use. The mode of delivery and methods of handling should be consistent with the protection of the assembly and with the packaging methods employed, which should also meet applicable regulations such as the IAEA Safety Series No. 6 (Regulations for the Safe Transport of Radioactive Material). The methods should include any requirements necessary to avoid the possibility of accidental criticality conditions during all the operations.



**Safety Guide Q8**

**QUALITY ASSURANCE IN RESEARCH  
AND DEVELOPMENT**



## CONTENTS

1.	INTRODUCTION .....	173
	Background (101–102) .....	173
	Objective (103) .....	173
	Scope (104) .....	173
	Structure (105) .....	173
2.	MANAGEMENT .....	174
	General (201–203) .....	174
	Quality assurance programme (204–205) .....	174
	Grading (206–207) .....	175
	Organization (208) .....	176
	Responsibilities (209–212) .....	176
	Interfaces (213) .....	177
	Training and qualification (214–216) .....	177
	Non-conformance control and corrective actions (217–219) .....	177
	Document control and records (220–225) .....	178
3.	PERFORMANCE .....	179
	Planning and preparation for research and development (301–313) .....	179
	Conducting research and development (314–319) .....	181
	Data analysis and reporting (320–322) .....	181
4.	ASSESSMENT .....	182
	Management self-assessment (401–402) .....	182
	Independent assessment (403–405) .....	182
	ANNEX: FLOW DIAGRAM OF A TYPICAL EXPERIMENTAL RESEARCH AND DEVELOPMENT PROJECT .....	184



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to research and development (R&D) for nuclear power plants.<sup>1</sup>

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in each stage of a nuclear power plant project. This guide covers R&D work on items, services and processes impacting nuclear safety during siting, design, construction, commissioning, operation and decommissioning of nuclear power plants. The impact on safety may occur during the performance of the R&D work, or owing to the application of the results of the R&D. The guide may, with appropriate modification, also be usefully applied at nuclear installations other than nuclear power plants.

## STRUCTURE

105. This Safety Guide is arranged into four sections and one annex:

Section 2 describes QA for the management responsibilities for R&D activities.

---

<sup>1</sup> In addition to this Safety Guide, there are two Safety Standards on nuclear research reactor design and operation, IAEA Safety Series No. 35-S1 and IAEA Safety Series No. 35-S2, respectively.

- Section 3 describes QA for the performance of R&D activities.
- Section 4 describes QA for the assessment of R&D activities.
- Annex is a flow diagram of a typical experimental R&D project.

## 2. MANAGEMENT

### GENERAL

201. The objective and direct results of basic and applied research are the development of new knowledge or analytical studies (that may or may not have any known application to technological processes or products). The objective and direct products of engineering development are the development of prototype devices, new software, new testing methods, new or improved technological products or processes, or new industry standards that can be used in nuclear power plants. R&D activities have to be performed in a manner which provides assurance that safety requirements are adequately addressed. This should be accomplished by conducting the R&D work under an effective QA programme.

202. The starting point of an R&D project might be a hypothesis to be tested, a problem to be solved, or the performance of an item to be improved, and there may be many possible solutions and technologies that could be used. A typical R&D project is described in the flow diagram of the Annex.

203. R&D organizations should consider applying the guidance given in the other QA safety guides to their facilities.

### QUALITY ASSURANCE PROGRAMME

204. The responsible organization shall ensure that its QA programme is implemented for R&D activities important to safety by developing plans for each R&D project. The specialities of R&D as outlined in paras 201 and 203 and in the Annex should be taken into account.

205. For success in R&D work, managers at all levels should:

- Cultivate and sustain an environment that fosters and encourages creativity, intellectual stimulation, innovation and collaboration;

- Require good work practices as the only acceptable way of performing and supporting R&D;
- Lead by example and demonstrate personal commitment to continuous improvement;
- Empower personnel at all levels in the organization;
- Acknowledge excellence in performance;
- Ensure that sufficient qualified resources are available and set priorities for their deployment;
- Avoid overloading researchers with administrative tasks by providing adequate administrative support;
- Ensure that intellectual property rights are preserved and protected.

For further guidance on establishing a QA programme see Safety Guide Q1.

## GRADING

206. Nuclear safety shall be the fundamental consideration when identifying the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

207. The following should also be considered in the grading process:

- The intended end use of the knowledge, data, technological process or technological product that will result from the R&D, particularly in terms of its impact on nuclear safety;
- The amount and nature of the materials to be used and the degree to which the work poses risks or hazards to personnel, the public and the environment;
- The ability to demonstrate, test or repeat the results;
- The scale and technical complexity of the activity and the facilities to be used;
- Whether a new concept, a proven concept, or an extension to a new application is involved;
- The managerial complexity of the activity, the involvement of multiple customers, multiple external or internal organizations, different objectives and responsibilities;
- The impact that missed milestones or delayed milestones will have on the schedule, the ease or difficulty of schedule recovery, the loss of key personnel and delays in recruiting new personnel, and in receiving critical equipment or making it functional;

- The extent to which other work depends on the results of the R&D project;
- The expectations or desired performance of the results.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

208. Management should ensure that roles, responsibilities, authorities and interfaces are clearly defined and understood, particularly between the functions of: (1) managing the resources necessary to support research work; (2) performing the research; and (3) carrying out assessments over the course of the R&D project. These relationships can be complex because some researchers may also have staff functions and carry out their different functions at different times. In every case, however, the functions of research and independent assessment should be organized so that they are clearly separated. Some researchers may be working at universities or at other institutions which are sharing an interest in the R&D project. In these cases, agreed methods of collaboration should be adopted.

## RESPONSIBILITIES

209. Management should assign a principal investigator/researcher to be responsible for developing an R&D plan and for performing and/or supervising the work defined in the plan. The principal investigator/researcher may subsequently assign some or all of the work to other researchers, engineers or technicians. When work is assigned, a description of the roles, responsibilities and authorities for the work should be described in the R&D plan.

210. The management of the organization responsible for R&D should ensure that the roles, responsibilities and authorities for reviewing and approving R&D plans are defined. Reviewers should consider, for example, the technical direction of the work, user requirements, assumptions, resources and schedule implications.

211. Senior management should review the possible alternatives and document its decisions, justifying its choice of a specific direction and the rationale for eliminating alternatives.

212. Prior to the application of the results of any R&D work, the responsible organization should ensure that the work results have been properly validated, the safety

implications assessed, and approval obtained, if appropriate, from the regulatory body (see the Code 50-C-G (Rev. 1)).

## INTERFACES

213. Interfaces should be described in the R&D plan and arrangements between the organizations performing work should be agreed to. For example, the following interfaces should be addressed:

- Organizational interfaces at the start of the R&D work;
- Interfaces between internal and external organizations during the R&D work;
- Interfaces with similar R&D projects;
- Interfaces at the end of the R&D work, such as those related to the use and application of the results.

For further guidance on interfaces see Safety Guide Q1.

## TRAINING AND QUALIFICATION

214. Personnel shall be trained and qualified so that they are competent to perform their assigned work and so they understand the safety consequences of their activities.

215. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work.

216. Training should also be provided commensurate with the hazards associated with the work being performed and with its nuclear safety importance. The principal investigator/researcher performing or assessing R&D for a nuclear power plant should have a basic knowledge of nuclear safety. For further guidance on training see Safety Guide Q1.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

217. Management should establish a non-conformance control and corrective action process that distinguishes the difference in approach for the following:

- Errors detected in data, calculations, reasoning, assumptions, programming, measuring;

- Differences between anticipated results, actual results and results from similar tests;
- Failures or incidents during testing;
- Non-conformance with procedures and specifications.

218. Although procedures and specifications may be available at the start of the R&D work, controlled change and deviation from these procedures may occur often as a legitimate component of the conduct of R&D.

219. Deviations from expectations prescribed in the R&D plan should be recorded and analysed to determine if they are true non-conformances, or if they are improvements which actually benefit the R&D project. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

221. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of R&D records.

222. Management should establish requirements for ensuring that all appropriate aspects of R&D work are adequately documented and recorded. This includes work from the initial conception and design of the R&D plan through to the conduct and analysis of the research results.

223. Laboratory and work notebooks and other recording methods should be used.

224. Entries in laboratory notebooks should be traceable to the work performed and developed to an adequate level of detail, and should be legible, complete and correct.

225. All appropriate laboratory notebooks, other records and the data from the R&D work should be retrievable and protected from loss or damage. For further guidance on document control and records see Safety Guide Q3.

### 3. PERFORMANCE

#### PLANNING AND PREPARATION FOR RESEARCH AND DEVELOPMENT

301. The principal investigator/researcher should prepare an R&D plan that includes a written description of the proposed R&D work. The plan should describe the content and extent of the R&D work to be performed and possible results, hypotheses and calculated predictions. The detail contained in the plan should be only as complex as the R&D project demands and should ensure that the work can be replicated by a qualified peer.

302. The R&D plan should incorporate user requirements and expectations, and should reference applicable technical standards. It should also describe or refer to the environmental, safety, health and regulatory requirements that apply, how they will be handled, and how funding and other resources will be made available for clean-up at the end of the project. The plan should include the expected or intended influence of the results on nuclear safety.

303. The R&D plan should describe the purpose of the work. It should also identify criteria that can be used to assess success or failure of the work and to indicate when it is completed. Hold points at which management (and/or peers) can review and consider these criteria should be included.

304. The R&D plan should provide a brief historical overview of the work. This should include references to publications that describe previous experiments, theories, feedback from the users of the products of previous R&D work, or technological developments that have led to the work described in the R&D plan.

305. The R&D plan should contain a description of the basic conditions and of the relevant components of the experimental equipment/apparatus and their configuration. A description of any unusual or potentially problematic techniques, special tools and experimental methods that will be employed in the performance of the work and the way in which these will be handled, should also be included.

306. The R&D plan should describe how support and technical personnel having the necessary education, experience and skills will be assigned to perform the work.

307. The principal investigator/researcher should ensure that the R&D plan is reviewed and approved (see paras 210 and 211).

308. The R&D plan should describe dependencies or relationships with other projects or areas of R&D. If similar work is to be performed elsewhere, this should be stated together with a brief explanation of how the work could be co-ordinated.

309. The R&D plan should identify the proposed duration (term) of the work and how resources will be planned and allocated. Considerations are, for example, staff, graduate students, post-doctoral fellows, budgets and equipment.

310. The R&D plan should describe milestones and deliverables for the work, including, for example, the construction of items, scheduled evaluations and assessments, the development of technological processes or products, and the presentation of interim and final research results.

311. The R&D plan should describe the facility and equipment requirements for carrying out the work and include:

- An explanation of how the facilities will be used, the required location and gross floor area, and a brief description of the probable impact on the responsible organization's services;
- A statement of whether or not major modifications to existing facilities will be needed in order to perform the work;
- A statement of whether outdoor work is required and, if so, its location and environmental impact;
- A description of the means of collecting and processing samples; if published techniques are to be used, they should be referenced;
- Identification of equipment and materials already in place to perform the work, and details of new equipment and materials that will have to be procured;
- Preparation of commissioning procedures for new equipment.

For further guidance on procurement see Safety Guide 50-SG-Q6.

312. Sound engineering and scientific practices should be applied to the design and construction of the equipment/apparatus described in the R&D plan. The design and configuration of the equipment/apparatus should be documented. For further guidance on design see Safety Guide Q10 and Code on the Safety of Nuclear Research Reactors: Design, IAEA Safety Series No. 35-S1.

313. Sound engineering and scientific practices should be applied to the design and application of supporting computer software. The design assumptions, range of applicability and user's instructions should be documented. Performance criteria for software validation should be defined to ensure that the R&D goals are achieved.

## CONDUCTING RESEARCH AND DEVELOPMENT

314. All work performed as a part of the R&D plan should follow sound engineering and scientific principles in order to ensure that goals are achieved.

315. The principal investigator/researcher should ensure that relevant documentation is available in a language appropriate to the users.

316. The items associated with the R&D plan should be properly stored and shelf-life limitations should be observed.

317. During the commissioning of the equipment/apparatus or prototype, the calibration and performance requirements of test, measurement and diagnostic equipment/apparatus should be defined to a level of detail that ensures that the R&D goals are achieved. Calibration and performance requirements for test, measurement and diagnostic equipment/apparatus should be maintained throughout the data gathering activities. For further guidance on calibration see Safety Guide Q4.

318. In the operation/data gathering stage, the principal investigators/researchers should ensure that the systems and subsystems of the experimental equipment/apparatus are functioning as intended. This includes, for example:

- Visually or computationally monitoring the apparatus to ensure systems are operating properly, for example checking power supplies and devices that use gases and fluids, and are correctly calibrated;
- Ensuring that the proper materials and chemicals are being used;
- Monitoring performance against safety requirements;
- Monitoring data rates to ensure they are appropriate;
- Ensuring that the data which will enable the researcher to achieve the research objectives are being recorded.

319. Personnel performing the R&D and support work should evaluate their own performance and look for ways to improve the quality of their work.

## DATA ANALYSIS AND REPORTING

320. When analysing data for acceptability, researchers should define:

- The assumptions and the methods used;
- The results obtained and the results used, so that competent experts can evaluate how the data were interpreted;

- The methods used to identify and minimize measurement uncertainty;
- The analytical models used;
- Whether the R&D results have been documented adequately and can be validated.

321. The final reports should describe, for example:

- The results obtained, and their range of application and validation;
- The relationship of the results to previous publications, experiments, theories or technological developments;
- A description of the apparatus and the operations/data gathering activities;
- A description of significant problems that occurred during the operations/data gathering activities;
- A description of data analysis issues similar to those listed in para. 320;
- A summary of the work performed, including conclusions, recommendations and a description of any possible impacts on safety objectives.

322. Management should review and approve the final research report.

## **4. ASSESSMENT**

### MANAGEMENT SELF-ASSESSMENT

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

402. Management, the principal investigator/researcher and researchers should assess the performance of the R&D plan to a level of detail that ensures that accepted practices are being employed and that objectives are being met. For further guidance on self-assessment see Safety Guide Q5.

### INDEPENDENT ASSESSMENT

403. Independent assessments of the R&D plan should be conducted to evaluate progress towards achieving the defined performance objectives. For example, independent assessments should evaluate:

- The success criteria defined in the R&D plan;
- The achievement of scheduled milestones, including deliverables such as constructing and testing equipment/apparatus and presenting interim and final research results;
- The assessments performed by management;
- The effectiveness of human and material resource management;
- The manner in which research activities are being documented;
- The fulfilment of regulatory requirements.

404. Independent assessments should assess the adequacy of management's support for the activities defined in the R&D plan, for example human, material and financial resources.

405. Independent assessments should evaluate how effectively organizational interfaces are functioning for the work described in the R&D plan. For further guidance on independent assessment, see Safety Guide Q5.

## Annex

### FLOW DIAGRAM OF A TYPICAL EXPERIMENTAL RESEARCH AND DEVELOPMENT PROJECT

The quality of R&D work and of the results depends on the precise definition of the objectives and internal and external user requirements, and on the clarity of insight of researchers in testing theory, extending the results of previous experiments, utilizing feedback from the users of previous research results and efficiently guiding their projects. The quality of the results can be gauged by the peer acceptance of new theories, the discovery or application of new physical effects, the development of solutions to problems, increased precision and accuracy in measurements, or by the effectiveness of the performance improvements that are developed.

R&D is quite different from, for example, designing, constructing or operating a nuclear plant. In these other functions, a precisely described result can be defined from the beginning and can be described in design specifications, process descriptions and procedures. Specifications exist for most materials, tests, inspections and methods used in these processes. For example, the quality of manufacturing processes can be determined directly and quantitatively by how well the products conform to specifications. In other words, the quality of the products of these manufacturing functions is determined by judgements on how well, and for how long, the products satisfy their intended use. However, while established procedures may be available to begin an R&D project, deviation from these procedures may occur often as a legitimate component of the conduct of R&D. Entirely new procedures are often developed through a process of trial and error. The creative and uncertain nature of R&D makes the knowledge and expertise of individual researchers essential to the quality of the work and the results. It also makes documenting the progress of R&D essential, because the described path will serve as a guide for others to follow, reproduce or avoid and will serve as a clear record of performance problems and their solutions.

The flow diagram (Fig. A.1) describes a typical experimental R&D project. While there are numerous ways to describe R&D processes, one way is to differentiate between three stages:

- (1) The trial or scoping stage — where arbitrary boundary conditions, for example in a test, are used to observe and identify the different parameters that can have influence on the phenomenon or problem area, and also the degree of their influence, in order to obtain indications as to the possible consequences this phenomenon could have. Most QA methodologies (other than correct and accurate documentation) are not necessary at this stage because nothing is known by the researcher. The creativity, inspiration and intuition that lead researchers to

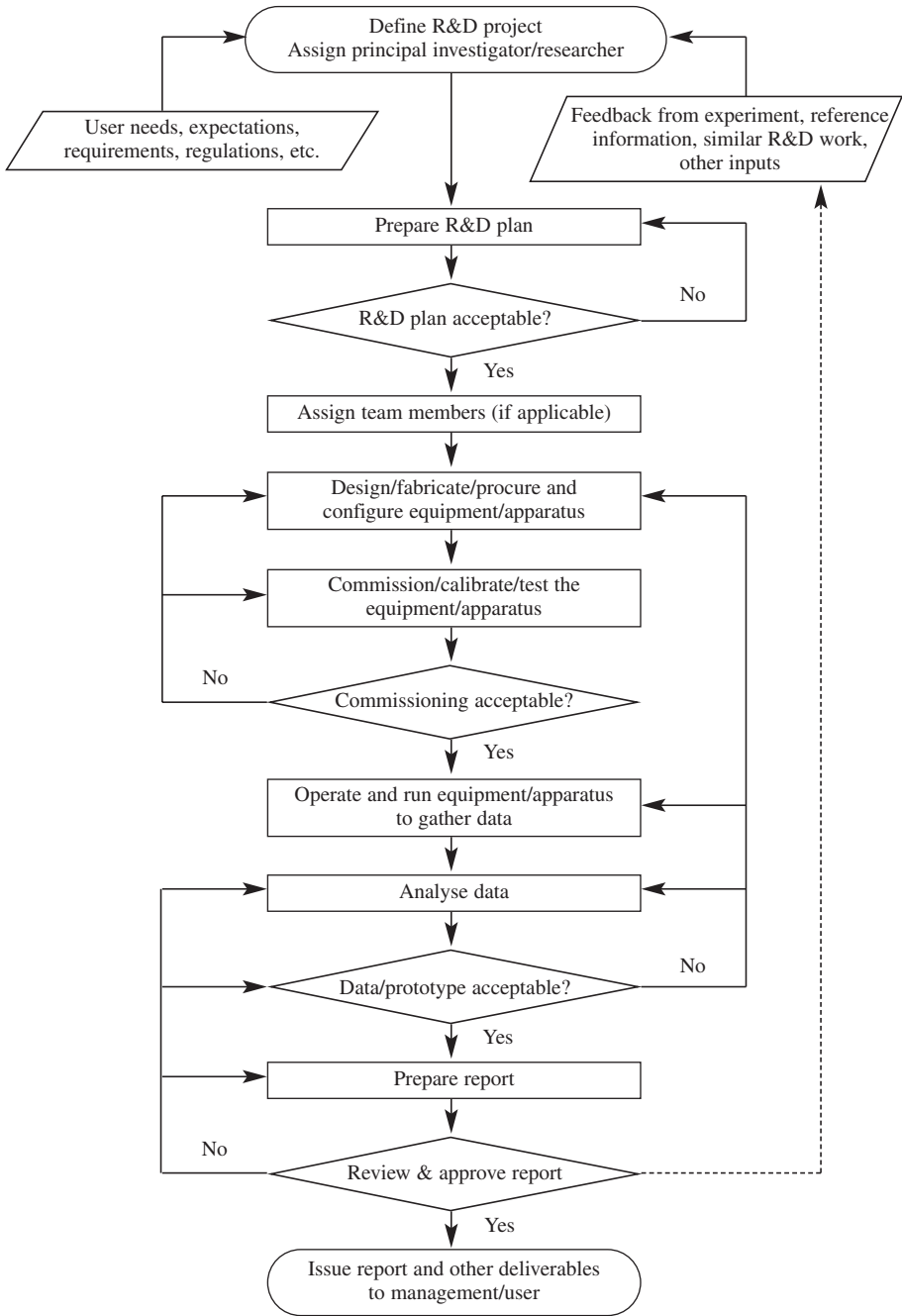


FIG. A.1. Flow diagram of a typical experimental R&D project.

their first notions or first concrete ideas about the problem are the most important factors at this stage of R&D.

- (2) The systematic investigation stage — where the relevant parameters from the first stage are identified and systematically investigated to determine the qualitative and quantitative influences of the different parameters. Tests at this stage are normally performed by systematically varying one or more parameters under well controlled test and boundary conditions. Most QA methodologies will already play an important role at this stage of R&D since the establishment of the influences of different parameters and differing test conditions requires very specific knowledge and control of all the known parameters. These data must be adequately recorded so that they can be independently validated and reproduced by competent scientific peers.
- (3) The data analysis and reporting stage — where data have to be produced so that they can be used as the basis for judging the adequacy of the measurements that were taken with respect to the phenomenon or problem that originated the investigation. The rigorous application of QA methodologies is necessary since the published data may be used in safety evaluations or as input to actual nuclear power plant conditions or systems.

## **Safety Guide Q9**

### **QUALITY ASSURANCE IN SITING**



# CONTENTS

1.	INTRODUCTION .....	191
	Background (101–102) .....	191
	Objective (103) .....	191
	Scope (104–105) .....	191
	Structure (106) .....	192
2.	MANAGEMENT .....	192
	Quality assurance programme (201–205) .....	192
	Grading (206–207) .....	193
	Organization (208–210) .....	193
	Interfaces (211) .....	194
	Training and qualification (212–213) .....	195
	Planning (214–216) .....	195
	Non-conformance control and corrective actions (217–218) .....	195
	Document control and records (219–222) .....	196
	Human factors (223) .....	197
3.	PERFORMANCE .....	197
	General .....	197
	Sources of data (301–302) .....	197
	Data format (303–306) .....	198
	Work procedures and instructions (307–309) .....	198
	Measuring and test equipment (310) .....	199
	Verification (311–317) .....	199
	Work planning (318–324) .....	200
	Procurement (325–326) .....	201
	Input requirements (327–329) .....	201
	Work control (330–335) .....	202
	Computer modelling (336–340) .....	202
	Physical models (341–344) .....	203
	Collection of data (345–349) .....	204
	Reviewing data, calculations and results (350–353) .....	204
	Analysis of data (354–361) .....	205
	Output documentation and reporting (362–367) .....	206
	Site survey .....	207
	Preliminary report (368–370) .....	207
	Survey plan (371) .....	207
	Final survey report (372–373) .....	208

Site evaluation and site confirmation .....	208
General (374–376) .....	208
Preparations for fieldwork (377–381) .....	209
Field and laboratory work (382–388) .....	209
4. ASSESSMENT .....	210
Management self–assessment (401) .....	210
Independent assessment (402) .....	211
ANNEX I:       EXAMPLES OF SITING ACTIVITIES WHICH MAY REQUIRE PROCEDURES .....	212
ANNEX II:      DESIGN, TESTING, APPLICATION AND CHANGE CONTROL FOR COMPUTER MODELLING .....	213

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment on basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code), and complies with the requirements of the Code 50-C-S (Rev. 1).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the siting stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in the siting stage of a nuclear power plant project and covers items, services and processes impacting upon nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the siting stage of a nuclear power plant. The siting stage overlaps with other nuclear power plant stages such as design, construction and commissioning. The responsible organization may establish separate organizations for these stages or combine them under one organization. Whichever organizational arrangement is utilized, the responsibilities and interfaces shall be clearly defined and understood.

## STRUCTURE

106. This Safety Guide is arranged into four sections and two annexes:

Section 2 provides guidance on QA for the management activities of siting.

Section 3 provides guidance on QA for the performance activities of siting.

Section 4 provides guidance on QA for the assessment of siting activities.

Annex I gives examples of siting activities which may require procedures.

Annex II provides guidance on design, testing, application and change control for computer modelling.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of siting for the nuclear power plant. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. The siting process generally consists of the following: site survey, site evaluation and site confirmation. The responsible organization is required to establish and implement a QA programme in order to ensure that studies, evaluations and analyses, and all siting activities important to safety are correctly performed and provide a consistent basis for making decisions.

203. Procedures shall be defined by the responsible organization for controlling siting activities. Arrangements shall be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them is controlled. The responsible organization needs to consider the QA programme for siting as a long lead item so that it can be implemented when siting work begins. A list of examples of siting activities which may require procedures is contained in Annex I.

204. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.

205. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the responsible organization if required. Guidance on the documents required from the supplier for submission to the responsible organization and the timing of such submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme see Safety Guide Q1.

## GRADING

206. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

207. The grading process should also consider the following:

- The intended end use of the knowledge and data that result from siting activities, particularly in terms of their effect on nuclear safety;
- The ability to demonstrate, test or repeat results;
- The scale and technical complexity of the siting activity, whether it is a new or proven concept or model that is being applied, or an extension of a new application;
- The managerial complexity of the activity, the involvement and co-ordination of multiple disciplines, work units or internal and external organizations, with divided or contingent objectives and responsibilities;
- The extent to which other siting work, or later work, depends on the results of the siting activities;
- The expectations or desired use or application of the results.

For further guidance see Safety Guide Q1.

## ORGANIZATION

208. The responsible organization should formally appoint a person on its staff to be responsible for siting activities<sup>1</sup>. This person is usually called the project manager for siting.

---

<sup>1</sup> In some Member States the appointed person is the head of the siting organization.

209. The project manager for siting should have the necessary resources within the siting organization to discharge the following responsibilities:

- Ensuring that an effective QA programme is implemented;
- Ensuring that siting work is carried out in accordance with requirements, procedures and instructions, including the implementation of specified requirements;
- Ensuring that siting work undertaken, including work by service organizations, is co-ordinated, conducted and completed in accordance with planned programmes of work.

210. The project manager for siting should ensure that tasks such as the following are carried out:

- Preparing the work plan for siting activities,
- Identifying specific work packages for siting,
- Identifying required specialist services,
- Identifying disciplines needed in individual special teams,
- Writing and reviewing interim phase reports,
- Writing, reviewing and approving the final report,
- Collating information on siting criteria.

## INTERFACES

211. Since it is likely that the work could be shared between the siting organization and various specialist services and consultants, the organizational charts should show the parties involved, the interfaces between them and the lines of reporting and communication. Interface arrangements should be agreed between the siting organization and other organizational units performing the work. They should be defined in writing and should be included in procurement documents where appropriate. The following examples of interfaces should be addressed:

- The siting organization and the responsible organization,
- The siting organization and consultants and various specialists,
- The siting organization and laboratories,
- The siting organization and the principal designer,
- Specialist groups and the laboratories,
- Between technical discipline units within the siting organization,
- The siting organization and the regulatory body (see the Code 50-C-G (Rev. 1)),
- The siting organization and local authorities.

## TRAINING AND QUALIFICATION

212. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities, for example errors in the collection and analysis of data, the formulation of site characteristics and modelling.

213. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training see Safety Guide Q1.

## PLANNING

214. Siting activities should be planned. Computer aided planning is desirable. The plan should define:

- the siting activities to be performed in manageable units (work breakdown structure);
- the planned sequential order and duration of these activities;
- the resource allocation for each activity.

215. Whilst the siting organization shall retain responsibility for co-ordinating and planning the overall siting activities, suppliers should be responsible for producing detailed plans of the work that they will be carrying out and for obtaining the siting organization's approval of these plans where necessary.

216. Planning should take into account requirements for studies, evaluations and analyses relative to site survey, site evaluation and site confirmation, and their safety importance such as:

- The need for the identification, preparation and control of procedures and work instructions;
- The need for special equipment, software or materials;
- The need for competent personnel.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

217. Management shall establish a non-conformance control and corrective actions process that defines how the following are to be dealt with:

- Errors in: data, data collection, recording or reporting; calculations, reasoning, assumptions and conclusions; software coding; and measuring.
- Non-conformance with procedures and specifications.

218. Procedures and specifications should be made available before the start of work on the gathering and analysis of data. Deviation from these procedures may occur as a legitimate component of the work process or the introduction of improvements as a result of experience gained during the execution of the tasks. In such cases the deviation from expectations should be recorded and analysed to determine if it is a true non-conformance and if so its acceptability on the basis of technical or scientific reasoning. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

220. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of siting records.

221. Sufficient records should be prepared and retained during siting work to enable the process to be repeated if necessary. Records should support final conclusions and permit tracing of results to source data and information. Permanent records for siting activities should be identified.

222. The following are examples of records which are generated during siting:

- The data collected and the results of studies, evaluations, analyses, observations, explorations, testing, measurements, monitoring, calculations and reports of conclusions regarding the accepted site.
- Field and laboratory logs and test data, notebooks, drawings and sketches from field observations and explorations, soil samples and field notes on discussions with local experts.
- Records of field and laboratory checks and verifications; decisions on the need and method of filling information and data gaps.
- The basis and justification for the final ranking of potential site areas.
- The reasons for rejection of unacceptable site areas.
- The results of reviews and evaluations of siting activities.
- The documents on evaluation of design basis parameters from observed data.

All such records and data should be retrievable and protected from loss or damage. For further guidance on documents control and records see Safety Guide Q3.

## HUMAN FACTORS

223. Suitable working environments shall be provided and maintained so that work can be carried out safely and satisfactorily without imposing unnecessary physical and psychological stress on the siting personnel.

### 3. PERFORMANCE

#### GENERAL

##### **Sources of data**

301. The data that should be collected during site survey, site evaluation and site confirmation shall be specified.

302. Typically, the sources of data are:

- (a) Current and historical documents. For example census, meteorological, seismological, survey records.
- (b) Indirect exploration. Data or information inferred or calculated from indirect tests/data or mock-up investigations but collected for other purposes.
- (c) Direct exploration. Data or information obtained from samples, from direct observations or from in situ tests.
- (d) Laboratory testing. Data or information obtained from tests conducted on samples obtained from direct exploration.

The following sources apply for site confirmation:

- (e) Design and construction. Data or information from investigations conducted during design and construction.
- (f) Commissioning. Data or information obtained while demonstrating the functional adequacy of plant components, systems and structures.
- (g) Operation. Data and information from monitoring programmes, studies and tests carried out to ensure that characteristics essential to safety are maintained throughout the life of the nuclear power plant.

## **Data format**

303. The format and standards to be used for collecting, classifying and presenting the data should be decided and the decisions documented. The format and standards include, for example, scales, nomenclature, reference co-ordinates, dates, tables and diagrams.

304. The format should be consistent and should facilitate an easy comparison of results between sites. The format should allow for prompt identification of gaps in information.

305. Requirements should be specified for classifying, logging and reporting data from field activities (for example surveys, borings, excavations, data on soil, rock, water and meteorological conditions, and air samples and tests).

306. Tests, samples and field data should be identifiable in field logs and in other relevant reports. The work project number, sample number and type, and the location and date of sampling should be included.

## **Work procedures and instructions**

307. Siting work should be performed in accordance with specified procedures and instructions.

308. The type and format of procedures and instructions can vary depending on the application involved and the normal practices of the organization performing the work. The primary consideration is to ensure that they are suitable for the people doing the work, and that they are accurate, clear, concise and unambiguous. For example, they may include checklists or refer to standards.

309. Work procedures and instructions should include:

- The data to be acquired and their accuracy;
- The test facilities and equipment to be used;
- The method and the accuracy required of the equipment;
- Prerequisites and preparations;
- Methods for analysis and for analysing data;
- Requirements governing samples, including method, frequency, sample validity, identification and source, handling, storage and analysis;
- The method of recording and documenting the results (both field and laboratory).

It may be useful to group the work procedures and instructions into separate procedures manuals for various siting activities. For further guidance on procedures and instructions see Site Survey for Nuclear Power Plants, IAEA Safety Series No. 50-SG-S9.

### **Measuring and test equipment**

310. Measuring and test equipment which is used for siting activities, data collection, inspections and tests shall be of the proper type, range, accuracy and precision and be in good condition. For further guidance on measuring and test equipment see Safety Guide Q4.

### **Verification**

311. Work performed during siting should be verified to confirm that it is correct. The type and extent of verification activity should be specified. Verification may include an independent check of methods and instruments for field and laboratory activities, and a demonstration of their proper use by the teams performing the work.

312. Verification planning should identify the activity to be verified and include, for example:

- The extent of verification;
- The verifier, i.e. a peer, a review committee or a third party;
- The method of verification and the reporting requirements;
- The point in the work cycle where the verification is to be performed.

313. Verification methods include, but are not limited to:

- Reviews and checks;
- Alternative analyses;
- Laboratory and field testing;
- Inspection and surveillance;
- Prototype testing.

314. Documents which form part of, or support, siting decisions should be reviewed to confirm that they are correct and satisfactory, and are complete as to assumptions, support data and conclusions.

315. Calculations should be verified by alternative analyses. For this purpose simplified calculations may be used. If differences arise which substantially modify the final results and conclusions of the original calculations, a more complete and

thorough review should proceed. The analyses, assumptions, initial conditions, boundary conditions and results should be documented.

316. For field and laboratory activities, appropriate verifications should be specified.

317. Computer software used for analysing data and in the development, application and maintenance of computer models should be verified and validated prior to use.

### **Work planning**

318. The siting activities should be organized and performed in such a way that relevant information will be found, collected and scrutinized. The most important factor that should be considered is the effect that will be caused by a siting work error, or equipment malfunction affecting the choice of site and subsequently the safety of the nuclear power plant.

319. Siting activities should be identified and planned so that they are carried out in the proper sequence. The methods by which the results and the supporting output documents are reviewed for acceptance should also be identified.

320. Siting activities should be planned to ensure that, for example:

- data are adequate and are recorded correctly;
- analytical techniques, equipment and instructions are used correctly;
- data are correctly interpreted;
- computer programs are adequate and are used correctly;
- samples are collected, handled, shipped and stored properly;
- samples are correctly and adequately identified;
- technicians and operators of instruments or equipment are adequately trained.

321. The project manager for siting should subdivide the overall siting work into discrete work packages. The scope of each work package and the individual team member or the organization carrying it out should be identified. When changes in scope are necessary and when all or portions of the work are to be reassigned, a change control should be applied.

322. When specialist groups or organizations are assigned work, they should examine the work packages in detail to ensure they understand the technical content and the objectives. Incomplete, ambiguous or conflicting information, data or results should be resolved with the siting organization.

323. When field or laboratory testing is necessary, planning should result in the production of a test programme document and test procedures and instructions for the performance of the tests specified. Detailed guidance should be prepared for choosing the number of samples to be taken, the location of the sampling points, and their vertical and horizontal spacing.

324. The test programme document should include, directly or by reference:

- The tests or experiments to be performed and their general sequence,
- The objectives of the tests or experiments,
- The testing criteria,
- The reporting requirements.

## **Procurement**

325. During siting, the procurement of services predominates over the procurement of items. The work that could be procured includes, for example, surveying and searching technical and scientific literature, collecting and reviewing historical data and evaluating their validity, and making field observations and measurements, hand and computer calculations, analyses, laboratory tests and monitoring.

326. The procurement of such specialist services may be carried out directly by the siting organization or it may be assigned to the project management team. In either case, responsibilities should be defined to ensure that a competent special service is selected and that the work is performed and assessments are carried out. For further guidance on procurement see Safety Guide Q6.

## **Input requirements**

327. Requirements which have to be demonstrated in order to prove and support siting concepts and conclusions, for example those related to design basis parameters, should be identified.

328. These requirements should be detailed to the degree necessary to provide a reference for making decisions, interpreting data and verifying results.

329. The selection of these requirements should be subject to review and approval.

## **Work control**

330. Siting activities, including those associated with compiling, gathering and analysing the data and reporting conclusions and recommendations, should be controlled to ensure the results and the supporting documentation such as maps, drawings, photographs, calculations, field notes and historical information are traceable to their sources.

331. Good work practices which can influence the quality of data to be collected or analysed or which can influence the conclusions drawn from the data should be identified and implemented. For example, the availability and the compatibility of the data are important in choosing the analytical methods and the models to be used, and for the reviews and analyses to be effective. Therefore, the precision, nature, time span and scope of the data to be collected should be specified beforehand.

332. Arrangements should be made to ensure that data and samples will be identified from their point of origin to their final use in calculations and models and in support of conclusions.

333. Documents containing data which have been interpreted, analysed or validated, experimental results, results from field measurements or tests, and other formal documents which are produced during the data gathering and data analyses should be independently reviewed and checked.

334. Studies, evaluations and analyses should be documented in sufficient detail in terms of purpose, method, assumptions, data inputs, references and units, so that a person technically qualified in the subject can review, understand and verify the adequacy of the results.

335. Conclusions should be adequately documented to permit traceability to original input requirements, and to make it possible to study information, experimental data, field measurements, and models and their interpretation.

## **Computer modelling**

336. The QA programme should be applied to the design, testing, application and change control of quantitative models used in siting, such as seismic models, hydrological models and dispersion models. It covers all codes, including modified versions, used in mathematical modelling, numerical analysis, standard test-case data libraries, sensitivity studies, benchmarking against existing verified programmes or comparisons with alternative calculations or experience.

337. Models should be developed in accordance with technically sound methods and practices. They should accurately reflect the acquired data and appropriately represent the system or subsystems. The data used for developing the models should be protected against loss, damage or destruction, and should be traceable to their source.

338. Some models may have already been validated for other circumstances; in this case the model can be validated for a particular new application by showing that the site characteristics are similar to those for which it has already been validated, or that any differences in the site characteristics will result in conservative results.

339. The validation will have a limited range of applicability. A thorough understanding of the model is necessary to determine this range. For reliable results, therefore, validation should only be applied in this range.

340. A sensitivity analysis should be performed to assess the potential uncertainties resulting from the use of the model, especially the more sophisticated models. Further guidance on modelling is given in Annex II.

### **Physical models**

341. Physical laboratory models may be used mainly to test hydrodynamic and aerodynamic processes. These models should be validated.

342. The models which are applied in the site selection and confirmation stages can vary from simple to complex. In many applications, simple models are satisfactory and the use of complex models is not required. When a simplified model conservatively represents an adequate basis for site selection, it should be preferred. The selection of the model to be used should be justified.

343. The selection of input parameters and the adjustment of models to fit specific situations can depend on the characteristics of the site and its region and on certain design features of the plant. It is particularly important, therefore, that the limitations of the model be determined and specified.

344. The validity of the model to be used should be determined so as to ensure that the site evaluation procedure is adequately conservative. If for a typical application of a selected model no validation has yet been performed, the model must be validated or the potential for errors evaluated and taken into account.

## **Collection of data**

345. Data should be acquired according to technically sound methods and practices, to ensure that they are protected against loss, damage or destruction, are traceable to source and are readily retrievable.

346. As the specified data are collected, the sources should be rigorously recorded. Attention should be paid to cross-references. Accurate characterizations of the data should be used, for example estimated values, extrapolated values or unrecorded information from local specialists. When contradictions in data collected from more than one source arise, they should be explained and a decision taken on the basis of technical judgement, experience, safety consequences and the authenticity of the source.

347. The data should be developed into a coherent, well documented description of site characteristics. Lack of confidence in the quality of the data, i.e. in their accuracy, applicability, completeness or quantity, may preclude their use. In such cases a pragmatic approach should be used, based on expert judgement. The use of such data should be declared, justified and authorized.

348. If statistical data on a national, continental or worldwide basis are used, the values obtained should be examined to determine whether or not they need to be adjusted to compensate for unusual characteristics of the site and its surroundings. Where the available information is insufficient, it will be necessary to perform field and laboratory investigations.

349. The availability, precision, nature and scope of data to be collected should be compatible with the methods and models in which they will be used.

## **Reviewing data, calculations and results**

350. As the data are collected they should be checked for accuracy, applicability and completeness. Checks should also be performed to ensure that the data have been accurately transcribed.

351. Critical reviews of reports, analyses, calculations and other output documents should be carried out by persons who were not involved in performing the work. The reviews should determine if the objectives of the preliminary report have been met and if the results are acceptable and were concluded on the basis of sufficiently accurate and complete data which were analysed according to specified scientific procedures.

352. Persons should be assigned to perform these reviews. A possible arrangement for integrating such reviews is to establish a siting review committee. This committee should include the project manager for siting and specialists in the discipline to be reviewed.

353. Reports of these reviews should be submitted to the siting organization. Any unresolved deficiencies revealed by the reviews should be handled in accordance with the procedures for non-conformance control and corrective actions (see paras 217 and 218).

### **Analysis of data**

354. The data should be compiled, critically examined and analysed in an organized manner. Attention should be given to:

- data that can have direct influence on the acceptability of a site;
- data that can substantially influence the design basis criteria of a site;
- ensuring that the precision, nature and scope of the data are compatible with the methods and models in which they will be used;
- ensuring that the information collected is complete, reliable and relevant for reviewing safety considerations.

355. Conclusions should be sufficiently documented and traceable to the original information and data, including any interpretations of these.

356. Where a choice of analytical methods is possible, the reason for the choice followed should be substantiated. The limitations of each method should be determined.

357. Where not all the information necessary to form conclusions is available, such limitations and gaps in the data should be clearly identified. The need for, and the method of, filling gaps should be assessed.

358. When analysing data for acceptability, reviewers should define, for example:

- The statistical methods to be used for the analysis of results;
- The assumptions and methodologies used for the analysis of data so that competent peers can evaluate how the data was interpreted;
- The methods used to identify and minimize measurement uncertainty;
- The sensitivity of results due to variations in data.

359. At the pre-operational stages of a nuclear power plant, additional measurements may be required to confirm the values used in the design basis and, if necessary these should be identified and communicated to the responsible organization.

360. The limitations of the data and the uncertainties of estimates derived from the data should be determined and considered in the analysis. In the analysis of data, an understanding of the degree of validity to be given to field measurements should be obtained.

361. Analysts should ensure that their results and the methods they use can be followed, reproduced and evaluated by competent peers. They should define, for example:

- The statistical methods used;
- The assumptions and the analytical methods used;
- The methods used to identify and minimize measurement uncertainty;
- The initial conditions, boundary conditions and constraints applied.

### **Output documentation and reporting**

362. Data, analyses, calculations, tests and reviews, proposals, recommendations, conclusions and decisions regarding siting should be documented to allow for evaluation.

363. Where not all the information necessary to finalize conclusions is available, such limitations should be identified.

364. Output documents should discuss the identified input requirements in such a way as to demonstrate that the relevant aspects have, or have not, been considered and have, or have not, been proven.

365. Reports describing the intermediate and final results in different areas of investigation, and an analysis of them, should be prepared and transmitted to the appropriate management. The reports should describe such items as:

- The relationship of the results to previously known information, tests or theories;
- A description of the data gathering activities;
- A description of significant problems that occurred during data gathering activities, studies, analyses and testing;
- A summary of the work, including considerations, conclusions and recommendations.

366. Field reports should cover all results and observations called for in instructions and should include the following:

- The applicable procedure or instruction used;

- All pertinent data and notes;
- Data, results and observations in the form specified (for example tables, curves, narrative);
- Discussion of significant conditions encountered, errors introduced and the accuracy of results.

367. In addition to the above, laboratory reports should also include the identification of the activity or test performed, the equipment used, the sample tested, the date of the test, and the procedure used.

## SITE SURVEY

### **Preliminary report**

368. A site survey should be carried out to identify one or more sites that would probably be suitable for detailed characterization later in the siting process. Site survey activities are generally limited to the collection, compilation and analysis of available data in the region of interest.

369. Before the site survey begins the preliminary report should be written, reviewed and approved. Details on the contents of the preliminary report are given in Site Survey for Nuclear Power Plants, IAEA Safety Series No. 50-SG-S9.

370. The preliminary report should be used by the survey team members as a reference for writing each individual interim report at the completion of each phase.

### **Survey plan**

371. A site survey plan should be developed and should include, for example, the following:

- The procedure to be used for the site survey and the proposed separation into phases, for example regional analysis, screening, comparison and ranking;
- The site characteristics to be considered;
- The data required (the type and degree of comprehensiveness);
- All possible sources of required data;
- The approach (parallel or serial) to be used for collecting data;
- Provisions for checking and reviewing results and calculations;
- Provisions for collecting information from sources known only to local experts;
- The identification and description of the tasks to be performed;

- Diagrams showing the sequence of the various tasks;
- The methods and criteria to be used for performing regional analyses and for screening, comparison and ranking;
- An outline of procedures for applying these criteria and a list of sources of information needed for their application;
- Key events and requirements for interim reporting after each identified phase.

### **Final survey report**

372. The final survey report should be comprehensive and clear as to its intent and its conclusions.

373. The final survey report should contain the complete results and an analysis of them. It should contain, for example, the following:

- A clear presentation of the data, the procedures and considerations and recommendations;
- Limitations or uncertainties of the data, analyses, computer programs and procedures;
- A complete description of the region studied;
- A comparison of the sites investigated;
- The reasons for rejecting unacceptable sites;
- The preferred candidate sites.

## **SITE EVALUATION AND SITE CONFIRMATION**

### **General**

374. During the site evaluation, all of the sites selected during the survey phase should be studied in sufficient detail so as to permit selection of one which is suitable for the construction and safe operation of a nuclear power plant. To do this, the site evaluation phase must produce information to provide reasonable assurance that site conditions are good enough and sufficiently well understood to permit engineering solutions of actual or potential problems. The site related design bases are determined during this period. The reviews that are carried out are more detailed. They in turn require more detailed information about the sites as well as elementary information about the design of the nuclear power plant, including, for example, its basic safety features. Where existing data are inadequate, supplementary data from field explorations and laboratory testing and modelling should be obtained.

375. During the site confirmation the characteristics of the site chosen should be completed and monitored. In general, it includes further studies and investigations which are carried out after the start of construction and carried on into commissioning and operation. Parameters which have been estimated during site evaluation are often verified through measurements during site confirmation.

376. The collection of data should continue throughout the construction stage and should be required during operation to verify information obtained prior to construction and to gather additional data which are available only after excavation has begun.

### **Preparations for fieldwork**

377. Fieldwork includes, for example, surveying, experiments, boring, test excavations, trenching, seismic monitoring, geological investigations (both site and regional) and testing of model structures.

378. To obtain a complete understanding of site characteristics, it is necessary to select the correct locations for carrying out fieldwork. If instrumentation is to be used or installed, its position and exposure may be important for obtaining representative data. Monitoring frequencies and recording times should be determined and specified.

379. Before any equipment is installed on the site, the site terrain should be examined to ensure that the positions selected will provide data which are as representative and as complete as necessary.

380. When drilling is to be performed, requirements should be specified for the appropriate abandonment and sealing of boreholes and wells and for recording their location.

381. When sampling is to be performed, the methods, places and size should be chosen on the basis of information required. Existing standards or guides should be checked for their applicability.

### **Field and laboratory work**

382. Arrangements should be introduced to ensure the accuracy of surveying results, since most subsequent analyses, results and interpretations related to safety are based on surveying data.

383. Checks of the surveying activities should be conducted during the work to ensure satisfactory performance. Records of survey activities should be maintained.

384. Field sampling, in situ and laboratory testing, and the collection, classification, logging and reporting of relevant field and laboratory data should be performed in accordance with appropriate procedures or instructions specific to the activity.

385. Testing methods and laboratory practices should be in accordance with standard and nationally recognized methods unless specially developed methods are specifically required.

386. When unusual circumstances are encountered, they should be recorded and reported. Adequate checks should be specified and conducted while the work is in progress to ensure that work is performed according to requirements.

387. Field and laboratory equipment should be maintained in good working order. Such equipment should be checked before, during and after the performance of related activities to ensure accuracy.

388. During the performance of fieldwork, controls should be implemented to ensure, for example, that:

- The location of a measurement or of an item such as a geological feature is accurately recorded;
- The type and number of borings, excavations, geophysical and geological surveys, and samplings of soil, rock ground, water and air are identified;
- Proper sample handling, storage and shipping methods are used to prevent disturbance or changes in properties or in data.

Similarly, during laboratory work, the preservation of sample integrity and identification should be maintained.

## **4. ASSESSMENT**

### **MANAGEMENT SELF-ASSESSMENT**

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

## INDEPENDENT ASSESSMENT

402. Typical subjects to be addressed by independent assessment during siting are:

- Interfaces
- Work planning for field activities
- Methods for handling errors and non-conformances
- Traceability of data
- Specifications for data format, work instructions, field samples and output documents
- Selection and monitoring of special service organizations
- Conduct of field and laboratory work.

For further guidance on independent assessment see Safety Guide Q5.

## **Annex I**

### **EXAMPLES OF SITING ACTIVITIES WHICH MAY REQUIRE PROCEDURES**

- Establishment of requirements for the site survey report.
- Development and approval of the site survey plan.
- Selection of specialist services.
- Monitoring of specialist services.
- Establishment of requirements for the final siting report.
- Planning, assignment and control of work.
- Collecting, protecting and maintaining traceability of data.
- Establishment of the format of data.
- Analysis of data and documenting conclusions.
- Laboratory procedures.
- Establishment of requirements for test samples.
- Model development and validation.
- Changing data and changing conclusions.

## Annex II

### DESIGN, TESTING, APPLICATION AND CHANGE CONTROL FOR COMPUTER MODELLING

#### PLANNING

**A1.** Planning should result in identifying the data required, the systems and subsystems to be modelled, the modelling methods, and the activities required to select, develop, verify and validate the models.

**A2.** During planning the need for the following should also be identified:

- The analyses and reviews to be performed;
- Phenomena which have a bearing on the final outcome of the selection of the site including the phenomena which could change the state of a system;
- Emphasizing the use of real data as far as possible, and indicating when real data are not used;
- Model selection and development;
- Verification requirements (verification plan);
- Validation requirements (validation plan);
- Sensitivity requirements;
- Uncertainty requirements.

#### WORK CONTROL

**A3.** Standardized methods or instructions should be used for:

- Selecting the modelling approach,
- Developing a model,
- Verifying the model,
- Validating the model or determining the potential for errors,
- Correcting errors and non-conformances,
- Performing sensitivity investigations,
- Performing uncertainty estimates.

**A4.** The source of the data used to develop or to select the model should be identified and maintained. Examples of sources are: existing data files, literature, laboratory experiments, tests and field observations. This link should be preserved.

**A5.** Arrangements should be introduced to ensure that analytical methods are adequate and, for example, that:

- processes are expressed in quantitative mathematical form;
- data exist to evaluate physical constraints and boundary conditions;
- the system to be modelled is well characterized;
- there is a suitable linking of models so that evaluations can be performed reliably when specific models are integrated;
- consistent assumptions are applied through all models;
- there is the required independence of the state of the system to be modelled.

## MODEL SELECTION

**A6.** Because of the continual evolution of models, they need to be evaluated carefully before actual application. An accepted process and technical judgement are needed in selecting the modelling approach. All basic assumptions should be carefully analysed, with due account taken of the specific features of the siting area.

**A7.** The final selection of the model to be developed, or to be used, should be reviewed and approved. The justification should show that the model will adequately represent the system or subsystem and is appropriate to the current stage of the siting analysis. The justification of the selection should be documented.

**A8.** If the development of a model is required, phenomena which are decisive to the final results and conclusions, including those which comprise the whole system, its components and interrelationships, should be reviewed and approved prior to model development.

**A9.** Phenomena which could change the state of the system and phenomena which will make a significant contribution to the overall radiological impact should be identified.

**A10.** To ensure that the model selected is adequate for the application, the review and approval process should include:

- The model possibilities available for a particular analysis.
- Development processes, including verification and validation histories.
- Inherent assumptions and limitations, including simplifications to obtain solvable expressions.

- Sensitivity to various ranges of input data and coefficients.
- Stability characteristics due to numerical dispersion or oscillatory solution effects.

## MODEL DEVELOPMENT

**A11.** When a new model is to be developed, the requirements identified during planning should be followed.

**A12.** A development plan should define the development sequencing, the reviews, verification and validation that are to be performed.

**A13.** When a subsystem analysis is necessary, a strategy and specific criteria for the selection of subsystem models should be identified and subjected to review and approval. Confirmation that these criteria have been satisfied should be recorded.

**A14.** Where long term behaviour is an essential element of the model, the correlation between theory and experiment should be documented.

**A15.** Inefficiencies and instabilities which could introduce inaccuracy if the application required coupling of models should be prevented.

**A16.** Changes to models due to increased knowledge of the system, or resulting from conditions not considered early enough in development or during development, should be controlled and should be subject to the above requirements.

## MODEL SENSITIVITY

**A17.** The sensitivity of model calculations to input variation should be investigated. The method to be used should be specified. The models should be verified prior to investigations of their sensitivity.

**A18.** The strategy, technique, sample size, analyses and results should be reviewed to confirm that they are appropriate and accurate.

## UNCERTAINTY ANALYSIS

**A19.** All causes of uncertainties in the data and analyses should be identified and quantified.

**A20.** The method of performing the analysis and presenting the results should be specified.

**A21.** Reviews should be performed to confirm the adequacy of the method and the accuracy of the results and conclusions.

## MODEL VERIFICATION

**A22.** A method for carrying out model verification should be developed. The extent of verification should be determined during planning and should be performed by individuals other than those who developed the model being verified.

**A23.** The verification should confirm and demonstrate that:

- the model or corresponding computer program is a proper mathematical representation of the conceptual model;
- the equations have been correctly encoded and solved;
- the programme functions correctly under the set of conditions that bound its intended usage.

**A24.** Verification should include:

- In-process and final checking of the computer program during and after development to ensure that it is correct. The method of checking should be subject to approval;
- Comparison of the computed results with problem solutions. Formal testing should be conducted using problem sets described in the test plan.

**A25.** If another computer program is to be used for verification, it too should have been subjected to verification.

**A26.** The verification plan should contain:

- the model attributes to be tested,
- the type of test to be performed,
- the acceptance/rejection criteria,
- requirements for recording results and test history.

## MODEL VALIDATION

**A27.** A thorough understanding of the model and its range of applicability should be obtained and where possible the expected level of error determined and recorded.

**A28.** The requirements that have to be satisfied to demonstrate that the model and computer programs derived from it provide a good representation of the real process should be determined and specified in a validation test plan.

**A29.** The test plan should identify the validation method, for example comparison with field and laboratory data or comparison with natural systems, and should define the model features to be tested and the data to be used to test them. After validation, a programme of investigation should be carried out at the candidate site to determine key model parameters for matching the model to the site.

**A30.** Descriptions for each validation test case should be prepared and reviewed for approval. This review should ensure also that an appropriate method of collecting the data is specified. Persons conducting these reviews should be independent of those carrying out the work.

## MODEL REVIEW AND UPDATE

**A31.** Models should be reviewed at specified intervals and updated and revalidated as required.

**A32.** The review process should ensure that the models represent the latest field data and laboratory results, and represent the current revision of the system or subsystem during modelling.

## CHANGE CONTROL

**A33.** The integrity and configuration of the model should be maintained and protected by identifying and controlling model software components and changes to the software and the supporting software documentation.

**A34.** Arrangements should ensure that:

- it is understood at what point in the development a component becomes subject to configuration control;
- program components are identified;
- proposed changes to components receive the same level of review as originals and are handled comprehensively and accurately;

- approved changes are introduced and circulated with corrected documentation and program changes;
- the program and supporting documentation is verified and the program is re-validated.

## TRACEABILITY OF DATA

**A35.** The source of data which, when used in modelling, will affect or support conclusions on siting should be retained throughout the development of the model. Intermediate iterations and the final model should be traceable to and supported by the acquired input data.

**A36.** Adequate cross-referencing to specific data should be provided. The data format should be such that it can be reviewed and checked.

## RECORDS

**A37.** The following are examples of records and documents that should be retained:

- Justification of model selection,
- Confirmation that selection criteria have been satisfied,
- Experimental data related to the model,
- Results of sensitivity and uncertainty analyses,
- Reports showing that the required tests, verification and validation were performed,
- Records which show what the current program version is.

## **Safety Guide Q10**

### **QUALITY ASSURANCE IN DESIGN**



## CONTENTS

1.	INTRODUCTION .....	223
	Background (101–102) .....	223
	Objective (103) .....	223
	Scope (104–105) .....	223
	Structure (106) .....	224
2.	MANAGEMENT .....	224
	Quality assurance programme (201–204) .....	224
	Grading (205–206) .....	225
	Organization (207–208) .....	225
	Interfaces (209–211) .....	226
	Training and qualification (212–213) .....	226
	Planning (214–215) .....	227
	Non-conformance control and corrective actions (216) .....	227
	Document control and records (217–222) .....	227
	Human factors (223) .....	228
3.	PERFORMANCE .....	228
	General (301–303) .....	228
	Design inputs (304–305) .....	229
	Analysis of design requirement (306–308) .....	229
	Design models (309–311) .....	229
	Design review (312–316) .....	230
	Design verification (317–320) .....	231
	Alternative calculations (321–323) .....	231
	Qualification testing (324–328) .....	232
	Design validation (329–330) .....	232
	Design change control (331–335) .....	233
	Design outputs (336) .....	233
4.	ASSESSMENT .....	234
	Management self-assessment (401) .....	234
	Independent assessment (402) .....	234
	ANNEX I: EXAMPLES OF ACTIVITIES WHICH MAY REQUIRE PROCEDURES .....	235
	ANNEXII: TYPICAL DESIGN INPUTS .....	236



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code), and complies with the requirements of the Code 50-C-D (Rev. 1).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the design stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in the design stage of a nuclear power plant project or in any other stage where design activities are to be performed. It covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the design stage of a nuclear power plant. The design stage overlaps with other nuclear power plant stages such as siting, construction and commissioning. The responsible organization may establish separate organizations for these stages or combine them under one organization. Whichever organizational arrangement is utilized, the responsibilities and interfaces shall be clearly defined and understood and the status of the plant established at all times.

## STRUCTURE

106. This Safety Guide is arranged into four sections and two annexes:

Section 2 provides guidance on QA for the management activities of design.

Section 3 provides guidance on QA for the performance of design activities.

Section 4 provides guidance on QA for the assessment of design activities.

Annex I provides a list of examples of design activities which may require procedures.

Annex II provides a list of typical design inputs.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the nuclear power plant design. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. Procedures should be defined by the responsible organization for control of design activities to ensure that the design of the nuclear power plant fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them controlled. A list of examples of design activities which may require procedures is contained in Annex I.

203. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.

204. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the

responsible organization if required. Guidance on the documents required from the supplier for submission to the responsible organization and the timing of such submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme see Safety Guide Q1.

## GRADING

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

206. The design activities which could be graded include:

- The level and detail of analysis of design
- The need for and level of design review and approval
- The degree of verification of design
- The controls applied to design change
- The detail of design records and their retention times
- The need for alternative calculations to be carried out
- The need to qualify or test the design output
- The need for qualification tests for design.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

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

208. The responsibilities of the principal designer should include:

- Defining the base requirement/specification
- Involvement in design reviews
- Involvement in design verification
- Approval of detail design
- Review and approval of design changes during all stages
- Control of interfaces

- Review of relevant non-conformance applications
- Review and approval of the QA programme.

## INTERFACES

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

- (1) Interfaces between technical disciplines within the design organization;
- (2) Principal designer with:
  - siting organization,
  - construction organization,
  - commissioning organization,
  - operating organization,
  - decommissioning organization,
  - regulatory body (see the Code 50-C-G (Rev. 1)).

210. Each organizational unit performing design work should identify and document its interfaces for managing the flow of information. Responsibilities should also be defined and documented to cover the preparation, review, approval, issue, distribution and revision of associated information across the interface. The flow of design information and the mechanism for the resolution of any problems should also be defined.

211. A mechanism should be established for communication and feedback between the principal designer and other organizations involved in the other stages of the nuclear power plant project such as siting, construction, commissioning, operation and decommissioning, to ensure their needs are taken into account. For further guidance on interfaces see Safety Guide Q1.

## TRAINING AND QUALIFICATION

212. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

213. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training see Safety Guide Q1.

## PLANNING

214. Design planning should take place at the earliest opportunity before the beginning of design activities. Plans should define the activities to be performed in manageable units (work breakdown and structure).

215. Plans used in design should include the following, where appropriate:

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

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

216. A system for the control of non-conformances and their corrective actions should be established following the guidance in Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

218. The process for the preparation, modification and control of design information should include:

- Drawing office standards
- Standardized symbols
- Identification systems
- Indication of status
- Checking methods

- Requirements for review and approval
- Issuance, distribution and storage.

219. Design input documents and changes thereto should be controlled to ensure that current and appropriate documents are available for use such that:

- individuals or organizations responsible for preparing, reviewing, approving and issuing documents and revisions thereto are identified;
- the proper documents to be used in performing design activities are identified, including title, applicable revisions and date of issue, or any other relevant information that precisely identifies the document;
- interfacing design documents (internal and external) are co-ordinated and controlled;
- obsolete documents are removed from use.

220. Specifications and other design outputs such as installation, instructions and commissioning and test procedures should be controlled.

221. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of design records.

222. Record requirements should provide evidence that design activities have been adequately controlled and executed to ensure that the required safety is achieved. For further guidance on document control and records see Safety Guide Q3.

## HUMAN FACTORS

223. Suitable working environments shall be provided and maintained so that work can be carried out safely and satisfactorily without imposing unnecessary physical and psychological stress on personnel.

## **3. PERFORMANCE**

### GENERAL

301. The design activities should be carried out in a logical planned sequence to ensure that the designed nuclear power plant can be safely sited, constructed, commissioned, operated and decommissioned.

302. Design activities shall be performed in a controlled manner to ensure that specified requirements are correctly translated into design outputs, such as:

- Design computer codes/basic plant design
- Design specifications
- Functional specifications.

303. Where analytical and process control computer software is used, appropriate measures should be provided for its verification and validation.

## DESIGN INPUT

304. Design inputs (see Annex II) should be identified and documented. These inputs should be subject to review and approval by the principal designer. Any changes to design inputs should be identified, documented, approved by the designer and controlled in a timely manner.

305. Where incomplete, conflicting or unclear design input information is supplied, clarification should be obtained prior to commencement of design activities.

## ANALYSIS OF DESIGN REQUIREMENTS

306. Analysis of design should be performed in order to confirm or clarify the design basis parameters given by the customer.

307. The analysis should address the general design criteria as specified in the Code 50-C-D (Rev. 1).

308. Analysis should be sufficiently detailed and recorded to enable assessment by technical personnel other than those who carried out the analysis.

## DESIGN MODELS

309. An important element for consideration in the design process should be the use of models, either physical models built to scale or computer generated images.

310. These models should be used in the design process as follows:

- To enable the feasibility of the design of structures and layout of critical areas to be established.

- To provide a physical and visual aid in the control and allocation of space for equipment, pipework, services, separation and segregation of safety related plant components and systems, protection against and escape from hazards, and access for operation and maintenance.
- To identify potential problems/fouls and interfaces between buildings and plant components and systems.
- To co-ordinate interfaces between design suppliers.
- To provide an aid to construction planning and operator training.

311. Where models are used, they should be subject to formal methods of change control to ensure they remain valid representations of the current configuration.

## DESIGN REVIEW

312. At appropriate stages of the design, formal reviews of the design process should be planned, completed and documented. Participants in these reviews should include representatives of organizational units from the design organization concerned with the design stage being reviewed, and other personnel as required. Reviews may range from single person reviews to multi-organizational reviews.

313. The objective of the review is to provide assurance that the output documents will be correct and fully address the requirements (for example functional, safety and regulatory requirements, and industry codes and standards) of the design specification.

314. The scope and extent of the review should be determined by the principal designer. As part of the review it should be established that procedures have been followed, that designated personnel have participated, and that results are adequately documented and checked prior to the release of design documents.

315. The design review should anticipate and identify potential problem areas and inadequacies and initiate corrective actions to ensure that the final design meets the design intent.

316. In the design review certain basic questions should be addressed. These questions should include, but not be restricted to:

- Were design inputs correctly selected and incorporated?
- Have original design requirements been met?
- Is the design output information complete?

- Were any assumptions made, are they adequately described and what is their basis?
- Was an appropriate design methodology used and were designated design standards followed?
- Were design procedures followed?
- Is the design output reasonable when it is compared to the design input?

## DESIGN VERIFICATION

317. Design verification (often referred to as independent design verification) is the process of reviewing, confirming or substantiating the design to ensure that design requirements have been satisfied. This verification should include, but not be restricted to:

- Design process planning and performance
- Design input requirements
- Design interface controls.

318. Verification activities should be conducted as planned.

319. Design verification shall be performed and documented by competent individuals or groups who did not perform the original design, but who may be from the same organization. They should have access to all relevant information. Identification of checkers, verifiers and management personnel who give approvals shall be clearly indicated.

320. The extent of design verification should include such means as design reviews, use of alternative calculations or suitable test programmes. When establishing the extent of design verification in accordance with the graded approach, the design organization should consider the importance of the items to safety, the complexity of the design and the similarity with previously proven designs.

## ALTERNATIVE CALCULATIONS

321. Verification of the correctness of calculations or analysis should be achieved by comparing results with those obtained by alternative methods of calculation or analysis.

322. On completion of the alternative calculation, reviews should be performed to confirm the appropriateness of assumptions, design input data, and the computer code or other method of calculation used.

323. The alternative method need not produce exactly the same result as the original calculation or analysis, but there must be no unresolved differences which are of significance to safety.

## QUALIFICATION TEST

324. In certain circumstances design verification may be achieved by a suitable qualification test of a model or prototype.

325. Where a test programme is used to verify the adequacy of a design feature it should include suitable testing under the most adverse design conditions for the specific design features being verified.

326. Where testing cannot be carried out under the most adverse design conditions, testing may be permissible if the results can be extrapolated to the most adverse conditions; otherwise alternative methods of design verification should be applied.

327. Qualification testing should be performed at qualified testing facilities in accordance with procedures. The procedures should ensure that reference requirements and acceptance limits are prescribed and that the test configuration of the model or prototype is defined.

328. Test results shall be documented and reviewed by appropriate personnel to ensure that test requirements have been satisfied.

## DESIGN VALIDATION

329. Design validation shall be carried out to confirm by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled, and that the item conforms to defined requirements.

330. Design validation follows successful final design verification and should be performed on the final item under defined operating conditions, such as commissioning or pre-operational testing.

## DESIGN CHANGE CONTROL

331. Design changes, including changes to requirements and those found necessary by manufacturing, construction, testing, commissioning, operation or decommissioning experience, shall be controlled.

332. When design changes are made, the reason for the change should be documented.

333. Consideration should be given to the impact of these changes and the consequences to other design areas.

334. Design changes should be reviewed and approved either:

- by the same group or organization responsible for the original design documents;
- other design organizations which have proven competence in the specific design area and have access to original design information documents;
- the regulatory body, where appropriate.

335. Information concerning the changes should be transmitted to personnel or organizations potentially affected by the change.

## DESIGN OUTPUTS

336. Design output documents to be retained should typically include:

- Technical specification and amendments
- Design drawings
- Safety evaluations
- Design calculations and records of the checking of these calculations
- Approved design change requests
- Design reports
- Design verification and validation reports
- System descriptions
- Technical analyses, evaluations and reports.

## 4. ASSESSMENT

### MANAGEMENT SELF-ASSESSMENT

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

### INDEPENDENT ASSESSMENT

402. Typical subjects to be addressed by independent assessment during design are:

- Use of computers and software
- Design reviews
- Calculation control
- Use of models
- Document control of design outputs.

For further guidance on independent assessment see Safety Guide Q5.

## **Annex I**

### **EXAMPLES OF ACTIVITIES WHICH MAY REQUIRE PROCEDURES**

- Calculations
- Safety analysis
- Design review
- Design analysis
- Design models, their use and review
- Design change control
- Design outputs, their format and control
- Design verification
- Design validation
- Design planning
- Design inputs
- Design source data control
- Configuration control
- Drawing standards.

## Annex II

### TYPICAL DESIGN INPUTS

- Basic functional requirements of the structure, system or component
- Performance requirements
- Applicable codes, standards and regulatory requirements, including the relevant issue, revision or addenda
- Design conditions, such as pressure, temperature, fluid chemistry and voltage
- Loads, such as seismic, wind, thermal and dynamic
- Environmental conditions/effects
- Interface requirements including definition of the functional and physical interfaces involving structures, systems and components
- Material requirements
- Mechanical requirements
- Structural requirements
- Hydraulic requirements
- Chemistry or chemical requirements
- Electrical requirements
- Electromagnetic compatibility
- Layout and arrangement requirements
- Fire prevention and protection requirements
- Operational requirements and decommissioning requirements
- Radiation exposure limits and radiation protection requirements
- Control and instrumentation requirements
- Reliability requirements
- Test requirements
- Maintenance requirements
- Handling, storage and shipping requirements
- Probabilistic safety analysis
- Safety considerations-prevention of injury to personnel
- Feedback of experience
- Ergonomics considerations
- Other requirements to prevent undue risk to the health and safety of the public.

## **Safety Guide Q11**

# **QUALITY ASSURANCE IN CONSTRUCTION**



## CONTENTS

1.	INTRODUCTION .....	241
	Background (101–102) .....	241
	Objective (103) .....	241
	Scope (104–105) .....	241
	Structure (106) .....	242
2.	MANAGEMENT .....	242
	Quality assurance programme (201–204) .....	242
	Grading (205–206) .....	243
	Organization (207–208) .....	243
	Interfaces (209–210) .....	244
	Handover and transfer of responsibilities (211) .....	244
	Training and qualification (212–213) .....	245
	Planning (214–218) .....	245
	Non-conformance control and corrective actions (219) .....	246
	Document control and records (220–222) .....	246
	Industrial safety (223–226) .....	247
	Human factors (227–228) .....	247
3.	PERFORMANCE .....	248
	General (301) .....	248
	Procurement (302–303) .....	248
	Startup meeting (304) .....	249
	Review of suppliers documents (305) .....	249
	Control of design information (306–308) .....	249
	Approval of sub-suppliers (309) .....	250
	Housekeeping during construction and installation (310–311) .....	250
	Control of items (312–319) .....	250
	Measuring and test equipment (320) .....	252
	Verification of construction work (321–323) .....	252
4.	ASSESSMENT .....	253
	Management self-assessment (401) .....	253
	Independent assessment (402) .....	253
	ANNEX: EXAMPLES OF CONSTRUCTION ACTIVITIES WHICH MAY REQUIRE PROCEDURES .....	254



# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the construction stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in the construction stage of a nuclear power plant project or in any other stage where construction activities are to be performed. It covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the construction stage of a nuclear power plant. The construction stage overlaps with other nuclear power plant stages such as design and commissioning. The responsible organization may establish separate organizations for these stages or combine them under one organization. Whichever organizational arrangement is utilized, the responsibilities and interfaces shall be clearly defined and understood and the status of the plant established at all times.

## STRUCTURE

106. This Safety Guide is arranged into four sections and one annexes:

Section 2 provides guidance on QA for the management activities of construction.

Section 3 provides guidance on QA for the performance activities of construction.

Section 4 provides guidance on QA for the assessment of construction activities.

Annex provides examples of construction activities which may require procedures.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the nuclear power plant during construction. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. Procedures should be defined by the responsible organization for control of construction activities at the site to ensure that construction of the nuclear power plant fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them controlled. A list of examples of construction activities which may require procedures is contained in the Annex.

203. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.

204. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the responsible organization, if required. Guidance on the documents required from the supplier for submission to the responsible organization and the timing of such

submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme, see Safety Guide Q1.

## GRADING

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

206. The construction activities which could be graded include:

- Qualification of special construction processes and the personnel to carry them out
- Detail and need for inspection plans
- Level of traceability
- Level of in-process controls and need of hold points
- Records and archived samples.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

207. The responsible organization should formally appoint a person on its staff to be responsible for construction activities.<sup>1</sup>

208. The appointed person should have the necessary resources within the construction organization to discharge the following responsibilities:

- 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;

---

<sup>1</sup> In some Member States the appointed person is the head of the construction organization.

- Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work;
- Controlling access to the construction site.

## INTERFACES

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

- Construction organization with supplier
- Supplier with test and commissioning personnel, or organization
- Construction organization with operating personnel, or organization
- Suppliers with subsuppliers
- Construction organization with the principal designer<sup>2</sup>
- Construction organization with siting organization
- Interfaces between the construction organization and the regulatory body (see the Code 50-C-G (Rev. 1)).

210. Appropriate arrangements should be specified for the communication of quality problems or other matters requiring special attention. The form of communication should be specified. For further guidance on interfaces see Safety Guide Q1.

## HANDOVER AND TRANSFER OF RESPONSIBILITIES

211. Provisions shall be made by the construction organization to control and co-ordinate the handover of completed works from one supplier to another and to those responsible for commissioning of the nuclear power plant in order to maintain the integrity of the completed works. These provisions should include the following steps:

- (1) An orderly transfer of the responsibilities from the construction organization to the commissioning organization for components, systems, structures and their related records should be planned and implemented.

---

<sup>2</sup> The principal designer has responsibility for specifying the design requirements and for approving the design output on behalf of the responsible organization. Further explanation of the term “principal designer” can be found in Safety Guide Q10.

- (2) Documentation related to the transferred items should be reviewed by the construction organization for completeness and accuracy. Any non-conformance should be identified and resolved, and it should be ensured that the status of the items is clear.
- (3) When the construction and commissioning organizations are satisfied that the transfer can be accomplished, a joint check should be carried out of the transferred items and the associated documents. Both parties should sign formally to indicate transfer of responsibilities.

For further guidance on the transfer of responsibilities from construction to commissioning see Safety Guide Q12.

## TRAINING AND QUALIFICATION

212. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

213. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training see Safety Guide Q1.

## PLANNING

214. Construction activities should be planned. Computer aided planning is desirable. The plan should define:

- the activities to be performed in manageable units;
- the planned sequential order and duration of these activities;
- the resource allocation for each activity.

215. Whilst the construction organization shall retain responsibility for co-ordinating and planning the overall construction of the nuclear power plant, suppliers should be responsible for producing detailed plans of the work that they will be carrying out and for obtaining the construction organization's approval of these plans where necessary.

216. Planning should take into account requirements for site fabrication, installation, inspection and testing of structures, systems and components important to safety, such as:

- The need for the identification, preparation and control of procedures and work instructions;
- The need for special equipment or materials;
- The need for competent personnel;
- Inspection or regulatory body hold points;
- The need for environmental considerations.

These requirements should be identified by examination of the specifications for structure, system and component design, procurement documents and drawings, and construction work plans and schedules.

217. This examination should ensure that all activities necessary for site fabrication, installation, inspection and testing have been identified, and that they can be accomplished as specified.

218. The construction organization should confirm the adequacy of construction methods with reference to the principal designer where necessary.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

219. The non-conformances that are required to be reported to the construction organization should be identified. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

221. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of construction records.

222. Records should include all those which record the as-built condition of structures, systems and components. For further guidance on document control and records see Safety Guide Q3.

## INDUSTRIAL SAFETY

223. A policy reflecting Member State industrial safety regulations should be established for all personnel, including suppliers and visitors, and should refer to the rules and practices that are to be adopted. The policy should include arrangements for the effective planning, organization, monitoring and review of the preventive and protective measures.

224. Management should provide support, guidance and assistance for construction personnel in the area of industrial safety.

225. Construction personnel should understand how the industrial safety programme affects their individual work practices.

226. Industrial safety data should be monitored. Examples of items to be monitored include lost-time accidents, other accidents requiring medical attention, industrial safety non-conformances identified in the plant, and modifications with industrial safety implications.

## HUMAN FACTORS

227. Suitable working environments shall be provided and maintained so that work can be carried out safely and satisfactorily, without unnecessary physical and psychological stress on the personnel.

228. Human factors which influence the working environment and the effectiveness of personnel performance and their fitness for duty should be identified and addressed. These include, for example:

- The adequacy of resources, support and supervision needed to manage and perform the work;
- The frequency and clarity of communications;
- The availability of suitable tools and equipment;
- The limits on the duration of work time;
- The attention needed to be given to other factors, including personnel well-being, psychological, physiological and attitudinal problems, shift patterns and meal breaks;
- The availability of procedures that take into account human factor considerations.

### 3. PERFORMANCE

#### GENERAL

301. The principal activities of the construction organization personnel should include as a minimum:

- Controlling and supervising of suppliers;
- Ensuring that suppliers are established on the site in a controlled manner in allocated areas and are provided, where appropriate, with the necessary site services, information and instructions regarding the applicable industrial safety requirements;
- Preparing safe working procedures, including industrial safety procedures, for issue to both the personnel of the construction organization and the supplier, and establishing that the supplier's site industrial safety arrangements recognize the applicable documents;
- Monitoring the industrial safety policies and activities of all personnel on the construction site in order to ensure compliance with statutory and regulatory requirements;
- Planning and monitoring the progression of work to achieve completion to programme, including, where appropriate, the co-ordination of the activities of multidiscipline suppliers responsible for discrete technical areas;
- Ensuring that supplier work is carried out in accordance with procedures, specifications and drawings, that QA requirements are defined and implemented and installation checks are appropriate and in accordance with surveillance schedules;
- Carrying out a maintenance programme for equipment that could deteriorate during construction, such as dehumidification of electrical equipment and preservation of critical surfaces that could rust;
- Arranging the controlled handover of completed work from one supplier to another or to the construction organization;
- Obtaining baseline data for in-service inspection.

#### PROCUREMENT

302. Suppliers employed to construct the nuclear power plant should be selected from those who can demonstrate that they are suitably qualified and experienced to carry out such work.

303. Where information on suitable suppliers is lacking, interested organizations should be invited to pre-qualify for inclusion on a short list to whom tenders for the work concerned will be issued. For further guidance on the QA aspects for the procurement of items and services see Safety Guide Q6.

#### STARTUP MEETING

304. Following the award of a construction or installation contract, a startup meeting should be convened between the supplier and the construction organization to establish that the supplier is fully aware of the construction organization's requirements, for example:

- Interface arrangements
- Methods of communication
- Documents and information to be submitted
- Housekeeping
- Site security
- Site training
- Safety (radiological, nuclear and industrial)
- QA
- Control of sub-suppliers.

The meeting should also finalize the arrangements for satisfying these requirements.

#### REVIEW OF SUPPLIERS DOCUMENTS

305. The construction organization should ensure that documents requiring approval prior to the commencement any activity are identified in procurement documents. For further guidance see Safety Guide Q6.

#### CONTROL OF DESIGN INFORMATION

306. Lines of communication and arrangements for the issue of design information among involved organizations should be established. Prior to issue, the construction organization should ensure that the information being issued reflects the current site conditions. Particular attention should be paid to design information required at an off-site fabrication facility.

307. A process should be established to address queries from the supplier with respect to the design information issued. Where the query may have an impact on nuclear safety during operation, it should be addressed to the principal designer for a response.

308. Field changes which may arise during the construction activities and have impact on the design information (for example drawings, specifications, instructions) should be reviewed, actioned, approved and validated in accordance with Safety Guide Q10.

#### APPROVAL OF SUBSUPPLIERS

309. The construction organization should not allow any subsupplier to carry out work on the plant until it is satisfied as to the adequacy of the supplier's proposed arrangements for controlling the quality of the subsupplier's work, for example materials control and inspection arrangements. For further guidance see Safety Guide Q6.

#### HOUSEKEEPING DURING CONSTRUCTION AND INSTALLATION

310. To preserve the requisite quality of the item being constructed or installed, measures for performing housekeeping operation should be established and implemented in accordance with specified requirements. These should include methods and techniques for control of the site area, the facilities, and the material and equipment being incorporated into the nuclear power plant.

311. Cleanliness requirements for housekeeping activities should be established. These should take into account control of environmental conditions and personnel access. Where clean zones are used to achieve this control, they should be clearly marked, and procedures or instructions should be issued to regulate their usage.

#### CONTROL OF ITEMS

312. Items should be controlled from receipt through storage, handling and use, to prevent their abuse, misuse, damage, deterioration or loss of identification.

## **Receiving**

313. Where possible, items arriving at the construction site should be visually inspected before unloading to verify that there is no damage.

314. After receiving, inspection should be carried out to ensure that the applicable specifications are fulfilled, such as that:

- the item is configured correctly;
- identification and marking is adequate;
- manufacturing documentation is available as required;
- protective covers and seals are intact;
- coatings and preservatives have not been damaged;
- no physical damage has occurred;
- cleanliness is of the correct standard;
- inert gas blankets and the condition of desiccants, where relevant, have not been compromised;
- necessary tests of hardware characteristics have been performed.

For further guidance see Safety Guide Q4.

## **Storage**

315. Storage should be provided as specified to segregate and protect items prior to their installation and use. The methods and conditions of storage to prevent corrosion, contamination, deterioration and physical damage should be specified.

316. Storage areas should be established and controlled, taking account of aspects such as:

- Access
- Cleanliness and housekeeping practices
- Fire protection requirements
- Identification and marking of items
- Protective requirements relating to coatings, preservatives, covers and sleeves
- Prevention of physical damage
- Removal from and return to storage
- Environmental control (such as temperature and humidity)
- Preventive maintenance
- Security
- Items which have a limited shelf or service life
- Physical and chemical characteristics of items
- Safety grades.

Inspections should be performed as necessary to ensure that the specified conditions are maintained and any non-conformances are handled in accordance with para. 219. These inspections may need to continue during the commissioning and operation stages. Handover arrangements should be established.

## **Handling**

317. All items should be properly handled, with account taken of aspects such as:

- Weight
- Size
- Susceptibility to shock damage
- Surface finish
- Prescribed handling points
- Orientation
- Handling equipment and any tests required for it
- Vulnerability to degradation by static discharge
- Preservation of coatings
- Maintenance of environmental conditions.

318. The use of items such as special cartons, containers, protective devices, hoists, manipulators and transport vehicles should be considered where handling operations are of a nature likely to cause damage. Operators and handlers of all such items should be competent. Equipment for handling items should be used and maintained in accordance with Member State regulations and standards.

319. Items which the construction organization has procured for issue to the supplier should be controlled in accordance with paras 312–318 prior to issue to a supplier.

## **MEASURING AND TEST EQUIPMENT**

320. Measuring and test equipment which is used for construction activities, data collection, inspections and tests shall be of the proper type, range, accuracy and precision and be in good condition. For further guidance see Safety Guide Q4.

## **VERIFICATION OF CONSTRUCTION WORK**

321. The construction organization should establish verification methods and schedules which identify the level of inspection/verification required.

322. Before offering an item or service for acceptance, the supplier should verify that all defined procurement requirements have been satisfied. Acceptance by the purchaser should not absolve the supplier from responsibility to provide items and services fit for purpose nor should it preclude subsequent rejection.

323. Where necessary, the construction organization should issue procedures with standard forms for the recording of suppliers' inspection/verification activities. The verification method and the acceptance criteria should be clearly identified.

## **4. ASSESSMENT**

### MANAGEMENT OF SELF-ASSESSMENT

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

### INDEPENDENT ASSESSMENT

402. Typical subjects to be addressed by independent assessment during construction are:

- Safety issues
- Materials testing
- Suppliers audit procedures
- Housekeeping
- Preservation of completed work
- Supplier assessments
- Control and disposition of non-conforming items
- Control of equipment handover process
- Conformance of construction work to technical design requirements.

For further guidance on independent assessment see Safety Guide Q5.

## **Annex**

### **EXAMPLES OF CONSTRUCTION ACTIVITIES WHICH MAY REQUIRE PROCEDURES**

- Receipt and registration of contract documents
- Site contract review meeting
- Site contract startup meeting
- Confirmation of inspection levels
- Supplier site safety and security
- Review of supplier control arrangements
- Review of suppliers/subsuppliers
- Instructions to supplier
- Progress meeting
- Supplier monitoring
- Soil and concrete sampling
- Queries and changes to design
- Handover/transfer of responsibilities
- Emergency preparedness (for sites in close proximity to operational plant)
- Housekeeping during construction.

**Safety Series Q12**

**QUALITY ASSURANCE IN COMMISSIONING**



## CONTENTS

1.	INTRODUCTION .....	259
	Background (101–102) .....	259
	Objective (103) .....	259
	Scope (104–105) .....	259
	Structure (106) .....	260
2.	MANAGEMENT .....	260
	Quality assurance programme (201–204) .....	260
	Grading (205–206) .....	261
	Organization (207–208) .....	261
	Interfaces (209) .....	262
	Transfer of responsibilities (210–213) .....	262
	Training and qualification (214–215) .....	263
	Planning (216–218) .....	263
	Radiological safety (219–220) .....	264
	Industrial safety and security (221–224) .....	264
	Emergency planning and preparedness (225–227) .....	264
	Human factors (228–229) .....	265
	Non-conformance control and corrective actions (230–232) .....	265
	Document control and records (233–235) .....	266
3.	PERFORMANCE .....	266
	General (301–304) .....	266
	Design control (305–306) .....	267
	Commissioning documents (307–310) .....	267
	Shift changeover (311–313) .....	268
	Component and system identification (314–315) .....	268
	Component and system status and control (316–321) .....	269
	Temporary modifications to components or systems (322–323) .....	269
	Component and system maintenance (324) .....	270
	Procurement (325) .....	270
	Handling and storing (326) .....	270
	Measuring and test equipment (327) .....	270
	Housekeeping and cleanliness (328) .....	270
	Verification of commissioning activities (329–335) .....	271

4.	ASSESSMENT .....	271
	Management self–assessment (401) .....	271
	Independent assessment (402) .....	272
ANNEX I:	EXAMPLES OF COMMISSIONING ACTIVITIES WHICH MAY REQUIRE PROCEDURES .....	273
ANNEX II:	EXAMPLE OF COMMISSIONING DOCUMENT STRUCTURE .....	274

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code), and complies with the requirements of the Code 50-C-O (Rev. 1)).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the commissioning stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in the commissioning stage of a nuclear power plant project or in any other stage where commissioning activities are to be performed. It covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the commissioning stage of a nuclear power plant. The commissioning stage overlaps with other nuclear power plant stages such as construction and operation. The responsible organization may establish separate organizations for these stages, or combine them under one organization. Whichever organizational arrangement is utilized, the responsibilities and interfaces shall be clearly defined and understood and the status of the plant established at all times.

## STRUCTURE

106. This Safety Guide is arranged into four sections and two annexes:

Section 2 provides guidance on QA for the management activities of commissioning.

Section 3 provides guidance on QA for the performance activities of commissioning.

Section 4 provides guidance on QA for the assessment of commissioning activities.

Annex I gives examples of commissioning activities which may require procedures.

Annex II gives an example of a commissioning document structure.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the nuclear power plant commissioning. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. Procedures shall be defined by the responsible organization for control of commissioning activities at the site to ensure that commissioning of the plant fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them controlled. A list of examples of commissioning activities which may require procedures is contained in Annex I. For further guidance on commissioning procedures see Safety Guide 50-SG-O4.

203. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme but shall retain overall responsibility for the implementation and effectiveness of the programme.

204. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the

responsible organization if required. Guidance on the documents required from the supplier for submission to the responsible organization and the timing of such submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme see Safety Guide Q1.

## GRADING

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

206. Commissioning activities that could be graded include:

- Independent verification of construction activities
- The degree of phase and integrated testing
- Individual component testing
- The detailed analysis of commissioning tests
- The records required from commissioning activities
- Non-conformances that should be reported to the principal designer<sup>1</sup>
- The amount and detail of commissioning documents
- The installed equipment requiring calibration.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

207. The responsible organization should formally appoint a person on its staff to be responsible for commissioning activities.<sup>2</sup>

208. The appointed person should have the necessary resources within the commissioning organization to discharge all responsibilities. A commissioning group may be established, consisting of several teams with delegated tasks, to execute specific

---

<sup>1</sup> The principal designer has responsibility for specifying the design requirements and for approving the design output on behalf of the responsible organization. Further explanation of the term “principal designer” can be found in Safety Guide Q10.

<sup>2</sup> In some Member States the appointed person is the head of the commissioning organization.

commissioning activities with the authority to operate the necessary components and systems. For each of these activities, personnel with authority to execute and document the work should be identified.

## INTERFACES

209. Where more than one organization is involved in commissioning activities, the responsibility of each organization involved shall be clearly established and documented. Internal and external interfaces should be considered and procedures established for the identification, review, approval, release, distribution and revision of documents that cross organizational boundaries. Interfaces that the commissioning organization should address include, for example:

- Suppliers of items, services and civil works,
- Consultants,
- Inspection agencies,
- Regulatory body (see the Code 50-C-G (Rev. 1)),
- Construction organization,
- Operating organization,
- Principal designer,
- Other support functions.

## TRANSFER OF RESPONSIBILITIES

210. An orderly transfer of responsibilities, from the construction organization to the commissioning organization for components, systems and structures and their related records, should be planned and implemented.

211. The construction handover package should be reviewed by the commissioning organization for non-conformances, which should be identified and resolved, and for ensuring that the status of the items is clear.

212. When the commissioning organization is satisfied that the transfer can be accomplished, a joint check with the construction organization should be carried out of the transferred items and the associated documents. Parties should sign formally to indicate transfer of responsibilities. After transfer has been accomplished, problems, failures or design changes may necessitate the return of a system, component or

structure to the construction organization. When this is done, the procedures described in paras 210 and 211 should be performed again for the affected areas.

213. On completion of commissioning, a documented transfer of the whole plant to the operating organization should be undertaken. Safety Guides Q11, Q13 and 50-SG-O4 provide additional information on the transfer from construction to commissioning and from commissioning to operation.

## TRAINING AND QUALIFICATION

214. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

215. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training see Safety Guide 50-SG-O1 (Rev. 1).

## PLANNING

216. Commissioning activities shall be planned. Computer aided planning is desirable. The plan should define:

- the activities to be performed in manageable units;
- the planned sequential order and duration of these activities;
- the resource allocation for each activity;
- the verification activities;
- the persons responsible for each activity.

217. Whilst the commissioning organization shall retain responsibility for co-ordinating and planning the overall commissioning of the nuclear power plant, suppliers should be responsible for producing detailed plans of the work that they will be carrying out and obtaining the commissioning organization's approval of these plans where necessary.

218. The commissioning, modification, replacement, preventive maintenance and repair of all components and systems during commissioning should be planned, approved and controlled. For further guidance on planning see Safety Guide 50-SG-O4.

## RADIOLOGICAL SAFETY

219. The responsible organization shall establish and implement a radiation protection programme (additional details are contained in Safety Guide 50-SG-O5 and IAEA Safety Series No. 115).

220. Radiation exposure trends should be determined for each working group, area and activity. Annual limits should be established for radiation exposures and these should be made as low as is reasonably achievable.

## INDUSTRIAL SAFETY AND SECURITY

221. A policy reflecting national industrial safety and security regulations and organizational industrial safety rules should be established, covering all site personnel, including visitors.

222. The specific requirements for the safety of components from the commencement of commissioning should be detailed in the applicable commissioning documents (see paras 307–310).

223. During commissioning, special care should be taken to clearly identify the operational status of plant items so that all staff are aware of any potential hazards. Such hazards include pneumatic, hydraulic and electrical energizing of equipment, and/or pressurizing systems with compressed gases, water, steam or other fluids. Temporary connections to systems and equipment may have to be utilized.

224. As systems and components are commissioned, they should be placed under security to control access and prevent inadvertent damage.

## EMERGENCY PLANNING AND PREPAREDNESS

225. Reference emergency conditions shall be identified and the organizational infrastructure required for coping with them developed.

226. The resources and facilities for emergencies shall be made available. Personnel should receive continuing training, by testing of emergency plans and procedures, through drills and exercises and public information activities.

227. Emergency plans and procedures should be revised and improved as a result of feedback from drills and exercises. For further guidance see the Code 50-C-O (Rev. 1), and Safety Guides 50-SG-O6 and 50-SG-G6.

## HUMAN FACTORS

228. Suitable working environments shall be provided and maintained so that work can be carried out safely and satisfactorily, without imposing unnecessary physical and psychological stress on the nuclear power plant personnel.

229. Human factors which influence the working environment and the effectiveness of personnel performance and their fitness for duty should be identified and addressed. This includes, for example:

- The adequacy of resources, support and supervision needed to manage and perform the work;
- The adequacy of lighting, access and commissioning aids;
- The adequacy of alarms, such as number, position, grouping, colour coding and audibility prioritizing;
- The frequency and clarity of communications;
- The availability of the right tools and equipment;
- The limits on the duration of work time for commissioning personnel;
- The attention needed to be given to other factors for control room staff, including personnel well-being, psychological, physiological and attitudinal problems, shift patterns and meal breaks;
- The availability of procedures that take into account human factor considerations.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

230. Where a non-conformance occurs in items under test, the non-conformance and its corrective action should be reviewed to determine whether it has invalidated testing previously completed. All necessary tests should be performed again if they have been invalidated.

231. Where, during commissioning of items, an item as designed is found unsuitable for its purpose, or fails to satisfy the prescribed tests, it should be modified accordingly, using procedures established as required by para. 305.

232. All non-conformances should be resolved before commissioning activities are considered to be complete. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

234. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of commissioning records.

235. Records should include all those which record the commissioning activities of components and systems. For further guidance on document control and records see Safety Guide 50-SG-Q3

## **3. PERFORMANCE**

### GENERAL

301. The commissioning programme shall be established and followed to demonstrate that the nuclear power plant, especially items important to safety, has been constructed and functions according to the design intent, and to ensure that weaknesses are detected and eliminated.

302. An appropriate programme should be prepared and implemented for each of the major system areas and for phase testing which sets out the principles and objectives of the component completion and nuclear power plant commissioning tests, as well as detailing the testing to be carried out on the components, systems and structures. Each programme should contain sufficient information about the design, function and performance of the components, systems or structures to adequately characterize them and to aid the definition of the proposed tests. The programme should describe the proposed component, system or structure completion and commissioning tests and clearly address any specific industrial safety precautions or measures required during the tests in order to protect personnel and components.

303. During commissioning tests, detailed diagnostic data should be collected on components, systems or structures having nuclear safety significance and the initial operating parameters should be recorded.

304. During the commissioning stage, the as-built operating characteristics of safety and process systems should be determined and documented. Operating set points should be adjusted to conform to design values and to safety analysis. Training procedures and operational limits and conditions should be modified to reflect accurately the operating characteristics of the systems as-built. For further guidance on commissioning objectives, activities and procedures see Safety Guide 50-SG-O4.

## DESIGN CONTROL

305. Any changes to the design required as a result of commissioning activities should be reviewed, approved and validated by the principal designer.

306. Results of commissioning activities should be reviewed by the principal designer to ensure that testing methodologies have demonstrated that equipment functionality is acceptable. Changes to the design specification or system modification, including changes to computer software identified during testing, are considered in Safety Guide 50-SG-Q10.

## COMMISSIONING DOCUMENTS

307. The commissioning documents should clearly identify the requirements, intent, test objectives, limiting criteria, test conditions and procedures, special equipment, personnel requirements, special precautions, acceptance criteria and the records to be generated.

308. A representative of the principal designer and, where necessary, one from the construction organization, should be included in the review process of commissioning testing procedures.

309. On the basis of the tests scheduled in the programme, component completion procedures and commissioning procedures should be written for each component test or system test. Each procedure should detail the objectives of the testing proposals and contain detailed instructions to members of the test team carrying out the work. In addition to the detailed step-by-step instruction, the procedure should also contain specific information about safety requirements, emergency procedures, programmes, test data collection and any limits and conditions.

310. Commissioning documents, component completion procedures, commissioning procedures and functional requirements documents should be reviewed and approved by groups representing the commissioning organization, the operation organization and suppliers as applicable. Annex II shows an example of a commissioning document structure.

## SHIFT CHANGEOVER

311. Shift changeover shall be carried out according to a formal process. An account of plant and work status is usually presented in reports and logs which follow a standard format.

312. The process of shift changeover should identify the persons involved, their responsibilities, the locations and the conduct of shift changeovers, and the method of reporting plant status, including provisions for special circumstances such as abnormal plant status and staff unavailability.

313. Shift changeover should address the following:

- Commissioning status of major equipment;
- Significant safety and general plant parameters (including any identified trends);
- Systems in an abnormal or degraded configuration, testing anomalies;
- Significant new defects since the previous shift;
- Schedules and duration of current and planned work, outages and work permits;
- Special instructions from commissioning management;
- Temporary commissioning instructions, design changes and notices;
- Handover of keys;
- Review of logs.

## COMPONENT AND SYSTEM IDENTIFICATION

314. A system should be developed to ensure that systems and components important to safety are uniquely identified and should be related to the identification used in test and commissioning documentation.

315. The system and component identification should be transferable to the operation stage without any substantial changes. Components and systems temporarily

installed for the commissioning period should be identified in a manner different to permanent components and systems.

## COMPONENT AND SYSTEM STATUS AND CONTROL

316. Measures shall be established to ensure that the status is controlled and maintained of components and systems which are installed, operated or modified in accordance with appropriate specifications and procedures.

317. The release of components or systems for specific tests, maintenance or modification during commissioning and their return to commissioning should be controlled and documented.

318. When components or systems are taken out of service, verification should be provided to the extent necessary to assure that the correct items were removed from service. This should be done by inspection or testing of the appropriate components and controls, together with the use of appropriate tags and records, or by indirect means such as observation of indicators and status lights.

319. When specific tests, maintenance or modifications are completed, commissioning personnel should ensure that the component condition has been returned to its normal status or is in accordance with its approved modified status.

320. If normal conditions cannot be restored, a clearly defined reporting route should be available to commissioning personnel for the problem to be identified to management for appropriate action to be taken.

321. Records shall be maintained to show the status of components or systems during testing, modification or maintenance.

## TEMPORARY MODIFICATIONS TO COMPONENTS OR SYSTEMS

322. Temporary modifications that are required to carry out any specific commissioning tests should be controlled.

323. Temporary modifications should only be carried out to approved procedures, with formal reporting links established to resolve any problems encountered during the modification process. Such procedures should give assurance that other tests

which may be in progress will not be affected. Components and systems should be returned to their previous state after completion of the work for which the temporary modification was carried out. For further guidance see Safety Guide Q13.

## COMPONENT AND SYSTEM MAINTENANCE

324. A maintenance programme for components and systems defining frequency and type of maintenance to be performed should be established and implemented throughout the commissioning stage. It should be periodically reviewed. A maintenance history should be built up for the operation stage of the plant.

## PROCUREMENT

325. During commissioning, procurement should be performed according to the guidance given in Safety Guide Q6.

## HANDLING AND STORING

326. Handling instructions and procedures should be provided for items that may be damaged if handled incorrectly. Items should be stored under conditions appropriate to their susceptibility to environmental deterioration and periodically inspected as necessary. Appropriate procedures should be produced to maintain the preservation status of all installed items. Particular attention should be paid to identifying safety related items where special preservation measures are required, for example maintaining nitrogen blankets.

## MEASURING AND TEST EQUIPMENT

327. Measuring and test equipment used in commissioning for data collection, inspection and tests shall be of the proper type, range, accuracy and precision and be in good condition (see Safety Guide Q-4).

## HOUSEKEEPING AND CLEANLINESS

328. Activities should be accomplished under suitably controlled conditions. The cleanliness of structures, systems and components including the safe disposal of combustible or explosive material and debris should be considered.

## VERIFICATION OF COMMISSIONING ACTIVITIES

329. Measures should be established to verify that:

- Test prerequisites are in accordance with test procedures;
- Parameters are within proper ranges for test conditions;
- The implementation of commissioning activities is in accordance with plans;
- Stage reviews have been conducted as required;
- Hold point requirements have been satisfied before work proceeds beyond the hold point concerned.

330. Verification methods and acceptance criteria should be clearly described in the relevant work documents.

331. The principal designer should verify that testing is in accordance with design intent and that design requirements have been met.

332. Where the purpose of testing is to verify design values, the test document should include or refer to acceptance criteria.

333. Inspection requirements should be specified in commissioning documents. Inspection and confirmatory checking should be performed and documented to verify compliance with specific requirements for the conduct of commissioning tests.

334. Commissioning results shall be reviewed and approved by qualified and authorized persons to verify the completeness of tests performed and confirm that an item or activity to which the records or results apply is satisfactory. A representative of the principal designer should take part in the review.

335. The results of commissioning tests should be promptly recorded and evaluated to provide clear indication that the design requirements have been met. When design requirements have not been met, a non-conformance should be recorded.

## 4. ASSESSMENT

### MANAGEMENT SELF-ASSESSMENT

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

## INDEPENDENT ASSESSMENT

402. Typical subjects to be addressed by independent assessment during commissioning are:

- Interfaces
- Safety management
- Temporary modifications
- Plant labelling
- Housekeeping
- Plant status identification
- System for walkdowns.

For further guidance on independent assessment see Safety Guide Q5.

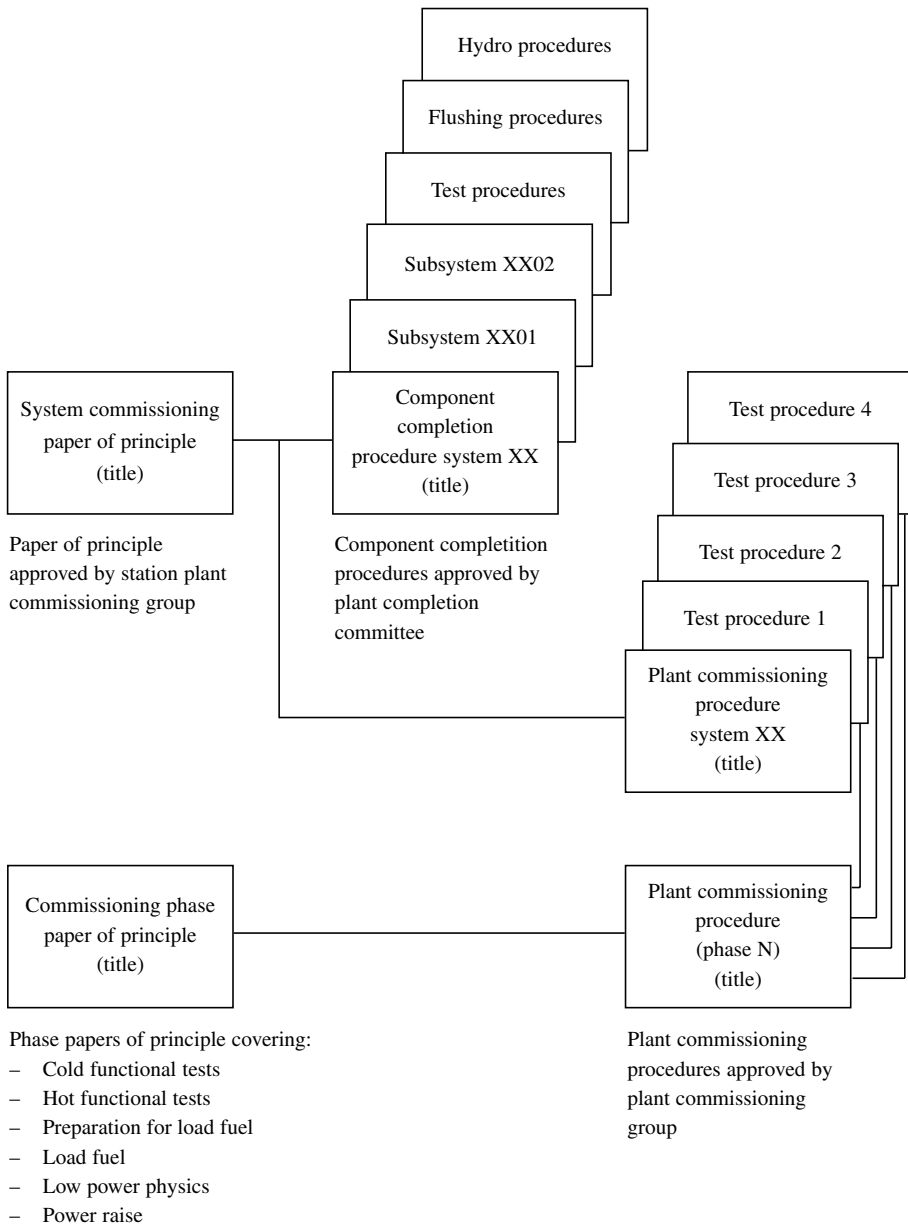
## Annex I

### EXAMPLES OF COMMISSIONING ACTIVITIES WHICH MAY REQUIRE PROCEDURES

- Definition and approval of component nomenclature.
- Preparation of component manuals and operating instructions.
- Arrangements for working party subgroups and test teams.
- Component or system take-over.
- Control of delivery, installation and changes to on-line software.
- Control of commissioning flushing effluent.
- Test and commissioning documentation, numbering and structure.
- Control of temporary changes to equipment, materials and software.
- Site access control during commissioning.
- Preventive maintenance required during commissioning.
- System and component status during commissioning.
- Radiation protection programme during and after loading the reactor core.

## Annex II

### EXAMPLE OF COMMISSIONING DOCUMENT STRUCTURE



## **Safety Guide Q13**

### **QUALITY ASSURANCE IN OPERATION**



## CONTENTS

1.	INTRODUCTION .....	279
	Background (101–102) .....	279
	Objective (103) .....	279
	Scope (104–105) .....	279
	Structure (106) .....	279
2.	MANAGEMENT .....	280
	Quality assurance programme (201–204) .....	280
	Grading (205–206) .....	280
	Organization (207–208) .....	281
	Interfaces (209) .....	281
	Training and qualification (210–211) .....	282
	Non-conformance control and corrective actions (212–214) .....	282
	Document control and records (215–217) .....	283
	Security (218) .....	284
	Transfer from commissioning to operation (219–222) .....	284
	Industrial safety (223–228) .....	284
	Fire protection (229–230) .....	285
	Emergency planning and preparedness (231–233) .....	285
	Human factors (234–235) .....	286
	Performance indicators (236–238) .....	286
3.	PERFORMANCE .....	287
	General (301–302) .....	287
	Line managers and supervisors (303–305) .....	288
	Planning (306–310) .....	289
	Working documents (311–315) .....	290
	Housekeeping and cleanliness (316) .....	291
	Measuring and test equipment (317) .....	291
	Shift changeover (318–321) .....	291
	Normal operating procedures (322–323) .....	292
	Temporary procedures (324–325) .....	292
	Emergency operating procedures (326–328) .....	293
	Verification (329–330) .....	293
	Surveillance (331) .....	294
	Testing (332–340) .....	294
	Software (341) .....	295
	Identification and labelling (342–343) .....	295

Equipment status and control (344–350) . . . . .	295
Temporary modifications (351–354) . . . . .	297
Fuel handling (355) . . . . .	297
Radioactive waste management (356–358) . . . . .	298
Plant maintenance (359–367) . . . . .	298
Maintenance shift changeover (368) . . . . .	300
Maintenance facilities and equipment (369) . . . . .	300
Control of external personnel (370–371) . . . . .	301
In-service inspection (372) . . . . .	301
Radiological safety (373–374) . . . . .	301
Environmental monitoring (375–376) . . . . .	301
Core management (377) . . . . .	302
Plant modification and design control (378–388) . . . . .	302
Plant history (389–394) . . . . .	304
Periodic safety review (395–400) . . . . .	305
Chemistry and radiochemistry (401–403) . . . . .	306
Condition monitoring (404) . . . . .	307
Review of operating experience (405) . . . . .	307
Procurement (406–408) . . . . .	308
Handling and storing (409–419) . . . . .	308
 4. ASSESSMENT . . . . .	 310
Management self-assessment (501) . . . . .	310
Independent assessment (502) . . . . .	310
 ANNEX I: EXAMPLES OF OPERATION ACTIVITIES WHICH MAY REQUIRE PROCEDURES . . . . .	  312
 ANNEX II: CONDITION MONITORING . . . . .	 314

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment on basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code) and complies with the requirements of the Code 50-C-O (Rev. 1).

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the operation stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the quality assurance (QA) programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate QA programmes in the operation stage of a nuclear power plant project or in any other stage where operation activities are to be performed. It covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the operation stage of a nuclear power plant. The operation stage overlaps with other nuclear power plant stages such as commissioning and decommissioning. The responsible organization may establish separate organizations for these stages or combine them under one organization. Whichever organizational arrangement is utilized the responsibilities and interfaces shall be clearly defined and understood and the status of the plant established at all times.

## STRUCTURE

106. This Safety Guide is arranged into four sections and two annexes:

Section 2 provides guidance on QA for the management activities of operation.

- Section 3 provides guidance on QA for the performance activities of operation.
- Section 4 provides guidance on QA for the assessment of operation activities.
- Annex I provides examples of operation activities which may require procedures.
- Annex II provides guidance on condition monitoring.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the nuclear power plant during operation. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. Procedures shall be defined by the responsible organization for control of operating activities at the site to ensure that operation of the nuclear power plant fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them controlled. A list of examples of operation activities which should require documented procedures is contained in Annex I.

203. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.

204. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the responsible organization if required. Recommendations on the documents required from the supplier for submission to the responsible organization and the timing of such submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme see Safety Guide Q1.

### GRADING

205. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded

approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

206. The operation activities which could be graded are:

- Level and detail of operating instructions
- Types of installed equipment requiring calibration
- Reporting level and authorities of non-conformances and corrective actions
- Need for formal shift operating logs
- Testing, surveillance and inspection activities
- Equipment to be included in plant status control
- Controls applied to the storage and records of spare parts
- Need to analyse plant history for items
- Need to carry out condition monitoring.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

207. The responsible organization should formally appoint a person on its staff to be responsible for operation activities.<sup>1</sup>

208. The appointed person should have the necessary resources within the operating organization to discharge the following responsibilities:

- Operating the plant within operational limits and conditions;
- Ensuring that all activities are carried out in accordance with statutory or regulatory requirements;
- Ensuring that all activities are carried out so as to assure safety of the public, personnel, plant and equipment.

## INTERFACES

209. Interfaces shall be described in the QA programme. Arrangements should be agreed between the operating organization and other organizations performing work at or in support of the nuclear power plant. The following examples of interfaces should be addressed:

---

<sup>1</sup> In some Member States the appointed person is the head of the operating organization.

- Divisions within the nuclear power plant (for example divisions responsible for nuclear safety, industrial safety, radiation protection and accident management);
- Personnel within a shift;
- One operating shift and another;
- The operating shift and management;
- The operating shift, maintenance and other on-site services;
- The plant management and off-site organizations;
- The plant management and the organizational unit responsible for design;
- The plant management and the emergency support organization;
- The plant management and the regulatory body (see the Code 50-C-G (Rev. 1));
- The plant management and the construction/commissioning organization.

For further guidance on interfaces see Safety Guide Q1.

## TRAINING AND QUALIFICATION

210. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

211. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training see Safety Guides Q1 and 50-SG-O1 (Rev. 1).

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

212. During operation, non-conformances shall be identified. They could be detected by:

- Routine observations of equipment performance and condition during normal operation and tests;
- Routine plant inspections and maintenance;
- Consumption of consumable materials by equipment (oil, gases or power);
- Personnel, work and processes monitoring;
- Monitoring of installed items (condition monitoring);
- Review of records of corrective maintenance or unavailability of equipment;
- Performance based assessments;
- Feedback of experience.

213. With account taken of safety, reliability, compliance with operational limits and conditions, frequency of occurrence and personnel competence, criteria should be developed for:

- Rating the priority and significance importance of non-conformances;
- Labelling non-conforming items, when applicable;
- Reporting non-conformances to the person in charge of plant operation;
- Involving the principal designer;<sup>2</sup>
- Determining what corrective work is to be done and when;
- Determining the need for cause analysis;
- Identifying those responsible for the above;
- Identifying potential for common cause failures.

214. Non-conformances having a significant or immediate impact on plant operation, such as limiting conditions for operation, should be reported to the shift supervisor.<sup>3</sup> For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## DOCUMENT CONTROL AND RECORDS

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

216. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of operation records.

217. Records should include all those which record the operating condition of components and systems. For further guidance on document control and records see Safety Guide Q2.

---

<sup>2</sup> The principal designer has responsibility for specifying the design requirements and for approving the design content on behalf of the responsible organization. Further explanation of the term 'principal designer' can be found in Safety Guide Q10.

<sup>3</sup> The title 'shift supervisor' denotes the individual in charge of shift operation for one or more units. The responsibilities of this individual and the title may vary depending on the organizational arrangements of Member States.

## SECURITY

218. Requirements for plant security are given in the Code 50-C-O (Rev. 1) and in Safety Guide 50-SG-O9.

## TRANSFER FROM COMMISSIONING TO OPERATION

219. Arrangements should be established and implemented to ensure that nuclear power plant components, systems and structures are formally transferred from the commissioning organization to the operating organization. It should be ensured that:

- Components and systems are checked for proper identification, completion of commissioning tests and inspections, cleanliness, lubrication, positioning of switches and valves, calibration of instruments, lagging condition, absence of leaks and proper status of safety devices;
- Non-conformances and other open issues have been resolved;
- Commissioning documentation is complete;
- The as-built condition of the plant is defined.

220. There should be a documented transfer of components, systems and structures and the related records from the commissioning organization to the operating organization. The status of components, systems and structures should be included in the transfer documents.

221. Operating personnel should ensure that the transfer documents are correct and complete.

222. Similar arrangements need to be established to transfer components, systems and structures from the operating organization to the decommissioning organization. For further guidance on the transfer from commissioning to operation see Safety Guide 50-SG-O4.

## INDUSTRIAL SAFETY

223. A policy reflecting Member State industrial safety regulations should be established for all personnel, suppliers and visitors, and should refer to the industrial safety rules and practices that are to be adopted. The policy should include arrangements for the effective planning, organization, monitoring and review of the preventive and protective measures.

224. The operating organization should provide support, guidance and assistance for plant personnel in the area of industrial safety.

225. Nuclear power plant personnel should understand how the industrial safety programme affects their individual work practices.

226. Industrial safety data should be monitored. Examples of items to be monitored include lost-time accidents, other accidents requiring medical attention, industrial safety non-conformances identified in the plant, and modifications resulting from industrial safety concerns.

227. The underlying causes of industrial accidents and industrial safety problems should be identified and corrected. Results of cause analyses should be used to identify opportunities to improve industrial safety. Lessons learned from investigations and from other industry operating experience should be used to improve performance.

228. Applicable industrial safety information should be obtained and screened. Relevant material and any required actions should be incorporated into the plant's industrial safety policy and disseminated to other nuclear power plants.

## FIRE PROTECTION

229. The operating organization shall establish and implement a fire prevention and protection programme to protect personnel and items. The programme should provide methods and effective means for preventing, detecting, controlling and promptly extinguishing fires, and should be consistent with Member State regulatory requirements. The programme should also contain measures for controlling generation, storage and disposal of combustible materials.

230. Periodically, drills and exercises should be conducted to confirm the fire protection programme's implementation and effectiveness. For further guidance see Safety Guide 50-SG-D2 (Rev. 1).

## EMERGENCY PLANNING AND PREPAREDNESS

231. Reference emergency conditions shall be identified and the organizational infrastructure required for coping with them developed.

232. Resources and facilities for emergencies shall be made available, and personnel should receive continuing training by testing of emergency plans and procedures, and through drills and exercises, and public information activities.

233. Emergency plans and procedures should be revised and improved as a result of feedback from drills and exercises. For further guidance see the Code 50-C-O (Rev. 1) and Safety Guides 50-SG-O6 and 50-SG-G6.

## HUMAN FACTORS

234. Suitable working environments shall be provided and maintained so that work can be carried out safely and satisfactorily, without imposing unnecessary physical and psychological stress on the plant personnel.

235. Human factors which influence the working environment and the effectiveness and fitness of personnel for duty should be identified and addressed. This includes, for example:

- The adequacy of resources, support and supervision needed to manage and perform the work;
- The adequacy of lighting, access and operator aids;
- The adequacy of alarms; such as number, position, grouping, colour coding, audibility prioritizing;
- The frequency and clarity of communications;
- The availability of suitable tools and equipment;
- The limits on the duration of work time for operators, maintainers and technical advisers;
- The attention needed to be given to other factors for control room staff, including personnel well-being, psychological, physiological and attitudinal problems, shift patterns and meal breaks.
- The availability of procedures that take into account human factor considerations.

## PERFORMANCE INDICATORS

236. The operating organization is responsible for identifying and monitoring parameters which provide information regarding nuclear safety, operational performance and the effectiveness of management processes. Performance indicators comprise data collected from all of these parameters. They can be used to make comparisons

with other nuclear power plants to identify improvement opportunities. Some regulatory and industry organizations may require that specific performance indicators be measured and reported periodically.

237. Performance indicators should be used as tools for involving plant personnel in improving performance and safety. Performance indicators should be established to help minimize or reduce the following:

- Unplanned challenges to safety related systems,
- The number of forced outages,
- Plant and equipment unavailability,
- Personnel errors,
- Lost-time accidents,
- Radiation exposure;
- Contamination,
- The production of radioactive waste,
- The amount of rework,
- The number of outstanding work requests,
- Failure rates of equipment and components,
- The effects of plant ageing,
- Incidents and unusual events;
- Non-conformance with operating limits and conditions.

238. The results of performance indicators and other related information should be trended and reported to provide feedback on plant performance. The reports should include trends of the indicators with a brief explanation for trends that appear to be unusual (positively or negatively), with any proposed corrective actions where necessary.

### **3. PERFORMANCE**

#### **GENERAL**

301. Operating personnel are responsible for operating the nuclear power plant in accordance with operational limits and conditions (see Safety Guide 50-SG-O3). Work that can affect safe and reliable operation shall be approved and carried out with full knowledge of the control room staff.

302. Good practices in operation should be applied and include, for example:

- Acknowledging, analysing for priority and responding to alarms;
- Eliminating the causes of alarms;
- Maintaining plant logs on the key operating and safety parameters and key event categories;
- Acting professionally in the control room by paying attention to access, house-keeping and general conduct;
- Optimizing the amount of paperwork and paper reference material in the control room;
- Communicating information on operation activities to other plant personnel;
- Being prepared for emergency situations.

#### LINE MANAGERS AND SUPERVISORS

303. As part of their daily responsibilities, line managers and supervisors should review the conduct of work under their responsibility. To do this, they should keep abreast of general plant conditions, monitor work to ensure it is being conducted safely and in accordance with requirements, ensure non-conformances are identified and resolved, and be alert to improvement opportunities.

304. Line managers and supervisors should periodically evaluate plant operation and documents, examine non-conformances, and evaluate the implementation of corrective actions in order to assist in the planning of future work.

305. Supervisors should recognize and encourage good work practices by promoting the following:

- Attention to detail;
- Good industrial safety practices (for example appropriate use of safety equipment, proper handling of hazardous chemicals);
- Radiological protection practices, for example proper use of ALARA concepts and minimizing the spread of contaminants;
- Proper use of pre-job briefings and applicable training (for example mock-up training);
- Adherence to documents and compliance with work hold points;
- Accountability for tools, chemicals and materials;
- Use of correct tools and equipment;
- Use of decontamination facilities to reduce the volume of radioactive waste,

- permit clean work on formerly contaminated equipment and reduce contamination on reusable items;
- Use of glove boxes or temporary containments for work on contaminated equipment to prevent airborne contamination or the spread of contamination;
- Clean and orderly work sites;
- Sensitivity to the time required to perform work, especially if a limiting condition for operation is involved;
- Proper use of post-job reporting and, when applicable, post-job critiques.

## PLANNING

306. Arrangements shall be established and implemented to ensure that work at the nuclear power plant is properly planned and completed in a safe and efficient manner. A computer aided planning system is desirable. Planning shall, for example:

- Identify the work necessary to operate and maintain the nuclear power plant;
- Identify the relative importance of the work processes, using a graded approach;
- Describe the performance of work by referencing clear, concise and unambiguous work instructions;
- Identify any special requirements that are part of the work process, such as radiation protection, fire protection, isolation and tagging requirements, and inspection and testing requirements;
- Identify the required records, such as work completion and spare parts used;
- Identify the status of work;
- Identify if the work is safety related or not;
- Identify any related safety hazards;
- Ensure the work is authorized;
- Estimate personnel requirements and any special training needs;
- Specify any reviews required upon completion.

307. A work request system should be used to facilitate and control work, by ensuring that work is systematically planned, accomplished and documented.

308. The planning system should list and be able to sort all work requests on the basis of work description, priority assigned, date initiated and configuration requirements to perform the work. The system should be able to track the status of all work requests, in particular those on hold for planning, spare parts, materials or other constraints. The system should be capable of tracking completion of testing prior to return to service.

309. Detailed planning for outages should be accomplished and a tracking system should be used to monitor completion status and to ensure controlled execution of outage activities. Outage planning should be a continuing process involving the next scheduled outage and several future outages. Milestones should be developed and used to track the progress of pre-outage work. Planning should be completed as far in advance as possible, as circumstances may cause the outage to begin earlier than planned.

310. The outage plan should include an overall plan to control and properly sequence outage tasks. Sufficient detail should be included to co-ordinate the work and track progress. The schedule forms the basis for outage progress reporting. A review should be conducted after each outage to seek to improve the strategy for the next planned outage.

## WORKING DOCUMENTS

311. Prior to the performance of work, suitable documents shall be provided to enable personnel to carry out their tasks correctly, safely and efficiently.

312. Personnel should be aware that they are responsible for performing assigned tasks in accordance with these documents.

313. Vendor supplied documents, such as operating, maintenance, test and calibration instructions, and approved drawings with acceptance criteria, could provide suitable instructions. In that case, the applicable sections should be specified in plant documents.

314. Personnel should be made aware of the process for reporting non-conformances in working documents and encouraged to report any such non-conformances.

315. The detail of working documents should strike a balance between written instructions and personnel competencies and be based on the complexity, periodicity and importance of the work being described. For example, startup procedures should include provisions for determining that certain prerequisites have been met, including confirmation that instruments are operable and properly set; valves are properly aligned; required procedures, tests and calibrations have been completed; and required approvals have been obtained. Working documents should provide sufficient flexibility to accommodate variations in the work methods but define any limitations (technical, managerial, etc.). For further guidance on working documents and their development see Safety Guides 50-SG-O9, Q1 and Q3.

## HOUSEKEEPING AND CLEANLINESS

316. Maintaining plant cleanliness should be considered an essential activity, and standards for housekeeping and cleanliness should be established to:

- prevent contamination of items and protect open systems and equipment from foreign material during maintenance and modification;
- require the removal of contaminants and the prevention of contamination;
- control the movement of materials, equipment, tools and personnel in and out of work areas;
- ensure that cleanliness inspections are performed immediately prior to system/component closure;
- reduce the risk of conventional accidents such as fires.
- minimize the risk of injuries.

## MEASURING AND TEST EQUIPMENT

317. Equipment used for monitoring the operation of plant systems, and for data collection, inspections and tests, shall be of the proper type, range, accuracy and precision and be in good condition (see Safety Guide 50-SG-Q4).

## SHIFT CHANGEOVER

318. Shift changeover shall be carried out according to a formal process. An account of plant and work status is usually presented in reports and logs which follow a standard format.

319. The process of shift changeover should identify the persons involved, their responsibilities, the locations and the conduct of shift changeovers, and the method of reporting plant status, including provisions for special circumstances such as abnormal plant status and staff unavailability.

320. Shift changeover should address the following:

- Operating status of major components and systems;
- Significant safety and general plant parameters (including any identified trends);
- Systems in an abnormal or degraded configuration; testing anomalies;
- Significant new defects since supervisor's previous shift;

- Schedules and duration of current and planned work, outages and work permits;
- Special instructions from the operating organization;
- Temporary operating instructions, design changes and notices;
- Handover of keys;
- Review of logs.

321. On shift changeover, the incoming control room operator should inspect the control panels, observing the following:

- Annunciations in alarm condition,
- Equipment in abnormal condition,
- Trends shown on data recorders,
- Indications of key safety parameters.

#### NORMAL OPERATING PROCEDURES

322. The following typical operating procedures should be provided:

- Initial startup and startup after refuelling, from cold or hot conditions and after reactor trips
- Controlled shutdown and reactor trip
- Steady state power operation
- Fuel loading and unloading
- Load changing
- Testing.

323. Procedures are also required to enable the operator to correct alarm conditions for those events where system complexity might lead to operator uncertainty. For further guidance see Safety Guide 50-SG-O9.

#### TEMPORARY PROCEDURES

324. Temporary procedures/instructions may be issued only when permanent procedures do not exist. The document control requirements for temporary procedures should be the same as the controls applied to permanent procedures. Acceptable occasions for temporary procedures are as follows:

- Providing guidance in unusual situations not within the scope of the normal procedures;

- Ensuring orderly and uniform operation for short periods when a system or a component is performing in a manner not covered by existing procedures or has been modified or extended in such a manner that portions of existing procedures do not apply.

325. Temporary procedures should designate the period of time during which they may be used. Their status should be periodically (typically at monthly intervals) reported to the plant management together with any numerical trends.

## EMERGENCY OPERATING PROCEDURES

326. Expected emergency conditions shall be identified and procedures for dealing with them prepared for use when required.

327. Since emergencies may not follow anticipated patterns, the procedures should provide for sufficient flexibility of actions to accommodate variations, including multiple and sequential failures.

328. The objective of emergency procedures is to return the plant to a condition covered by normal procedures or to provide for a safe extended shutdown period under emergency conditions.

## VERIFICATION

329. Operating items, services and processes requiring periodic verification shall be identified in operating procedures or other relevant documents. The following are typical operating activities that are subject to verification:

- Important operating manoeuvres;
- Restoration following maintenance or testing;
- Run-in following repair or maintenance;
- Status of the systems needed for startup;
- Equipment operation during testing;
- Equipment line-ups;
- Availability of stand-by components;
- Work that affects personnel safety.

330. Normal alignment should be confirmed by a combination of functional tests, performance tests and physical verification. Physical verification should not be used where it would result in excessive radiation exposure.

## SURVEILLANCE

331. A surveillance programme shall be established and implemented. It should consist of planned activities carried out to verify that the plant is operated within the operational limits and conditions and to detect in time any deterioration of items that could result in an unsafe condition (in some Member States surveillance is referred to as performance monitoring). For further guidance on surveillance see Safety Guide 50-SG-O8 (Rev. 1).

## TESTING

332. The following categories of tests should be conducted:

- Tests during the initial operation stage,
- Surveillance tests during the operation stage,
- Functional tests during the operation stage.

333. Tests during the initial operation stage are performed to:

- demonstrate the performance of systems and components that could not be tested prior to operation;
- confirm or determine those parameters and characteristics that need to be known but which could not have been accurately predicted;
- confirm that the plant conforms to applicable design and safety requirements.

334. Surveillance tests during the operation stage are performed to:

- ensure that systems and components are available to operate as designed;
- detect degradation;
- provide data for refining system reliability calculations;
- reveal unsatisfactory trends in the performance of individual components or component types on a long term basis.

335. The scope and frequency of surveillance tests should be specified and shall be consistent with regulatory requirements.

336. Functional tests during the operation stage are used to demonstrate satisfactory performance following maintenance, modification, replacement or significant procedural changes.

337. Operating parameters for testing shall be prescribed. If a test requires the parameters to be outside of their normal range, their limits shall also be prescribed.

338. Parameters such as direction of rotation, bearing temperatures, vibration, time delays and ability to operate with remote and local controls should be examined during functional surveillance tests.

339. The recording and presentation of testing results should permit easy comparison with previous tests and the detection of changes from previous tests and from the reference values measured during equipment commissioning.

340. Non-conformances found during testing should be analysed and systematically corrected within specified time limits in order to restore operability and to decrease the probability of recurrence.

## SOFTWARE

341. Computer software that could affect safe and reliable plant operation should be validated and periodically tested to ensure continued computer program integrity.

## IDENTIFICATION AND LABELLING

342. Plant areas and installed items shall be uniquely and permanently labelled to provide plant personnel with sufficient information to positively identify them.

343. The identification should be consistent with the identification codes and terminology used in operation documents.

## EQUIPMENT STATUS AND CONTROL

344. The control room staff shall be informed of, and approve, work in the plant affecting the status of systems and components. Operators should be kept informed of the plant status by:

- Operator surveillance
- Communications
- Checklists
- Logkeeping
- Records of alarms
- Reports of abnormal system conditions
- Reports on defective equipment

- Shift changeover briefings among the operating crew
- Work authorization and tagging systems
- Control of temporary and permanent plant modifications.

345. There shall be a system to confirm plant configuration. Control measures, such as locking and tagging, should be documented and be used to ensure the protection of personnel and equipment during maintenance, modification and testing and to prevent inadvertent operation. The positions of valves, switches and other items important to safe operation shall be known.

346. Work authorization procedures should clearly define the responsibilities related to equipment isolation, post-maintenance testing and restoration to service. Procedures should be implemented to control the placement and removal of caution, warning and information tags installed on equipment for the protection of personnel or equipment. Tags should be periodically reviewed for accuracy and continued applicability.

347. Prior to granting permission for work, operating personnel should verify that the system or component can be released, determine how long it may be out of service, and determine what functional testing or redundant systems are required prior to and during the out-of-service period. Granting of such permission should be documented. Potential nuclear power plant or system degradation should be considered when a subsystem is to be removed for maintenance or surveillance testing to ensure that the nuclear power plant configuration is not outside the operational limits and conditions.

348. When systems or components are removed from service, confirmation should be specified to the extent necessary to ensure that the proper item was removed. This may be carried out by independent physical confirmation of the appropriate equipment and controls, along with the use of appropriate tags and records, or by indirect means, such as observation of indicators and status lights. The confirmation may be waived if the only way of accomplishing it would result in excessive radiation exposure.

349. When systems or components are ready to be returned to service, operating personnel shall confirm its functional acceptability. Attention should be given to the restoration of normal conditions, such as: removing jumpers used during maintenance or testing; returning valves, breakers or switches to proper startup or operating positions from “test” or “manual” positions; and ensuring that all alarms which are indicative of inoperative status are extinguished.

350. The status of inspections, calibrations and tests performed on individual systems or components in the nuclear power plant should be indicated by the use of markings such as stamps, tags, labels, routing cards or other suitable means, including identification numbers which are traceable to records of the status of inspections, calibrations and tests. Control room indicators and operating devices that are out of service should be appropriately tagged or labelled.

## TEMPORARY MODIFICATIONS

351. The operating organization shall establish a system to control temporary modifications, such as temporary by-pass lines, electrical jumpers, lifted electrical leads, temporary trip-point settings, temporary blank flanges and temporary defeats of interlocks. The system should provide for the necessary authorizations, precautions, documentation and removal of temporary modifications.

352. Line management should periodically review outstanding temporary modifications to confirm their continued need and to check that operating procedures, instructions, drawings and operator aids conform to the approved configuration. Immediate action should be taken to remove those whose need has passed. The status of temporary modifications should be periodically (typically at monthly intervals) reported to the plant manager.

353. The authorization of proposed temporary modifications shall ensure that they do not involve or cause a change in the approved operational limits and conditions or result in an unreviewed safety question. The review of proposed additional temporary modifications should also consider existing temporary modifications and the effect of the proposed change.

354. The number of temporary modifications should be minimized. A time limitation should be specified for their placement.

## FUEL HANDLING

355. Fuel handling shall be carried out under controlled conditions from the time of receipt of fuel through core loading, approach to criticality, on-line refuelling, and fuel removal, storage, transportation and disposal. For further guidance on fuel handling see the Code 50-C-O (Rev. 1) and Safety Guide 50-SG-O10. Additional details are contained in IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material.

## RADIOACTIVE WASTE MANAGEMENT

356. The generation of radioactive waste should be minimized and provisions made for the safe handling, storage, transport and disposal of radioactive waste liquids, solids and gases.

357. The control of radioactive wastes should ensure they are within authorized limits and conditions and should include for example:

- Identifying the source,
- Segregating the waste,
- Identifying quantities and activity levels,
- Carrying out treatment and conditioning,
- Using appropriate packaging and transportation methods,
- Establishing correct storage and disposal,
- Maintaining inventories,
- Preventing unauthorized access,
- Generating records.

For further guidance on radioactive waste management see Safety Guide 50-SG-O11.

358. The operating organization is responsible for ensuring that the transportation of radioactive waste to a licensed repository satisfies regulatory requirements, and that the wastes conform to the disposal requirements of the repository and the regulatory body. For further guidance on the transport of radioactive material see Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material.

## PLANT MAINTENANCE

359. Before commencement of operation, the operating organization shall prepare a maintenance programme. The maintenance programme should be developed during the pre-operational stages. It should be prepared by personnel with maintenance experience. Pertinent information from designers, manufacturers and other operating organizations should be used.

360. Successful implementation of the maintenance programme requires the following:

- Planning and prioritization of maintenance work;
- Availability of qualified personnel with suitable skills;
- Practicable maintenance procedures;

- Availability of spare parts;
- Availability of special tools and equipment;
- A satisfactory working environment, including isolation, work protection and consideration of radiation hazards;
- Performing the required inspections and tests.

361. To assist in selecting and scheduling maintenance work, the programme should establish an equipment database for plant equipment which records the following:

- Identity of the manufacturer,
- Model number of each item,
- Relevant information, such as vendor manuals and drawings, spare part reference numbers, and cross-references for equipment which is common to various systems.

362. Corrective maintenance (the repair and restoration of defective items) is normally carried out using a work control system. In cases where the defective item affects the safe and reliable plant operation, the deficiency should be brought to the attention of the control room staff and where appropriate to the management of the operating organization.

363. The frequency and severity of item failures should be recorded and analysed to identify the causes of the failures and to look for common mode failures. This information should be used as input to the preventive maintenance programme.

364. A preventive maintenance programme which prescribes the frequency and type of maintenance to be performed should be devised. Preventive maintenance includes measurement and analysis of the condition of equipment to predict its failure. Preventive maintenance typically includes:

- Lubrication
- Filter changes
- Replacement of consumable items
- Elimination of leaks
- Checking of protection from hostile environment
- Checking of equipment condition
- Vibration analysis
- Thermography
- Periodic calibrations or checking of calibrations.

365. Preventive maintenance actions that are deferred beyond specified time intervals should be reviewed, and approval obtained. This deferral should be reported periodically to the plant manager.

366. Plant maintenance work should be monitored and trends evaluated to identify necessary improvements. The following maintenance performance indicators should be considered:

- Unit forced outage rate,
- Availability of the same component in other systems,
- Availability of safety systems,
- Unplanned automatic scrams,
- Radiation exposure to personnel conducting maintenance activities,
- Injuries and accidents to personnel conducting maintenance,
- Maintenance backlog (corrective and preventive maintenance),
- Overtime worked by personnel involved in plant maintenance,
- Assessment results in maintenance areas.

367. The operating organization should participate in the maintenance process by:

- Frequent personal contact with maintenance staff, including the observation of work in progress;
- Establishing and implementing a set of maintenance performance indicators;
- Participating in evaluations of the maintenance process;
- Providing feedback derived from maintenance performance indicators for plant operations.

For further guidance on maintenance see Safety Guide 50-SG-O7 (Rev. 1).

## MAINTENANCE SHIFT CHANGEOVER

368. A formal shift changeover process shall be implemented by maintenance staff. The principles used by operation staff should be applied to ensure that the status of work in progress at shift changeover is understood. The use of log books is recommended.

## MAINTENANCE FACILITIES AND EQUIPMENT

369. Maintenance facilities and equipment shall be adequate to ensure that preventive and corrective maintenance can be performed effectively during operation, refuelling and major outages. Provisions, for example design change control, shall be made to ensure that additional building services, such as electrical, compressed air and water requirements for major temporary facilities, do not overload or compromise installed systems (see Safety Guide 50-SG-O7 (Rev. 1) for additional details).

## CONTROL OF EXTERNAL PERSONNEL

370. Personnel who are not dedicated to the nuclear power plant specific areas and personnel of external suppliers (external personnel) who perform maintenance or modifications on plant systems should be appropriately trained and qualified for the work they are to perform. These personnel shall receive general employee training and specific training in appropriate nuclear power plant procedures and practices. Adequate time should be provided for this training. Experienced and qualified personnel could be allowed to bypass training by proving proficiency.

371. External personnel should perform maintenance under the same controls as, and to the same work standards as, nuclear power plant maintenance personnel. Plant supervisors should review the work of these personnel during preparation for work, at the job site, and during post-maintenance testing and acceptance inspection.

## IN-SERVICE INSPECTION

372. Before commencement of operation, an in-service inspection programme shall be prepared for implementation during the operating life of the plant to detect possible deterioration. For further guidance on in-service inspection see the Code 50-C-O (Rev. 1), and Safety Guides 50-SG-O2 and Q4.

## RADIOLOGICAL SAFETY

373. A radiation protection programme should be established and implemented.

374. Radiation exposure trends should be determined for each working group, area and activity. Annual goals should be established for radiation exposures to be made as low as is reasonably achievable. For further guidance see Safety Guide 50-SG-O5.

## ENVIRONMENTAL MONITORING

375. The methods and procedures for controlling and monitoring radioactive effluents on and off the site to maintain levels within operational limits and conditions shall be documented before plant operation. The site monitoring should start well before the plant startup.

376. Discharge pathways for radioactive releases and toxic releases to the environment shall be identified and monitored in accordance with details to be found in Safety Guides 50-SG-O5, 50-SG-O9 and 50-SG-O11.

## CORE MANAGEMENT

377. Core loading, approaches to criticality, and safe and optimum operation of the reactor core without exceeding operational limits and conditions are carried out in accordance with the requirements of the Code 50-C-O (Rev. 1) and the recommendations given in Safety Guide 50-SG-O10.

## PLANT MODIFICATION AND DESIGN CONTROL

378. All personnel should be able to identify the need for a modification and report this need by submitting a design change request in accordance with modification procedures. Such requests should be subject to approval in accordance with plant procedures. Requests should be evaluated on the basis of their impact on plant safety and reliability, plant operation and performance, personnel safety and regulatory requirements. Considerations should include the requirements of training upgrades and associated hardware. Unnecessary changes should be screened out, and approved changes appropriately prioritized. Request originators should be informed of the status of their requests. The status of requests should be tracked through the modification process to ensure that associated work is completed. The backlog of modifications should be reviewed periodically and kept to a minimum.

379. An organizational unit should have overall responsibility for design changes. The organization responsible for maintaining design integrity should review and approve design changes. Design changes should be developed with plant input and should include a functional description of the modification, a validation that the proposed modification will solve any relevant problems, and a safety review that includes design inputs and plant safety considerations.

380. Work (for example design, procurement, installation) related to each modification request should be adequately scheduled and tracked through to confirmation of completion. Plant management should be kept informed of the status of this work and appropriate action should be taken to meet schedules. The monitoring of the modifications through review, approval, design, implementation, testing and closeout should be carried out to ensure that modifications are completed in accordance with plant priorities.

381. Modifications scheduled for outage work should be ready for implementation in advance of the outage. Sufficient time should be allowed for final reviews, preparation of materials, isolations, installation procedure preparation, workforce

scheduling, co-ordination of support work such as radiological controls and component isolations, and scheduling of post-modification testing.

382. The detailed design package for modifications should specify construction, installation, testing, environmental qualification, and functional testing requirements and test acceptance criteria. Designers should visit and examine the plant for the modification to identify and eliminate interferences and operating and maintenance problems, and to ensure that the field installation is accurately reflected on as-built drawings. Configuration control methods should exist to ensure that modifications in the same location do not conflict when installed, for example by using the same space, penetration or hanger.

383. Operability, maintainability, constructability, testability, human factors, ALARA principles and regulatory requirements should be considered throughout the modification process. The design change should be reviewed by those directly concerned and comments compiled and resolved by the design organization and other technical staff as appropriate. Industry and in-house operating experience, including procurement of equipment, should be considered.

384. Modification package reviews should ensure that previous plant modifications and industry experience inputs are not inadvertently deleted by the modifications. A safety review should be part of the technical review.

385. Procedures, instructions and acceptance tests should be used during the installation of modifications to ensure that the design requirements are met. Hold and inspection/witness points should be established when applicable during modification installation and testing.

386. Completed installations and system acceptance test results should be reviewed and verified against the approved design, by the designer, prior to plant acceptance of the modified system/component. Acceptance tests should include specific acceptance criteria based on performance criteria and testing requirements specified as part of the modification process.

387. Design documents (for example drawings, specifications) that have been revised or developed from the modification process should be subject to the requirements of configuration control. Changes to these documents should be traceable to the modification and submitted for approval prior to formal revision.

388. Training should be conducted to ensure that appropriate operation and maintenance personnel are familiar with modified systems and sufficiently knowledgeable

to operate and maintain that equipment in a safe and reliable manner. Appropriate training should be completed prior to the operation or maintenance of the modified system and should include required reading, pre-shift briefings or formal training, depending upon the complexity of the modification and its impact on plant operation and maintenance. Training packages (including plant simulators and their software) should be revised to reflect modifications. If major equipment changes are a part of the modification, associated hardware procurement and modifications necessary to support training should be developed in conjunction with the detailed design package.

## PLANT HISTORY

389. The plant history should contain data from the following subject areas:

- Operational performance
- Maintenance history file
- Inspections and tests
- Radiological protection
- Radioactive effluents and wastes.

390. The plant history system should identify the items for which historical data need to be collected. This compilation of data should provide an engineering database to permit easy cross-reference to information such as the equipment unique identification number and name, system, manufacturer, manufacturing records, model, serial number, other appropriate name plate data, lubrication data, applicable vendor manuals and drawings, spare parts reference numbers and common equipment.

391. The plant history system should define the type of data that should be collected and recorded, for example: operational parameters, incidents, reactor trips, malfunctions and transients, corrective maintenance records, preventive maintenance records, modification packages, repair information, startup test and other baseline data, appropriate surveillance test data, calibration data, spare parts information and applicable industry experience information.

392. Completed work records should be reviewed for retention requirements and applicable data entered in the plant history programme. Any apparent errors, inconsistencies or lack of detail should be referred back to the maintenance supervisor or another appropriate supervisor for resolution.

393. Maintenance planners, co-ordinators, supervisors and craftsmen should use plant history on a routine basis for maintenance planning to provide data such as previous maintenance work and results, special tool needs, type and quantity of lubricants needed, workforce and time requirements, parts information, and procedure or instruction needs.

394. These planning activities can be carried out manually or with automated analysis techniques. Persistent or recurring equipment and system problems should be reported to maintenance or technical support supervisors for corrective actions. These reviews can also help identify areas where decreased maintenance effort is warranted (for example, reduced preventive maintenance frequency). Plant history data should be used for:

- Failure analysis (provide some of the data needed to support the analysis and trending of failures);
- Conduct of maintenance assessments (provide an input to identify rework for the purpose of identifying maintenance programme improvements);
- Preventive maintenance (provide some of the data useful for identifying and justifying preventive maintenance programme changes);
- Outage planning (provide some of the data useful for post-outage evaluation and as a basis for planning the next outage);
- ALARA programme (provide work time data useful for radiological exposure evaluation and planning);
- Review of industry experience and vendor information;
- Extension of plant design life (life extension);
- Periodic safety review.

For further guidance see Safety Guide 50-SG-O12.

## PERIODIC SAFETY REVIEW

395. Periodic safety reviews should be performed to substantiate continued safe and reliable plant operation.

396. The responsible organization should define the scope and objectives of each safety review.

397. The review process should:

- confirm that the nuclear power plant and individual items are safe for a defined period of future operation;

- assess the effects of ageing in order to conservatively estimate the ability of items to perform safely during the defined period;
- identify and evaluate factors that could limit safe operation during the defined period;
- compare the original design safety case against current safety standards and requirements;
- identify improvements that are reasonably achievable.

398. The inputs to the review should include: operational performance data; results from in-service inspection; ageing and testing programmes; plant radiation levels; radiological and industrial safety performance; and planned and unplanned releases to the environment.

399. Any proposals arising from the review, such as plant modifications, changes to operational limits and conditions, and maintenance or test procedures, should be processed accordingly.

400. The results of periodic safety reviews should be used, for example, to:

- confirm that the nuclear power plant or individual items can be operated safely for a defined period of future operation;
- identify and evaluate factors that could limit safe operation during the defined period;
- revise the existing safety case to satisfy current safety standards and requirements;
- provide input to life extension studies.

## CHEMISTRY AND RADIOCHEMISTRY

401. Management should ensure that chemistry and radiochemistry work provides optimum protection for plant systems and materials. The requirements for chemistry and radiochemistry work should include:

- Chemistry and radiochemistry specifications, and actions required if specifications are exceeded,
- Performance specifications for equipment used to analyse or control water purity,
- Accuracy criteria for analyses,
- Chemistry and radiochemistry quality control,
- Goals for improvement in chemistry and radiochemistry.

402. The objective of these requirements is to ensure:

- continued safe operation,
- lifetime integrity,
- minimum corrosion and the build-up of radioactive contamination,
- minimum release of effluents to the environment.

403. Chemistry and radiochemistry work normally consists of:

- Monitoring, sampling and trending chemistry and radiochemistry parameters at specified frequencies to ensure the timely detection and correction of abnormal or unacceptable trends and conditions;
- Evaluating chemistry data to identify control problems and analytical errors, and to correct them;
- Controlling of laboratory conditions, practices, equipment and materials to ensure the accuracy of analytical results;
- Ensuring the proper handling, storage, use and disposal of bulk chemicals, spent resins, laboratory chemicals, corrosive agents and cleaning agents.

## CONDITION MONITORING

404. Monitoring of installed items should be carried out during the operation stage to confirm their satisfactory condition. Equipment, monitoring frequency, criteria and monitoring methods should be identified and should include, for example, those presented in Annex II. Information from condition monitoring should be fed back to those responsible for the review of the maintenance programme and used to improve performance.

## REVIEW OF OPERATING EXPERIENCE

405. The feedback of operational events at nuclear power plants is necessary to improve safety. Management should provide sufficient resources and dedicated personnel for the evaluation and feedback of operating events, including those from other plants. Management should clearly define responsibilities and should be sufficiently involved to ensure completion of any improvements and corrective actions arising (see the Code 50-C-O (Rev. 1)).

## PROCUREMENT

406. During the operation stage the following unique conditions may arise:

- (1) It may not always be desirable to procure replacement items to the same technical requirements that were applied in the procurement of the original item. In this situation, the items should be procured to requirements equivalent either to those specified for the original equipment or to those requirements specified by a properly reviewed and approved version of these requirements which may have resulted from an updating of original codes and standards.
- (2) It may not be possible to establish what technical requirements were specified for the original procurement. In this situation, an engineering evaluation should be conducted and new technical requirements established and documented. Care shall be exercised to specify performance requirements at least equivalent to the original performance requirements. This evaluation shall take into account interfaces and interchangeability, and ensure that safety functions are not adversely affected and that they are in accordance with regulatory or code requirements.
- (3) Replacement parts may be no longer available. In this situation, the parts may be manufactured on the site provided that all the requirements specified for the original part can be satisfied; or substitute items, including those of commercial grade, may be acquired following approval by the organizational unit having overall responsibility for design.

407. In all these situations, an engineering evaluation should be undertaken to determine if QA requirements are appropriate and whether they should be included in the technical specifications. If the original item was procured without specifically identified QA requirements, then, after a review of the nature and application of the item, it may be appropriate for spare and replacement parts to be similarly procured.

408. Optimum inventory stock levels of spare parts should be maintained. "Minimum/maximum" quantities of spare parts should be established for prompt reordering when the minimum has been reached. These limits should be reviewed periodically (for example, annually or upon each reorder) and adjusted on the basis of usage, maintenance experience, cost and lead time. For further guidance see Safety guide Q6.

## HANDLING AND STORING

409. Items shall be controlled to ensure that only correct items are used in the nuclear power plant. For this purpose, items should be identified. Physical identification

should be used to the extent possible and the identification should be transferred to each part of an item before it is subdivided.

410. Substitution of items should be controlled. Approval to use substitute items should be based on an engineering evaluation of the new items. This would include the use of commercial grade parts or materials in applications that have an impact on the safe operation of the plant.

411. Provisions should be made to prevent the damage, deterioration or loss of items. For this purpose, items should be stored in a manner that provides for ready retrieval and protection. Storage should be controlled to prevent deterioration of degradable material, such as O-rings and instrument diaphragms.

412. Preventive maintenance of items held in storage should be performed on items such as large pumps and motors, including periodically checking energized heaters, periodically changing desiccants, rotating shafts on pumps and motors, changing oil on rotating equipment, and other maintenance requirements specified by the vendor.

413. Items removed from or placed into stores, including surplus material returned to store, should be promptly documented so that the stores inventory is accurate. The stores record system should also indicate the location of materials and parts in the warehouse, stores issue room or other designated storage areas.

414. An item whose shelf-life has expired should be discarded unless an engineering evaluation is conducted and engineering approval obtained prior to use of the item.

415. For critical, sensitive, perishable or high value items, special coverings, equipment and protective environments, such as inert gas atmospheres, moisture and temperature control, should be specified and provided. These measures could also be applied to installed items subject to extended out-of-service conditions.

416. Controls should also be established for field storage of consumables such as lubricants and solvents to ensure they are properly stored and identified.

417. Storage practices should ensure that:

- corrosive chemicals are well segregated from equipment and metal stock;
- flammables are properly stored;
- radioactive material is properly controlled;

- stainless steel components are protected from halogens and from direct contact with other metals, particularly carbon steel;
- relief valves, motors and other equipment are stored on their bases;
- containers (boxes, barrels, crates) are stacked to reasonable heights and in accordance with vendor and storage instructions;
- parts, materials and equipment are repackaged, or protective caps reinstalled to seal items on which previous packaging or protective caps have deteriorated, or been damaged or lost while in storage;
- elastomers and polypropylene parts are stored in areas not exposed to light;
- machined surfaces are protected;
- equipment internals are protected from the ingress of foreign materials;
- material, equipment and storage facilities are properly protected from rodents;
- there is suitable segregation of safety related and non-safety-related components.

418. Access to storage areas should be restricted.

419. Items removed from storage shall be protected. Handling of items should consider factors such as weight, size, certification and regular inspection of hoisting/lifting equipment, chemical reactivity, radioactivity, susceptibility to physical shock, damage or electrostatic sensitivity, sling location, balance points and method of attachment. Special handling tools and equipment should be provided, controlled and inspected periodically as necessary to ensure safe and adequate handling.

## **4. ASSESSMENT**

### MANAGEMENT SELF-ASSESSMENT

501. Management self-assessment should be carried out in accordance with Safety Guide Q5.

### INDEPENDENT ASSESSMENT

502. Typical subjects to be addressed by independent assessment during operation are:

- Control room operation
- Equipment performance during normal operation and tests

- Operating experience and characteristics
- Abnormal amounts of corrective maintenance or high unavailability of equipment
- Trending and analysis problems, including the results of testing and in-service inspection
- Significant changes to procedures and other documents
- Unreviewed safety questions
- Abnormal occurrences and significant equipment failures.

For further guidance on independent assessment see Safety Guide Q5.

## Annex I

### EXAMPLES OF OPERATION ACTIVITIES WHICH MAY REQUIRE PROCEDURES

- Security
- Equipment control (for example locking and tagging)
- Surveillance inspection and test
- Calibration
- Equipment qualification
- Plant modifications
- Shift turnover
- Transfer of authority during emergency conditions
- Plant logs
- Access controls
- Temporary modifications
- Fire protection
- Housekeeping and cleanliness
- Assessments
- Operating experience feedback
- Work control
- Significant operational activities
- Incident investigation
- Organizational interfaces arrangements
- Qualification and training
- Planning and scheduling
- Industrial safety arrangements
- Emergency preparedness and response
- Plant identification and labelling
- Emergency operation
- Non-conformance reporting and corrective actions
- Material control
- Supervision of contractors
- Configuration management
- Conservation and preservation
- Document control
- Records management
- Core management
- Plant history data recording
- Computers and software management
- Control of experiments

- Periodic safety review
- Procurement
- Handling, storage and shipping
- Maintenance
- Radiological protection
- In-service inspection
- Fuel handling
- Events reporting
- Chemistry
- Radioactive waste and effluent management
- Environmental monitoring
- Grading
- Inventory controls
- Design control.

## Annex II

### CONDITION MONITORING

A.1. The condition monitoring programme should include:

- Vibration analysis, bearing temperature monitoring and lubrication oil analysis of rotating parts;
- Infrared surveys of heat producing equipment such as motors, circuit breakers, batteries and thermally insulated areas;
- Monitoring of readings of selected plant instrumentation against nominal values and acceptance criteria;
- Testing and analysis of check valves using acoustic monitoring;
- Testing and analysis of motor operated valves by performing current, voltage and timing checks;
- Insulation resistance checks.

A.2. The programme should refer to the standards that the items are required to conform with. Typically, these standards require that:

- Rotating equipment is operating in accordance with design specifications (for example, bearing temperatures normal, vibration levels normal, and shaft seal leakage limited to that required to cool and lubricate the shaft seals);
- Equipment is properly serviced (for example, lubrication, drive belts, filters);
- Fluid system integrity is maintained. Leaks that can be corrected during plant operation are repaired. Leakage from plant components that cannot be repaired under existing plant conditions is collected and routed to appropriate drains or collection facilities, particularly if this leakage could cause a further degradation of plant equipment, present a safety hazard or cause the spread of radioactive contamination;
- Temporary repairs are recorded and controlled. Permanent repairs are scheduled when plant conditions permit;
- Instruments and gauges are operational, calibrated, on scale, and indicate values representative of the existing system and equipment conditions;
- Energized electrical and electronic equipment is operable, supplied from normal power sources, and protected from adverse environmental effects such as leaks and overheating;
- Protective cabinet doors and electrical enclosure covers are installed to maintain design integrity (for example, all fasteners installed and tightened, filters cleaned);

- Equipment and systems are insulated to control heat transfer to or from the environment, to control ambient noise levels, and to provide personnel safety;
- Plant equipment and systems subject to corrosion are protected with a preservative to minimize corrosion;
- Temporary environmental protection is provided, where appropriate;
- Industrial safety is minimized (for example, chemicals, oils and solvents properly stored; fire barriers maintained; trip hazards non-existent);
- Radiological hazards are minimized (for example, radiological postings current and in place; radiological barriers and step-off pads properly established; sources of contamination identified);
- Walkway and equipment access is maintained;
- Equipment is clean (for example, dirt, debris, tools, parts and miscellaneous materials are not allowed to accumulate on equipment or inside electrical panels);
- Plant areas, rooms and grounds are maintained in a clean and orderly condition, including the storage of tools and material;
- Coatings or coverings used to seal walls and floors in potentially contaminated areas are in good condition and assist in controlling contamination;
- All modifications to the plant design are properly authorized and implemented;
- Illumination of areas, rooms and grounds is maintained in a manner that provides sufficient light to perform inspections and minor maintenance.



## **Safety Guide Q14**

# **QUALITY ASSURANCE IN DECOMMISSIONING**



## CONTENTS

1.	INTRODUCTION .....	321
	Background (101–102) .....	321
	Objective (103) .....	321
	Scope (104–105) .....	321
	Structure (106) .....	322
2.	MANAGEMENT .....	322
	Quality assurance programme (201–208) .....	322
	Grading (209–210) .....	323
	Organization (211–212) .....	324
	Interfaces (213) .....	324
	Transfer from operation to decommissioning (214) .....	325
	Training and qualification (215–216) .....	325
	Decommissioning strategy (217–219) .....	325
	Decommissioning plan(s) (220–221) .....	326
	Document control and records (222–225) .....	326
	Non-conformance control and corrective actions (226–228) .....	327
	Security (229) .....	328
	Industrial safety (230–235) .....	328
	Fire protection (236–237) .....	329
	Emergency planning and preparedness (238–240) .....	329
	Human factors (241–242) .....	330
3.	PERFORMANCE .....	330
	Line managers and supervisors (301–303) .....	330
	Work planning and control (304–308) .....	331
	Shift changeover (309–311) .....	332
	Safety evaluation of decommissioning activities (312–313) .....	333
	Design (314) .....	334
	Procurement (315) .....	334
	Construction (316) .....	334
	Verification (317) .....	334
	Housekeeping and cleanliness (318–319) .....	334
	Measuring and test equipment (320) .....	335
	Identification and labelling (321–323) .....	335
	Equipment status and control (324–325) .....	335
	Fuel handling (326) .....	336
	Radioactive waste (327–329) .....	336

Plant maintenance (330) . . . . .	336
Radiological safety (331–332) . . . . .	337
Environmental monitoring (333–334) . . . . .	337
Review of decommissioning feedback (335) . . . . .	337
Handling, storage and preservation (336) . . . . .	337
Final decommissioning report (337) . . . . .	338
4. ASSESSMENT . . . . .	338
Management self-assessment (401) . . . . .	338
Independent assessment (402–403) . . . . .	338
ANNEX: EXAMPLES OF DECOMMISSIONING ACTIVITIES WHICH MAY REQUIRE PROCEDURES . . . . .	339

# 1. INTRODUCTION

## BACKGROUND

101. This Safety Guide is part of the IAEA Nuclear Safety Standards (NUSS) programme. It gives recommendations relative to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (hereinafter known as the Code) and complies with the requirements of the Code 50-C-O (Rev. 1). Requirements and recommendations on all aspects of the safe decommissioning of nuclear facilities are provided in the IAEA Radioactive Waste Safety Standards (RADWASS) Programme. This Safety Guide is complementary to the respective RADWASS publications and provides details on the quality assurance (QA) for decommissioning of nuclear power plants. It should be used in support of that programme.

102. Methods and solutions for fulfilling the basic requirements of the Code other than those set out in Safety Guides may be acceptable provided they result in at least the same level of nuclear safety.

## OBJECTIVE

103. This Safety Guide provides recommendations on how to fulfil the requirements of the Code in relation to the decommissioning stage of nuclear power plants.

## SCOPE

104. This Safety Guide applies to the QA programmes of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate programmes in the decommissioning stage of a nuclear power plant project or in any other stage where decommissioning activities are to be performed. It covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, also be usefully applied at nuclear installations other than nuclear power plants.

105. This Safety Guide relates to the decommissioning stage of a nuclear power plant. The decommissioning stage overlaps with the operation stage. The responsible organization may establish separate organizations for these stages or combine them under one organization. Whichever organizational arrangement is utilized, the

responsibilities and interfaces must be clearly defined and understood and the status of the plant established at all times.

## STRUCTURE

106. This Safety Guide is arranged into four sections and one annex:

Section 2 provides guidance on QA for the management activities of decommissioning.

Section 3 provides guidance on QA for the performance activities of decommissioning.

Section 4 provides guidance on QA for the assessment of decommissioning activities.

Annex gives examples of decommissioning activities which may require procedures.

## 2. MANAGEMENT

### QUALITY ASSURANCE PROGRAMME

201. The responsible organization shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the nuclear power plant decommissioning. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.

202. After final shutdown there are no generally set technical conditions for the formal start of decommissioning activities. The border between operation and decommissioning is therefore difficult to define and the two stages often overlap.

203. In order to ensure that all activities are continually carried out under controlled conditions, the decommissioning QA programme should be developed from the operational QA programme and may overlap with it.

204. In many cases the operation staff may continue to operate the shut down nuclear power plant and unload the fuel and maintain the plant under the existing safety

assessment and the associated operational limits and conditions and QA programme. In other cases the fuel may be unloaded as part of the decommissioning process. The time at which decommissioning starts and the conditions under which it starts should be made clear in the decommissioning plan. The decommissioning QA programme should be based upon and developed from the operation QA programme.

205. Procedures shall be defined by the responsible organization for control of decommissioning activities to ensure that decommissioning of the plant fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and subsequent amendment of them controlled. A list of examples of decommissioning activities which may require procedures is contained in the Annex.

206. The responsible organization may delegate and/or require suppliers or other organizational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.

207. In such cases, the supplier(s) or other organizational units should prepare QA programmes for the work for which they will be responsible and submit them to the responsible organization if required. Guidance on the documents required from the supplier for submissions to the responsible organization and the timing of such submissions is given in Safety Guide Q6. For further guidance on the development and implementation of a QA programme see Safety Guide Q1.

208. The decommissioning process could continue for decades. During that period both the responsible organization and the decommissioning contractor could change and in between decommissioning phases there could be long periods of care and maintenance. Throughout this extended period a QA programme should continue to operate and arrangements made to ensure that appropriate records are produced, retained and transferred.

## GRADING

209. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.

210. Activities that could be graded in the decommissioning stage include:

- The need for and detail of decommissioning documents
- Management of decommissioning waste
- The review and approval of decommissioning documents
- The type and detail of training of decommissioning personnel.

For further guidance on grading see Safety Guide Q1.

## ORGANIZATION

211. The responsible organization should formally appoint a person on its staff to be responsible for decommissioning activities.<sup>1</sup>

212. The appointed person should have the necessary resources within the decommissioning organization to discharge the following responsibilities:

- Ensuring that decommissioning work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements;
- Ensuring that decommissioning work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work;
- Managing the decommissioning work and operating the remaining parts of the plant;
- Controlling access to the decommissioning site.

## INTERFACES

213. Interfaces shall be described between the decommissioning organization and other organizational units. Arrangements should be agreed between organizations performing work at or in support of the decommissioning of the nuclear power plant. The following examples of interfaces should be addressed:

- Organizational units within the nuclear power plant, for example units responsible for nuclear safety, industrial safety, radiation protection and accident management;

---

<sup>1</sup> In some Member States the appointed person is the head of the decommissioning organization.

- Maintenance and other on-site services;
- The decommissioning organization and off-site organizations;
- The decommissioning organization and the organizational units responsible for design;
- The decommissioning organization and the emergency support organization;
- The decommissioning organization and the regulatory body (see the Code 50-C-G (Rev. 1)).

For further guidance on interfaces see Safety Guide 50-SG-Q1.

## TRANSFER FROM OPERATION TO DECOMMISSIONING

214. Plant components and systems shall be formally transferred from the operating organization to the decommissioning organization. This transfer should ensure that:

- non-conformances and other open issues have been identified and documented;
- operating documentation is complete;
- the condition of the plant at transfer is defined.

## TRAINING AND QUALIFICATION

215. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

216. Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work. For further guidance on training and qualification see Safety Guides 50-SG-Q1 and 50-SG-O1 (Rev. 1).

## DECOMMISSIONING STRATEGY

217. Management should ensure that all the decommissioning options are considered and a strategy developed. Factors influencing all the options should be considered before a decision is taken on the final option. This could include a number of different phases with varying time-scales between them (phased decommissioning). The strategy should evaluate the decommissioning options, including factors such as the estimated radiation doses, waste arisings and destinations, and available technology. The regulatory body should be consulted in the development of the decommissioning strategy where appropriate.

218. Those determining the strategy should be in possession of all essential information concerning the design, construction and operation of the nuclear power plant.

219. The responsible organization should select a final decommissioning option, if necessary in consultation with the regulatory body.

#### DECOMMISSIONING PLAN(S)

220. An outline decommissioning plan should normally be completed during the initial design phase of the nuclear power plant by the principal designer.<sup>2</sup> This plan should be amended as necessary during the operation stage. A final decommissioning plan should be developed to implement the strategy, which should be made up of a number of separate documents and should be produced in stages, with an overall plan and then more detailed plans for each decommissioning phase. The overall plan should cover all decommissioning phases of the nuclear power plant, from the start of decommissioning until the site and its adjacent areas are rendered fit for their anticipated use. In cases where the selected option allows for a lapse of time between phases, the plans for each phase may be produced immediately before the start of the phase, with time allowed for the approval of the plan and its associated safety assessment.

221. All the documents that make up the decommissioning plan should be indexed within the plan with an identified issue status. They should be considered as controlled documents within the QA programme. Any alterations and amendments to the documents that make up the plan should be controlled and approved through the same route as the original document.

#### DOCUMENT CONTROL AND RECORDS

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

223. A records system should be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, storage, retrieval and disposal of decommissioning records.

---

<sup>2</sup> The principal designer has responsibility for specifying the design requirements and for approving the design output on behalf of the responsible organization. Further explanation of the term 'principal designer' can be found in Safety Guide Q10.

224. All important information associated with decommissioning should be adequately recorded, categorized for retention, and stored so that the information is retrievable for future use.

225. The records generated during decommissioning may include:

- The operational records handed over by the operating organization at the start of decommissioning;
- The decommissioning plan and subsequent amendments;
- The decommissioning QA programme description;
- Decommissioning safety assessments;
- Completed work packages and work plans with their associated records;
- Engineering drawings indicating the state of the nuclear power plant on the completion of defined decommissioning phases;
- Manufacturing and construction as-built records, including engineering drawings for any installation or construction work done as part of the decommissioning;
- The end state of the facility at each decommissioning phase;
- Personal radiological dose records of the decommissioning team;
- Radiological survey reports;
- Radioactive material waste records;
- Photographs, videos or other records taken of the nuclear power plant during decommissioning;
- Details of significant abnormal events during decommissioning and the actions taken.

For further guidance on document control and records see Safety Guide Q3.

## NON-CONFORMANCE CONTROL AND CORRECTIVE ACTIONS

226. During decommissioning, non-conformances should be identified. They may be detected during:

- Routine observations of equipment performance and condition during normal operation and decommissioning activities;
- Routine inspections and maintenance;
- Consumption of consumable materials by equipment;
- Work processes;
- Radiological monitoring;
- Condition monitoring;

- Review of records of corrective maintenance or unavailability of equipment;
- Feedback experience.

227. On the basis of a review of safety, reliability, compliance with operational limits and conditions of the remaining systems and components, the decommissioning plan requirements and the competence of available personnel, criteria should be developed for:

- Rating the priority, significance and importance of non-conformances;
- Labelling non-conformances, when applicable;
- Reporting non-conformances to the person in charge of plant operation and decommissioning;
- Involving the principal designer;
- Determining what corrective actions should be carried out and when;
- Determining the need for root cause analysis;
- Determining those responsible for the above.

228. Non-conformances having a significant or immediate impact on plant operation or decommissioning activities should be reported to the management. For further guidance on non-conformance control and corrective actions see Safety Guide Q2.

## SECURITY

229. Requirements for plant security are given in the Code 50-C-O (Rev. 1) and in Safety Guide 50-SG-O9.

## INDUSTRIAL SAFETY

230. A policy reflecting the Member State's industrial safety regulations should be established for all personnel, including suppliers and visitors, and should refer to the rules and practices that are to be adopted. The policy should include arrangements for the effective planning, organization, monitoring and review of the preventive and protective measures.

231. Management should provide support, guidance and assistance for decommissioning personnel in the area of industrial safety.

232. Personnel should understand how the industrial safety programme affects their individual work practices.

233. Industrial safety data should be monitored. Examples of items to be monitored include lost-time accidents, other accidents requiring medical attention, industrial safety non-conformances identified in the plant, and modifications resulting from industrial safety concerns.

234. The underlying causes of industrial accidents and safety problems should be identified and corrected. The results of cause analyses should be used to identify opportunities to improve industrial safety. Lessons learned from investigations and from other industry operating experience should be used to improve performance.

235. Applicable industrial safety information should be obtained and screened. Relevant material and any required actions should be incorporated into the plant's industrial safety policy and disseminated to other nuclear power plants.

## FIRE PROTECTION

236. Plant management should establish and implement a fire prevention and protection programme to protect items and personnel during decommissioning. The programme should provide methods for effective means for preventing, detecting, controlling and promptly extinguishing fires, taking into account changes resulting from decommissioning activities. The programme should be consistent with the Member State's regulatory requirements. The programme should also contain measures for controlling the generation, storage and disposal of combustible materials.

237. Periodically, drills and exercises should be conducted to confirm the implementation and effectiveness of the fire protection programme. For further guidance on fire protection see Safety Guide 50-SG-D2 (Rev. 1).

## EMERGENCY PLANNING AND PREPAREDNESS

238. Reference emergency conditions reflecting changes resulting from decommissioning activities should be identified and the organizational infrastructure required for coping with them developed.

239. Resources and facilities for emergencies shall be made available, and personnel should receive continuing training by the testing of emergency plans and procedures, and through drills and exercises and public information activities.

240. Emergency plans and procedures should be revised and improved as a result of feedback from periodic drills and exercises. For further guidance see the Code 50-C-O (Rev. 1) and Safety Guides 50-SG-O6 and 50-SG-G6.

## HUMAN FACTORS

241. Suitable working environments should be provided and maintained so that work can be carried out safely and satisfactorily, without imposing unnecessary physical and psychological stress on the plant personnel.

242. Human factors which influence the working environment and the effectiveness and fitness of personnel for duty should be identified and addressed. This includes, for example:

- The adequacy of resources, support and supervision needed to manage and perform the work;
- The adequacy of lighting, access and decommissioning aids;
- The adequacy of alarms such as number, position, grouping, colour coding and audibility prioritizing;
- The frequency and clarity of communications;
- The availability of suitable tools and equipment;
- The limits on the duration of work time for personnel;
- The attention needed to be given to other factors for control room staff, including personnel well-being, psychological, physiological and attitudinal problems, shift patterns and meal breaks;
- The availability of procedures that take into account human factor considerations.

## 3. PERFORMANCE

### LINE MANAGERS AND SUPERVISORS

301. As part of their daily responsibilities, line managers and supervisors should review the conduct of work under their responsibility. To do this, they should be aware of the nuclear power plant decommissioning status, monitor the work to ensure that the decommissioning is being conducted safely and in accordance with requirements, ensure that non-conformances are identified and resolved, and be alert to opportunities for improvement.

302. Line managers and supervisors should periodically evaluate decommissioning activities, operation and documents, examine non-conformances and evaluate the implementation of corrective actions in order to assist in the planning of future work.

303. Supervisors should recognize and encourage good work practices by promoting for example:

- Attention to detail;
- Good industrial safety such as appropriate use of industrial safety equipment and proper handling of hazardous chemicals;
- Good radiological protection practices such as the proper use of ALARA concepts and minimizing the spread of contaminants;
- Proper use of pre-job briefings and applicable training (for example, mock-up training);
- Adherence to documents and compliance with work hold points;
- Accountability for tools, chemicals and materials;
- Use of correct tools and equipment;
- Use of decontamination facilities to reduce the volume of radioactive waste, permit clean work on formerly contaminated equipment and reduce contamination on reusable items;
- Use of glove boxes or temporary containments for work on contaminated equipment to prevent the spread of contamination;
- Clean and orderly work sites;
- Sensitivity to the time required to perform work, especially if a limiting condition for operation is involved;
- Proper use of post-job reporting and, when applicable, post-job critiques;
- Other aspects of nuclear safety objectives.

#### WORK PLANNING AND CONTROL

304. Arrangements should be established and implemented to ensure that decommissioning work is properly planned and completed in a safe and efficient manner. Computer aided work planning is desirable. Work planning should, for example:

- Identify the work necessary to operate and maintain relevant plant systems;
- Identify the generation and management of wastes;
- Describe the performance of work by referencing clear, concise and unambiguous work instructions;
- Identify any special requirements that are part of the work process, such as radiation protection, fire protection, isolation and tagging requirements, and inspection and testing requirements;

- Identify the required records, such as work completion and spare parts used;
- Identify the status of work;
- Identify if the work is safety related or not;
- Identify any potential safety hazards;
- Ensure the work is authorized;
- Estimate personnel requirements and any special training needs;
- Specify any reviews required upon completion.

305. A work request system should be used to facilitate and control work to ensure that the decommissioning work is systematically planned in accordance with the requirements of the decommissioning plan.

306. The work planning system should list and be able to sort all work requests on the basis of work description, priority assigned, date initiated and plant conditions required to perform the work. The system should be able to track the status of all work requests, in particular those on hold for planning, spare parts, materials or other constraints. The system should be capable of tracking completion of testing prior to return to service.

307. Inspection and test plans should be used to control decommissioning activities. These plans should be supported by the use of individual task allocation documents, given to decommissioning personnel as an instruction to perform a task. For further guidance on inspection and test plans see Safety Guide Q4.

308. To ensure that decommissioning tasks are performed safely, a system may be used in which a permit to work is completed and authorized by a suitably qualified and experienced supervisor for each work package or task. The permit to work should be in the form of a checklist that indicates the precautions to be taken and the protective equipment to be used by persons doing the work, and should be signed by those persons, indicating that the conditions are understood and accepted. The permit to work should also be used to record the isolation of components or systems and the handover of components or systems on completion of the work.

## SHIFT CHANGEOVER

309. Shift changeover shall be carried out in accordance with a formal process. An account of plant and work status is usually presented in reports and logs which follow a standard format.

310. The process of shift changeover should identify the persons involved, their responsibilities, the locations and the conduct of shift changeovers, and the method of reporting nuclear power plant status, including any provisions that have been taken

for special circumstances such as abnormal nuclear power plant status and staff unavailability.

311. Shift changeover should address the following:

- Status of major equipment
- Significant safety and general plant parameters
- Significant changes in configuration since the previous shift
- Schedules and duration of current and planned work
- Special instructions from management
- Handover of logs
- Review of logs.

## SAFETY EVALUATION OF DECOMMISSIONING ACTIVITIES

312. Safety evaluations for decommissioning work packages should include:

- (1) A hazard evaluation of possible accident situations that might occur during decommissioning and that could potentially affect personnel, the public or the environment. The hazard evaluation should include an indication of the resulting doses to decommissioning personnel and the public, and the quantities of radioactive materials that may be released within the nuclear power plant or to the environment for each situation.
- (2) A description of the measures taken to ensure safety. These should include engineering, administrative and radiological protection measures for normal conditions and for the prevention of a possible accident situation. The measures should include:
  - appropriate scheduling of the decommissioning activities
  - inspections and tests to ensure the integrity of structures and systems as decommissioning proceeds
  - arrangements to limit the spread of contamination
  - effective testing of field equipment and tools
  - use of protective measures, including shielding where necessary
  - training of personnel.
- (3) The operational limits and conditions or changes to them that need to be applied to the nuclear power plant or associated systems during the decommissioning task. This is of particular importance while fuel is still in the nuclear power plant, where the decommissioning task could influence the shutdown condition or the operation of a safety mechanism.

- (4) A description of the maintenance requirements for safety related mechanisms.
- (5) A description of the emergency arrangements to mitigate the consequences of any accidents that may occur.

313. Decommissioning work packages could be treated as a modification to the nuclear power plant, and be subjected to the same controls and procedures as would have been applied to a modification during the operation stage (see Safety Guide Q13), with a requirement for formal approval before work is started.

## DESIGN

314. Where design forms part of decommissioning, the design work should be carried out in accordance with Safety Guide Q10.

## PROCUREMENT

315. During decommissioning, procurement should be performed according to the guidance given in Safety Guide Q6.

## CONSTRUCTION

316. Where construction forms part of decommissioning, the construction work should be carried out in accordance with Safety Guide Q11.

## VERIFICATION

317. The decommissioning organization should establish verification methods and acceptance criteria which identify the level of inspection/verification required.

## HOUSEKEEPING AND CLEANLINESS

318. Maintaining plant cleanliness should be considered an essential activity.

319. Procedures for housekeeping and cleanliness should be established to reduce the risks of cross-contamination and industrial accidents and incidents. This may include procedures to:

- prevent contamination of items and protect open systems and equipment from foreign material during maintenance, modification and decommissioning;

— control the movement of materials, equipment, tools and personnel in and out of work areas.

## MEASURING AND TEST EQUIPMENT

320. Equipment used for monitoring the operation of plant systems, for data collection, inspections and tests shall be of the proper type, range, accuracy and precision and be in good condition (see Safety Guide Q4).

## IDENTIFICATION AND LABELLING

321. Plant areas, installed items and decommissioning equipment should be uniquely and permanently labelled to provide plant personnel with sufficient information to positively identify them. Identification and labelling of waste containers is particularly relevant during decommissioning.

322. The identification should be consistent with the identification codes and terminology used in operation documents.

323. Care should be taken during dismantling activities to ensure that labels and identification tags of systems and components that are not being dismantled are not disturbed, removed or damaged.

## EQUIPMENT STATUS AND CONTROL

324. There should be a system to confirm the configuration of the nuclear power plant. Control measures, such as locking and tagging, should be documented and be used to ensure the protection of personnel and equipment. The positions of valves, switches and other items important to safety should be known.

325. Work authorization procedures should clearly define the responsibilities related to equipment isolation, post-maintenance testing and restoration to service. Procedures should be implemented to control the placement and removal of caution and warning information tags installed on equipment for the protection of personnel or equipment. Tags should be periodically reviewed for accuracy and continued applicability.

## FUEL HANDLING

326. If fuel handling is part of the decommissioning, it should be carried out under controlled conditions throughout fuel removal, storage, transportation and disposal. For further guidance see the Code 50-C-O (Rev. 1) and Safety Guide 50-SG-O10. Additional details for the off-site transport of fuel are contained in IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material.

## RADIOACTIVE WASTE

327. The amount of radioactive waste generated should be kept to the minimum practicable and provisions made for its safe handling, processing, storage, transport and disposal.

328. Controls should ensure that radioactive wastes comply with authorized limits and conditions and should cover:

- generation of waste;
- segregation of waste;
- quantities and activity levels of waste;
- processing, storage, transportation and disposal of waste;
- waste inventories;
- record requirements.

For further guidance see Safety Guide 50-SG-O11 and Safety Series No. 111-S-1, Establishing a National System for Radioactive Waste Management.

329. The decommissioning organization should be responsible for ensuring that the conditions for transportation of radioactive waste to a licensed repository satisfy governing regulatory requirements, and that the wastes conform to the disposal requirements of the facility and the regulatory body. Details for the off-site transport of radioactive material are contained in Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material.

## PLANT MAINTENANCE

330. Before the commencement of decommissioning, a maintenance programme for those parts of the nuclear power plant that are to be operated and maintained during

decommissioning should be prepared by personnel with maintenance experience. Pertinent information from designers, manufacturers and the operating organization should be used. For further guidance on nuclear power plant maintenance see Safety Guide 50-SG-O7 (Rev. 1).

## RADIOLOGICAL SAFETY

331. A radiation protection programme should be established and implemented.

332. Radiation dose levels and trends should be determined for each working group, area and type of work. Annual limits should be established for radiation doses and these should be made as low as is reasonably achievable. For further guidance see Safety Guide 50-SG-O5.

## ENVIRONMENTAL MONITORING

333. The methods and procedures for controlling and monitoring effluents on and off the site, to maintain levels within approved limits and conditions, should be documented before decommissioning starts. Monitoring should continue throughout decommissioning.

334. Discharge pathways for radioactive releases and toxic releases to the environment should be identified and monitored in accordance with the details in Safety Guides 50-SG-O5, 50-SG-O9 and 50-SG-O11.

## REVIEW OF DECOMMISSIONING FEEDBACK

335. The feedback of events during decommissioning at nuclear power plants is necessary to improve safety. Management should provide sufficient resources and dedicated staff for the evaluation and feedback of operating events, including those from other plants. Management should clearly define responsibilities and should be sufficiently involved to ensure completion of any improvements and corrective actions (see the Code 50-C-O (Rev. 1)).

## HANDLING, STORAGE AND PRESERVATION

336. Handling instructions and procedures should be provided for material, equipment and instrumentation that may be damaged if handled incorrectly. Items should

be stored under conditions appropriate to their susceptibility to environmental deterioration and periodically inspected as necessary. Appropriate procedures should be produced to maintain the preservation status of all installed components. Particular attention should be paid to identifying safety related components where special preservation measures are required, for example maintaining nitrogen blankets.

## FINAL DECOMMISSIONING REPORT

337. On completion of decommissioning or on the completion of a phase of decommissioning where there will be a considerable delay before the next phase is started, the responsible organization should produce a final decommissioning report.

## 4. ASSESSMENT

### MANAGEMENT SELF-ASSESSMENT

401. Management self-assessment should be carried out in accordance with Safety Guide Q5.

### INDEPENDENT ASSESSMENT

402. Independent assessment should be made from time to time by the decommissioning organization. These assessments should be scheduled to assure quality and provide confidence, especially at interfaces.

403. Typical subjects to be addressed by independent assessments during decommissioning are:

- Radioactive waste management
- Industrial safety
- Decommissioning plan activities
- Radiation protection
- Safety inspections
- Environmental monitoring.

For further guidance on independent assessment see Safety Guide Q5.

## Annex

### EXAMPLES OF DECOMMISSIONING ACTIVITIES WHICH MAY REQUIRE PROCEDURES

- Security
- Equipment control
- Equipment qualification
- Transfer of authority during emergency conditions
- Plant logs
- Access controls
- Fire protection
- Housekeeping and cleanliness
- Work control
- Incident investigation
- Planning and scheduling
- Emergency preparedness and response
- Plant identification and labelling
- Emergency operation
- Supervision of contractors
- Plant history
- Periodic safety review
- Radiological protection
- Fuel handling
- Event reporting
- Chemistry
- Radioactive waste and effluent management
- Environmental monitoring
- Inventory control
- Decontamination of systems and equipment
- Dismantling and demolition.



## CONTRIBUTORS TO DRAFTING AND REVIEW

Aguilar, J.M. (Code, Q1–Q14)	Spain
Alat, A. (Q9)	Turkey
Berci, K. (Q9)	Hungary
Bodnarczuk, M. (Q8)	United States of America
Bradford, P. (Q9)	United Kingdom
Butchart, P. (Code, Q2–Q12, Q14)	United Kingdom
Campbell, R.J. (Code, Q1, Q13)	United Kingdom
Caubit da Silva, A. (Code, Q1–Q14)	Brazil
Chen, C. (Code, Q1–Q14)	International Atomic Energy Agency
Clause, E. (Code, Q2–Q12, Q14)	France
Dąbek, W. (Code, Q1–Q14)	Poland
De Vrey, G. (Code, Q1–Q14)	Netherlands/European Commission
Derbyshire, D. (Q2–Q6, Q8)	United Kingdom
Dizadji, F. (Code, Q1–Q14)	European Commission
Dong, B. (Code, Q1–Q14)	China
Doumenc, A. (Q9)	France
Dragomirescu, A. (Code, Q1–Q14)	Romania
Duff, C.G. (Q9)	Canada
Dupuis, M.C. (Code, Q1–Q14)	France
Giuliani, P. (Q9)	Italy
Guerpinar, A. (Q9)	International Atomic Energy Agency
Hanney, K. (Q14)	United Kingdom
Hawkins, F. (Code, Q1–Q14)	United States of America
Hillairet, J. (Q2–Q6, Q8)	France
Ielasi, R. (Code, Q1–Q14)	Italy
Isaev, A. (Code, Q1–Q14)	Russian Federation
Ito, T. (Code, Q1, Q13)	Japan
Ivanier, D. (Code, Q1–Q6, Q8, Q13)	France
Jarrett, R. (Q7, Q9–Q12, Q14)	United States of America
Jones, A. (Code, Q7, Q9–Q12, Q14)	United Kingdom
Kaden, W. (Code, Q1–Q14)	Germany/Forum Atomique Européen
Kim, Y.S. (Code, Q7, Q9–Q12, Q14)	Republic of Korea
Kogure, H. (Q2–Q12, Q14)	Japan
Krishnan, S. (Q9)	India
Krüger, W. (Code, Q1–Q14)	Germany
Laraia, M. (Q14)	International Atomic Energy Agency
Laroche, G. (Code, Q7, Q9–Q12, Q14)	France
Levshin, E. (Code, Q2–Q12, Q14)	Russian Federation

Lyne, D. (Code, Q1–Q14)	International Organization for Standardization
Maurer, H. (Code, Q1–Q14)	European Commission
McNair, J. (Code, Q1, Q13)	United Kingdom
Mitchell, H. (Code, Q1–Q6, Q8, Q13)	United Kingdom
Miyakoshi, N. (Code, Q7, Q9–Q12, Q14)	Japan
Morrison, W. (Q9)	United States of America
Mucskai, G. (Code, Q1–Q14)	Hungary
Mullan, J. (Code, Q1–Q14)	Canada
Namestek, L. (Q9)	Czech Republic
Novak, S. (Code, Q1–Q14)	Slovak Republic
Oldfield, S. (Code, Q7, Q9–Q12, Q14)	United Kingdom
Pieroni, N. (Code, Q1–Q14)	International Atomic Energy Agency
Pinheiro, C. (Code, Q1–Q14)	Brazil
Redman, N. (Code, Q1–Q14)	United Kingdom
Rivas Lagunes, L. (Code, Q1, Q13)	Mexico
Sajaroff, P. (Code, Q1–Q14)	Argentina
Sánchez–Cabañero, J. (Q9)	Spain
Sandberg, B. (Code, Q1–Q14)	Sweden
Sayers, T. (Code, Q1–Q14)	United Kingdom
Singh, P. (Code, Q1–Q14)	India
Stuller, J. (Q2–Q6)	Czech Republic
Tendera, P. (Code, Q7, Q9–Q12, Q14)	Czech Republic
Truss, K. (Q2–Q6, Q8)	Canada
Udaondo, M. (Code, Q1–Q14)	Spain
Van Dornick, J. (Code, Q1–Q14)	Germany
Van der Geld, F. (Code, Q1–Q14)	Forum Atomique Européen
Vincze, P. (Code, Q1–Q14)	Hungary
Vladykov, G. (Code, Q2–Q12, Q14)	Russian Federation
Watanabe, K. (Code, Q1–Q14)	Japan
Watanabe, M. (Code, Q1–Q14)	Japan
Widmer, M. (Code, Q1–Q14)	France
Williams, B.J. (Code, Q7, Q9–Q12, Q14)	United Kingdom

## SELECTION OF ASSOCIATED PUBLICATIONS

### TECHNICAL REPORTS SERIES

397	Quality Assurance for Software Important to Safety	2000
317	Implementation of Quality Assurance Corrective Actions: Manual	1990
315	Quality Management for Nuclear Power Plant Operation: A Manual	1990
296	Regulatory Inspection of the Implementation of Quality Assurance Programmes: A Manual	1989

### SAFETY SERIES

113	Quality Assurance for the Safe Transport of Radioactive Material	1994
93	Systems for Reporting Unusual Events in Nuclear Power Plants: A Safety Guide	1989

### IAEA-TECDOC SERIES

1182	Quality assurance standards: comparison between IAEA 50-C/SG-Q and ISO 9001: 1994	2000
------	--	------

### PROCEEDINGS SERIES

STI/PUB/593	Quality Assurance for Nuclear Power Plants	1982
-------------	--	------