IAEA Safety Standards

for protecting people and the environment

The Management System for Nuclear Installations

Safety Guide

No. GS-G-3.5

IAEA
International Atomic Energy Agency

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available at the IAEA Internet site

http://www-ns.iaea.org/standards/

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at P.O. Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

OTHER SAFETY RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications. Security related publications are issued in the **IAEA Nuclear Security Series**.

THE MANAGEMENT SYSTEM FOR NUCLEAR INSTALLATIONS

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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 SAFETY STANDARDS SERIES No. GS-G-3.5

THE MANAGEMENT SYSTEM FOR NUCLEAR INSTALLATIONS

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2009

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Printed by the IAEA in Austria
September 2009
STI/PUB/1392

IAEA Library Cataloguing in Publication Data

The management system for nuclear installations. — Vienna : International Atomic Energy Agency, 2009.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020–525X ; no. GS-G-3.5)
STI/PUB/1392
ISBN 978–92–0–103409–0
Includes bibliographical references.

1. Nuclear facilities — Management. 2. Nuclear facilities — Reliability. I. International Atomic Energy Agency. II. Series.

IAEAL 09–00581

FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the contracting parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection

of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The safety requirements use 'shall' statements together with statements of

[1] See also publications issued in the IAEA Nuclear Security Series.

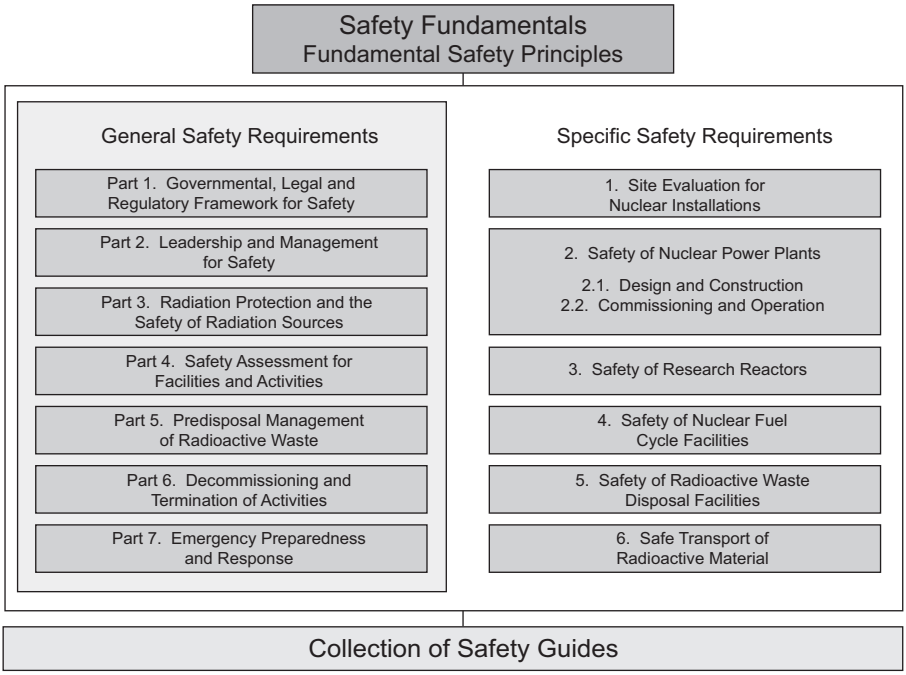

FIG. 1. The long term structure of the IAEA Safety Standards Series.

associated conditions to be met. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety

standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on

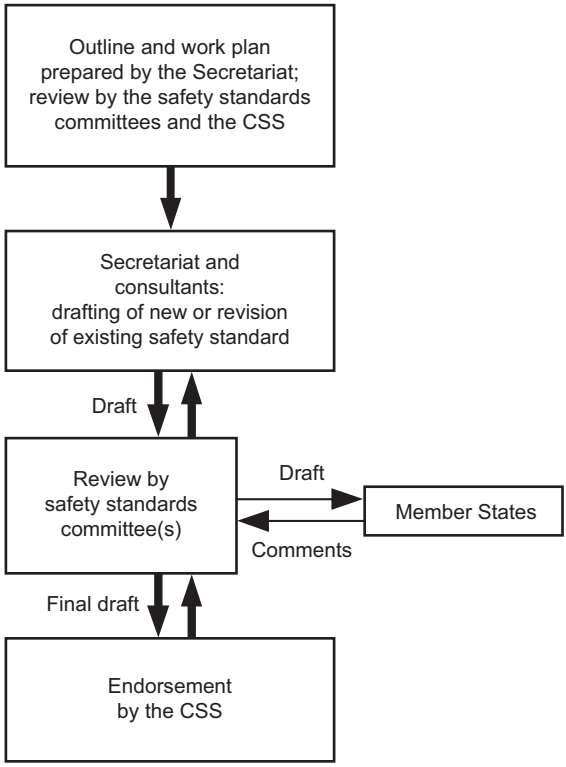

FIG. 2. The process for developing a new safety standard or revising an existing standard.

Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. This Safety Guide is issued in support of the Safety Requirements publication on The Management System for Facilities and Activities [1]. It provides recommendations in relation to nuclear installations[1] that are supplementary to the general recommendations provided in Ref. [2] on how to comply with the requirements established in Ref. [1].

1.2. This Safety Guide is one of several IAEA Safety Guides that recommend methods of meeting the requirements for management systems that are established in Ref. [1]. It supersedes Safety Guides numbers Q8–Q14 of Safety Series No. 50-C/SG-Q[2]. Application of the requirements for the management system throughout the lifetime of a nuclear installation will contribute to the achievement, maintenance and development of high levels of safety.

1.3. The use of methods and arrangements other than those set out in this Safety Guide for meeting the requirements established in Ref. [1] may be acceptable provided that they achieve at least the same level of safety.

OBJECTIVE

1.4. The objective of this publication is to provide recommendations and guidance supplementary to those provided in Ref. [2] for establishing, implementing, assessing and continually improving a management system that integrates elements of safety, health, environment, security[3], quality and

[1] 'Nuclear installations' includes nuclear power plants, other reactors (such as research reactors and critical assemblies) and nuclear fuel cycle facilities.

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, Safety Series No. 50-C/SG-Q, IAEA, Vienna (1996).

[3] This Safety Guide covers the security of nuclear installations, nuclear material and sources of radiation only to the extent that security measures for physical protection are essential to safety and the failure of such measures has consequences for safety.

economics[4]. All the topics covered correspond to requirements established in Ref. [1].

SCOPE

1.5. This Safety Guide is applicable throughout the lifetime of a nuclear installation, including any subsequent period of institutional control, until there is no significant residual radiation hazard. For a nuclear installation, the lifetime includes site evaluation, design, construction, commissioning, operation and decommissioning. These stages in the lifetime of a nuclear installation may overlap.

1.6. The recommendations made in this publication should be used in conjunction with the general recommendations provided in Ref. [2]. It is stated in each section whether this Safety Guide provides recommendations supplementary to those in Ref. [2] or whether there are no supplementary recommendations.

1.7. This Safety Guide may be applied to nuclear installations in the following ways:

(a) To support the development, implementation, assessment and improvement of the management system of those organizations responsible for research[5], site evaluation, design, construction, commissioning, operation and decommissioning of a nuclear installation;
(b) As an aid in the assessment by the regulatory body of the adequacy of the management system of a nuclear installation;
(c) To assist an organization in specifying to a supplier, via contractual documentation, any specific element that should be included within the supplier's management system for the supply of products[6].

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[4] Economic objectives are included in the list of elements that have to be integrated, as it is recognized that economic decisions and actions may introduce, or may mitigate, potential effects on safety.

[5] The term 'research' covers research on items, services and processes that may have an effect on safety in the stages of site evaluation, design, construction, commissioning, operation and decommissioning in the lifetime of a nuclear installation, and also the conduct of the research activities for which a nuclear installation (e.g. a research reactor) is built.

[6] A product is an output from a process. Examples include a piece of equipment maintained and electricity generated.

STRUCTURE

1.8. This Safety Guide follows the structure of the Safety Requirements publication on The Management System for Facilities and Activities [1], whereby:

(a) Section 2 provides recommendations on implementing the management system, including recommendations relating to safety culture, grading and documentation.
(b) Section 3 provides recommendations on the responsibilities of senior management[7] for the development and implementation of an effective management system.
(c) Section 4 provides recommendations on resource management, including guidance on human resources, infrastructure and the working environment.
(d) Section 5 provides recommendations on how the processes of the installation can be specified and developed, including recommendations on some generic processes of the management system.
(e) Section 6 provides recommendations on the measurement, assessment and improvement of the management system of a nuclear installation.
(f) Appendix I provides some examples of activities that could demonstrate the safety culture attributes. Appendix II provides guidance on implementing the management system requirements for research and development activities. Appendices III–VIII provide guidance on the specific processes to be developed for the various stages in the lifetime of a nuclear installation: site evaluation, design, construction, commissioning, operation and decommissioning. Annex I provides an example from a Member State of a methodology for grading the application of management system requirements.

[7] 'Senior management' means the person who, or group of people which, directs, controls and assesses an organization at the highest level. In nuclear installations, many different terms are used, including, for example: chief executive officer, director general, executive team, plant manager, top manager, site vice-president and managing director.

2. THE MANAGEMENT SYSTEM FOR NUCLEAR INSTALLATIONS

MEETING THE GENERAL REQUIREMENTS OF THE MANAGEMENT SYSTEM

2.1. The Safety Requirements publication [1] states in paras 2.1–2.4 that:

> "A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:
> — Bringing together in a coherent manner all the requirements for managing the organization;
> — Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
> — Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.
>
> "Safety shall be paramount within the management system, overriding all other demands.
>
> "The management system shall identify and integrate with the requirements contained within this publication:
> — The statutory and regulatory requirements of the Member State;
> — Any requirements formally agreed with interested parties (also known as 'stakeholders');
> — All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [3] and safety assessment [4];
> — Requirements from other relevant codes and standards adopted for use by the organization.
>
> "The organization shall be able to demonstrate the effective fulfilment of its management system requirements."

In this Safety Guide, 'the organization' would generally be the operating organization of the nuclear installation.

2.2. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are

supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

2.3. Senior management of the operating organization should be the sole source of operational direction for the installation. The management system should define the responsibilities of those persons responsible for each process (sometimes referred to as 'process owners') and of the managers and functions in the organizational structure, so that there are clear lines of authority and accountability. The persons responsible for each process should support the operational direction by assuming responsibility for developing effective processes and ensuring that they remain effective. The managers and functions in the organization should implement the processes within their areas of responsibility. More information regarding the operating organization can be found in Ref. [5].

2.4. Senior management should establish a reporting structure that should permit reporting on safety performance, efficiency in discharge of responsibilities and achievement of safety objectives. This reporting structure should include, but should not be limited to, the processes of the organization. It should be made clear in the management system what the reporting mechanisms are and who assumes specific responsibilities with regard to what, when and how to report and to whom. Care should be taken in designing the structure of the organization as this can affect the speed of decision making.

2.5. Guidance on the processes to be covered in the management system for the different stages in the lifetime of a nuclear installation is provided in Appendices III–VIII of this Safety Guide. Separate organizations may be established for these stages or they may be combined within one organization. Irrespective of the organizational arrangement used, responsibilities and interfaces should be clearly specified and understood. The management system should cover all the activities that are carried out at the relevant stage in the lifetime of the installation. It should be recognized that many activities and outputs from one stage may be necessary to aid work in later stages, and that this may impact the way in which this work is carried out. The management system, when applied in practice, should provide assurance that the nuclear installation will conform to specified requirements.

SAFETY CULTURE

2.6. Reference [1] states in para. 2.5 that:

> "The management system shall be used to promote and support a strong safety culture by:
> — Ensuring a common understanding of the key aspects of safety culture within the organization;
> — Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
> — Reinforcing a learning and questioning attitude at all levels of the organization;
> — Providing the means by which the organization continually seeks to develop and improve its safety culture."

2.7. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

2.8. Any effort to focus attention on developing or improving the safety culture of an organization should rely on a common understanding of the concept of safety culture. Every organization has its culture. Safety culture is that type of organizational culture where safety is of utmost priority, considered essential for the long term success of the organization. The issue is to make that safety culture strong and sustainable, so that safety becomes a prime responsibility or main focus for all types of activity.

2.9. Safety culture should be based on a set of safety 'beliefs' (assumptions) and on a code of conduct that reflects the right attitude to safety which is held in common by all individuals in the organization. Ultimately, the safety culture is manifested in individual and collective behaviour in the organization.

2.10. Senior management should establish and promote a set of principles to be used in decision making and promoting safety conscious behaviour. Examples of such principles used in some organizations are as follows:

(a) Everyone has an impact on safety.
(b) Managers and leaders must demonstrate their commitment to safety.

(c) Trust and open communication permeate the organization.
(d) Decision making reflects putting safety first.
(e) Nuclear technology is recognized as having unique safety implications.
(f) A questioning attitude is fostered.
(g) Organizational learning is encouraged.
(h) Training of personnel is encouraged.
(i) A proactive approach to safety is taken.
(j) Safety is constantly under review.

2.11. A common understanding by all individuals of the characteristics and attributes of a strong safety culture is a prerequisite, so that everyone can seek and identify strengths and weaknesses and thus enhance the safety culture. The framework identified in Ref. [2] consists of a set of five key characteristics (see Fig. 1), each of which has a number of attributes that have been identified as essential for achieving a strong safety culture. The details of each of the attributes can be found in Ref. [2]. The activities that could demonstrate the attributes of a strong safety culture are provided in Appendix I.

2.12. This framework can be used in two ways:

(i) To reach a common understanding of what factors should be considered in relation to safety culture;
(ii) To evaluate the strengths and weaknesses in an organization by means of both self-assessments and external review.

2.13. The following text provides further recommendations relating to each of the five characteristics of a strong safety culture.

Safety is a clearly recognized value

2.14. The ways that decisions are made and communicated are very important aspects of an organization's safety culture because decisions represent 'values in action'. The stated goals, strategies and plans for the organization establish its objectives and priorities in the short and longer terms. Reference [1] in para. 2.2 states "Safety shall be paramount within the management system, overriding all other demands". Managers should consider safety when establishing goals, strategies and plans, and should align the declared priorities and objectives when allocating resources.

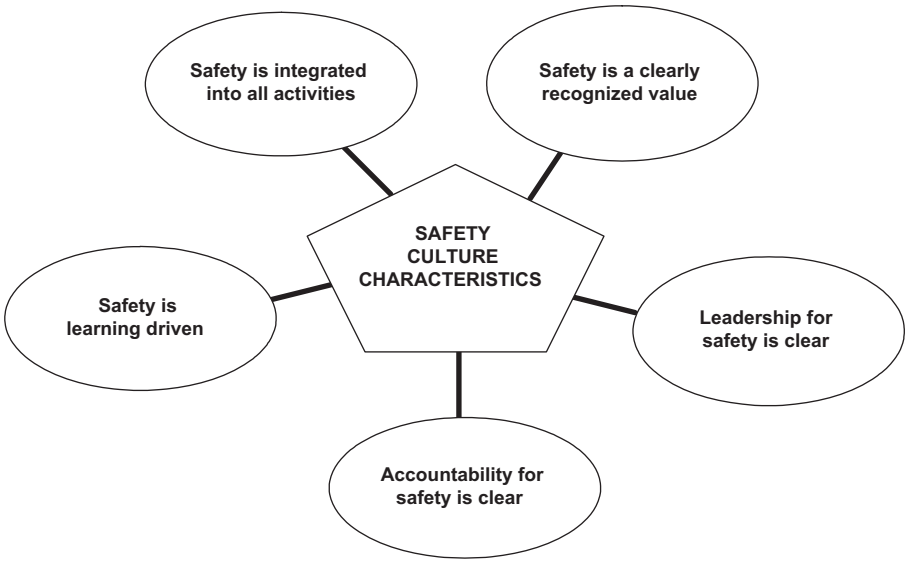

FIG. 1. Characteristics of a strong safety culture.

Leadership for safety is clear

2.15. Senior managers should be the leading advocates of safety and should demonstrate in both words and actions their commitment to safety. The 'message' on safety should be communicated frequently and consistently. Leaders[8] develop and influence cultures by their actions (and inactions) and by the values and assumptions that they communicate. A leader is a person who has an influence on the thoughts, attitudes and behaviour of others. Leaders cannot completely control safety culture, but they may influence it. Managers and leaders throughout an organization should set an example for safety, for example, through their direct involvement in training and in oversight in the field of important activities. Individuals in an organization generally seem to emulate the behaviours and values that their leaders personally demonstrate.

[8] The difference between management and leadership can be stated simply whereby 'management' is a function and 'leadership' is a relationship. Management ensures that work is completed in accordance with requirements, plans and resources. It is through leadership that individuals may be influenced and motivated, and organizations changed. Managers may also act as leaders.

Standards should therefore be set within the organization for aspects that are important for safety.

Accountability for safety is clear

2.16. Managers should establish the authorities and decision making powers for all positions in the organization. These powers should be exercised and there should be clear lines of authority for safety related matters. Accountability means that all individuals should know their specific assigned tasks (i.e. what they have to accomplish and by when, and how to recognize good results); if individuals are unable to execute their assigned tasks as expected, they should report this to their supervisors. The behaviour of managers towards the regulatory body should be such that strong signals are sent to individuals in the organization about respect for rules and the importance of safety. The organization and the regulatory body should be mutually independent and should have a constructive relationship.

Safety is integrated into all activities

2.17. The culture of an organization will encompass everything it does and so, with a strong safety culture, it should be clearly apparent that safety is integrated into all activities in the organization.

Safety is learning driven

2.18. An organization should continually strive to improve its performance so that it does not become complacent. Complacency is often a precursor to a serious decline in safety culture. Management should establish processes and should show by individual example and direction that it expects individuals to look for ways to learn and improve with regard to safety. Operating experience should be highly valued and the capacity to learn from experience should be well developed. Training, benchmarking and self-assessment are often used to stimulate learning and to improve performance.

2.19. A common understanding of what is meant by safety culture should be established. Training is one of the means by which individuals can achieve this understanding. Such training should not be considered a 'one-off' event but should be provided regularly to all individuals, including senior management.

2.20. Some organizations make use of facilitators who are knowledgeable in the area of safety culture, particularly in the initial efforts to raise awareness in the organization of issues relating to safety culture. As safety culture develops in the organization, facilitation skills should be developed for all individuals who will serve in management positions.

2.21. Safety culture should be enhanced by means of regular communication via media such as newsletters and intranets.

Improving safety culture

2.22. In developing a process for continually improving the safety culture in an organization, the following steps should be considered:

(a) Obtaining the commitment of senior management;
(b) Building a common understanding of safety culture;
(c) Describing the desired safety culture;
(d) Assessing the existing culture;
(e) Communicating the results of the assessment to all personnel in the organization;
(f) Identifying gaps, root causes and key initiatives for improvements;
(g) Communicating the direction of the organization and engaging the commitment of supervisors and personnel;
(h) Implementing change;
(i) Ensuring that the guiding principles of safety culture become the accepted way of working;
(j) Sustaining the change;
(k) Performing follow-up assessments.

2.23. In considering how to improve the safety culture, it should be borne in mind that the organization will already have a safety culture in some form that will have been influenced by the organizational culture, the organization's history and experience, and other cultural forces (e.g. the national culture). The challenge is to transform the existing safety culture for the organization's future success. Changing the safety culture should not be an end in itself though; it should be a means of contributing to achieving the goals of the organization. It should be recognized that it might take several years to achieve a profound change in the safety culture.

2.24. The best way of changing the safety culture is to understand and focus on what the new way of working should be and to clarify and communicate any

new behaviour and thinking necessary. The characteristics of a strong safety culture (Fig. 1) could help to identify the desired future state of the organization's safety culture. Once the desired future state is well understood, the present state of the safety culture should be assessed. The assessment should yield information on how the existing safety culture may help in achieving the desired new way of working and thinking. It should also identify any safety culture issues that could hinder the achievement of goals or the fulfilment of strategies, plans and objectives. A specific programme of change for the safety culture should then be designed to deal with these issues. The entire safety culture need not be changed: only the elements of it that could hinder the achievement of goals should be changed. As the gaps between the present state and the desired future state of the safety culture are identified, consideration should be given to what kind of change process is necessary. For this stage, there are no standard solutions and an organization should design its own approach. The approach may involve training, the creation of task groups, system changes, team building and coaching of senior managers and other individuals.

2.25. Major initiatives for changes that affect the safety culture should not be launched prematurely. A careful approach should be taken initially to ensure that everyone understands the new way of thinking and working, and to consider how the existing culture could help or hinder the new culture. The desired changes should build on the existing culture. It should be considered how the individuals who are the targets for change could be motivated to want to change, but such individuals should not become so anxious about learning new things as to resist change. Consideration should be given to how the existing culture can help the learning process and make individuals feel secure.

2.26. A major challenge in changing the safety culture is to develop a learning organization that will continually be able to make its own diagnosis, and to self-manage whatever transformations are necessary as the environment changes. An organization of this type is likely to be far more resilient and successful in dynamic, fast changing economic conditions. Ideally, all individuals should be involved in proactively contributing ideas for improvements. More sustainable approaches would involve encouraging individuals to work in teams and continually seek improvements by identifying and prioritizing actions to enhance safety in their own work areas. To facilitate this, individuals should be given the opportunity to compare their way of working with that of others, so that they are aware of what constitutes excellence in their area of work. Further guidance on safety culture is provided in Ref. [6].

Warning signs of a decline in safety culture

2.27. To prevent a significant degradation of safety, a proactive approach to the management of safety and safety culture should be established so that any problem may be detected and acted upon at an early stage. There is often a delay between the development of weaknesses in safety culture and the occurrence of a safety significant event. By being alert to the warning signs, management can take corrective actions in sufficient time to avoid adverse consequences for safety.

2.28. The management system should have in place the mechanisms by which managers are kept up to date with the warning signs that have been shown to precede organizational failures. Paragraph 2.29 provides examples of the stages of decline and their symptoms; these examples have been taken from a root cause analysis of failures in the management of safety and safety culture.

2.29. The following are typical symptoms of a decline in safety culture:

(a) Lack of a systematic approach to safety — unclear accountabilities, poor decision making processes, poor risk assessment processes, lack of a change management process.
(b) Procedures not being regularly reviewed and updated.
(c) Incidents not analysed in depth and lessons not learned — the recurrence of a problem indicating that the fundamental cause (or causes) has (have) not been properly identified.
(d) No actions taken or implemented in order to eliminate root causes.
(e) Resource mismatches — excessive project slippage, excessive overtime, lack of qualified and experienced personnel, increased use of contractors to perform key organizational activities for long periods of time.
(f) Increasing numbers of violations of rules — an increase in conscious deviations from rules, e.g. short cuts.
(g) An increasing backlog of corrective actions — an increase in the number of corrective actions that have exceeded their target date for implementation and an increase in the length of the delay.
(h) Lack of proper verification of readiness for operation — plant systems not properly verified before the startup of equipment, systems or plant after shutdowns for maintenance.
(i) Safety concerns of personnel not dealt with promptly — safety concerns are ignored or have to be raised repeatedly before action is taken, e.g. lack of a process to allow or encourage individuals to raise safety concerns that results in actions being taken.

(j) Disproportionate focus on technical issues — insufficient attention to issues of human performance, problems being perceived as technical challenges to be solved by engineering means only, without considering that the solution may involve aspects of human performance.
(k) Lack of self-assessment processes — the organization not recognizing deficiencies in attitudes to safety and behaviour and being unable to adopt a philosophy of continual improvement.
(l) Poor housekeeping — indicating lack of interest on the part of management and a poorly motivated workforce with little pride in the working environment.
(m) Failure of corporate memory — a lack of historical data and lack of a knowledge management programme to manage staff turnover. Disproportionate number of experienced individuals leaving the organization, e.g. when reorganizing and/or downsizing.
(n) Low status of individuals or units conducting assessments — lack of respect for findings of assessments, findings being ignored or not addressed in a timely manner.
(o) Failure to deal with the findings of independent external safety reviews — reluctance to accept proposals for changes that were not developed internally or lack of a process to monitor progress in implementing the recommendations of external reviews.
(p) Lack of corporate oversight — lack of awareness of safety issues at the corporate level, with safety issues being ignored in making business decisions.
(q) Lack of 'ownership' of safety — lack of recognition that everyone shares a responsibility for safety.
(r) Isolationism — safety practices and standards become unrelated to best practices and standards in the industry whereby the organization operates increasingly in a self-referencing mode.
(s) Lack of learning — unwillingness to share knowledge and experience with others, or to use the experience of others to improve safety at the installation. Organizations become complacent and focus on the successes of the past, and are reluctant to invest in acquiring new knowledge and skills for the future.

More information regarding the stages of decline in safety culture is provided in Ref. [7].

2.30. Reference [1] states in para. 2.5 that:

> "The management system shall be used to promote and support a strong safety culture by:
> — Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization."

2.31. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Human factors and the interaction between individuals, technology and the organization[9]

2.32. All safety barriers are designed, constructed, strengthened, breached or eroded by the action or inaction of individuals. Human factors in the organization are critical for safe operation and they should not be separated from technical aspects. Ultimately, safety results from the interaction of individuals with technology and with the organization.

2.33. The concept of safety culture embraces this integration of individuals and technical aspects. However, whereas the culture of an organization influences human behaviour through the values, beliefs and assumptions held by the personnel of the organization, there are also other factors that may have an influence on how humans act in a given situation.

2.34. In a strong safety culture, there should be a knowledge and understanding of human behaviour mechanisms and established human factor principles should be applied to ensure the outcomes for safety of individuals–technology–organization interactions. This could be achieved by including experts on human factors in all relevant activities and teams.

2.35. The interaction between the individual, technology and the organization can be explained as follows. In a given situation, individuals have various types of resource at their disposal to enable them to carry out a task successfully.

[9] In some States this interaction is referred to as 'man–technology–organization'.

These resources may be intrinsic to the individual in the form of competence, motivation, cognitive abilities, etc. Resources may also be physical resources (such as instrumentation, procedures or computer aids), or they may reside in the working environment, through teamwork, communication and leadership, in the management system and in the culture. When the content, design and organization of the task correspond to the individual's needs and capabilities, the conditions prevail for the individual to perform in a way that promotes safety. Thus, resources intrinsic and extrinsic to the individual may help in preventing human error by providing barriers to error.

2.36. When analysing events, consideration should be given to the possible influence of all these factors on human behaviour. These factors should also be considered when the purpose is to identify potential weaknesses in the interactions between individuals–technology–organization and to determine how to strengthen barriers or introduce new barriers to prevent human error. Ideally, interdisciplinary teams should carry out predictive and preventive analyses of these types of event. Such teams should include human behaviour competence, so as to analyse the individuals–technology–organization interactions from different perspectives in order to identify suitable barrier functions.

2.37. Individuals should also be trained in how to recognize situations that are likely to give rise to errors, so that they can avoid making mistakes. In addition, there are various activities that could be carried out on an individual basis to prevent error. Among these are:

(a) Pre-job briefings, asking the questions: What are the critical steps? What situations associated with the work assignment are likely to give rise to errors? What defences are in place to prevent events?
(b) Self-checks applying the stop–think–act–review (STAR) concept.
(c) Peer checks — having a second individual check the intended action prior to carrying it out.
(d) Three-way communication by which a message is communicated from one individual to another. The individual receiving the message repeats the message to confirm a clear understanding and the originator acknowledges that the message has been correctly understood and so closes the communication loop.
(e) Conservative decision making should be applied when there are no procedures in place or plans made for the activity. Further guidance is provided in Ref. [7].

GRADING THE APPLICATION OF REQUIREMENTS FOR THE MANAGEMENT SYSTEM

2.38. Reference [1] states in paras 2.6 and 2.7 that:

> "The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:
> — The significance and complexity of each product or activity;
> — The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;
> — The possible consequences if a product fails or an activity is carried out incorrectly.
>
> "Grading of the application of management system requirements shall be applied to the products and activities of each process."

2.39. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

2.40. To establish the necessary grading of an item, service or process, the responsible individual should be guided through a series of questions to enable them to determine the consequences of the inadequate performance or inadequate control of an item, service or process. Annex I provides an example of such a methodology for use in the operation stage and the considerations that need to be taken into account in grading management system requirements. The grading methodology used in other stages of the lifetime of a nuclear installation could reflect a similar methodology to that discussed in Annex I but which will address the factors relevant to the specific stage.

2.41. In general, application of the management system requirements should be most stringent for items, services or processes with the highest grade; for the lowest grade, application of the management system requirements may be the least stringent. The following are examples of areas where grading should be applied:

(a) Type and content of training;
(b) Level of detail and degree of review and approval of instructions;
(c) Need for, and level of, detail of inspection plans;
(d) Degree of in-process reviews and controls;

(e) Requirements for traceability of material;
(f) Type and level of detail in procurement documents;
(g) Type of assessment;
(h) Records to be generated and retained.

DOCUMENTATION OF THE MANAGEMENT SYSTEM

2.42. Reference [1] states in paras 2.8–2.10 that:

> "The documentation of the management system shall include the following:
> — The policy statements of the organization;
> — A description of the management system;
> — A description of the structure of the organization;
> — A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
> — A description of the processes and supporting information [e.g. procedures and instructions] that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.
>
> "The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.
>
> "The documentation of the management system shall reflect:
> — The characteristics of the organization and its activities;
> — The complexities of processes and their interactions."

2.43. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

2.44. Detailed working level documents include work instructions, technical instructions and drawings and typically cover the tasks within a process that are carried out within a department or by an individual. Some organizations develop a writers guide to ensure the consistency of the style and appearance of the documents. These documents are level 3 documentation, as described in Ref. [2].

2.45. Detailed working documents are used to describe specific work activities and to convey administrative and technical information to the individuals performing the work. The type and format of these documents may vary considerably, depending on their application.

2.46. The sections contained in detailed working documents are similar to the documents at level 2, although they contain considerably more detail on how the work is to be performed. The sections typically include the following twelve instructions:

(1) *Purpose*: Give a clear, concise statement explaining the specific purpose of the document and answering the question: What is the document intended for?

(2) *Scope*: Define the type and the scope of work and the places where the document applies, and delineate the boundaries of the functions, systems and areas treated in the document.

The above two item headings may not be necessary if the title of the document adequately conveys the purpose and scope, e.g. routine maintenance of turbine hall water coolant pump.

(3) *Responsibilities*: Define the duties of the individuals who are to apply the document. Identify these individuals and specify their responsibilities and when any necessary action should be taken.

(4) *Definitions*: Define words and terms used in the document that might cause confusion and which thus need clarification.

(5) *References*: Provide a bibliography of specifications, standards and other documents referenced in the document. If documents are referenced in part, state the relevant pages and paragraph numbers, which may include references to other work instructions. Documents referenced may also include applicable design documents or other source documents such as vendors' literature, engineering drawings or plant specifications.

(6) *Prerequisites*: State any independent actions that should be performed, and by whom they should be performed, prior to the use of the procedure or instruction. State any spare parts, special tools or instruments that are necessary (e.g. scaffolding or services); state also the necessary state of the plant, if relevant, and any special conditions necessary to simulate normal or abnormal operating conditions.

(7) *Precautions*: State what precautions are necessary to protect equipment, individuals, the public and the environment or to avoid abnormal conditions or an emergency. Highlight such precautions in this section, or identify them in the relevant steps of the procedure or instructions.

(8) *Limitations*: Are there any limitations on the parameters being controlled? Identify the corrective measures that may be used to restore such parameters to within the normal limits.

(9) *Actions*: Include a description of the functions or tasks to be performed in a process. Provide sufficient detail so that a competent individual can perform the functions or tasks without direct supervision. In some cases, it may be appropriate to provide step-by-step instructions.

(10) *Verification*: Identify any work activity that requires verification, including independent verification. Highlight the verification points at the relevant step in the procedure.

(11) *Acceptance criteria*: State criteria for the satisfactory completion of the task or function. If tolerances within prescribed limits are permissible, they should be specified together with any requisite actions (e.g. reporting). Specify the method of verification to be used. This can be included as part of the procedure or on a check sheet. Referenced documents may be used as a source of the details of acceptance criteria.

(12) *Records and check sheets*: Clarify which documents or forms are to be used and retained. Check sheets should be employed when complex procedures or instructions are used. A list should be added which specifies, by title, the records necessary to certify or provide evidence that the tasks required in the document have been accomplished and verified and examples of the documents or forms attached. Identify records as permanent or non-permanent in accordance with specified criteria, and specify the retention times for non-permanent records. Mark attached sample forms with 'specimen'. Record the date and identify the individuals performing the work and, where appropriate, the 'as found' condition, the corrective action performed and the 'as left' condition.

3. RESPONSIBILITY OF MANAGEMENT

COMMITMENT BY MANAGEMENT

3.1. Reference [1] states in paras 3.1–3.5 that:

"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement

of the management system and shall allocate adequate resources to carry out these activities.

"Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.

"Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.

"Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.

"Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system."

3.2. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

MEETING THE EXPECTATIONS OF INTERESTED PARTIES

3.3. Reference [1] states in para. 3.6 that:

> "The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."

3.4. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

3.5. To consider and respond to the expectations of interested parties, an organization:

(a) Should identify its interested parties and address their expectations within the management system;

(b) Should identify and agree which of the interested parties' expectations are to be satisfied and should ensure that they are communicated throughout the organization;
(c) Should take an approach such that ensuring safety overrides all other demands, especially in the event of contrary expectations on the part of different interested parties;
(d) Should translate the expectations identified into requirements on the organization;
(e) Should communicate the requirements throughout the organization;
(f) Should focus on improving processes to ensure value for the interested parties identified.

3.6. Formally agreed expectations of interested parties, in relation to a nuclear installation, should be addressed by the organization within the constraints imposed by statutory and mandatory requirements. Expectations of interested parties could be factored into elements such as:

(a) Safety;
(b) Availability;
(c) Reliability;
(d) Transparency;
(e) Communication;
(f) Cost;
(g) Liability;
(h) Environmental impact.

3.7. Management should practise ethical, effective and efficient compliance with current and prospective requirements and should communicate throughout the organization:

(a) The benefits to be gained for interested parties and by the organization by striving for excellence;
(b) The obligations of the organization with regard to its impact on society.

3.8. The process of assessing how the expectations of interested parties are satisfied should involve several steps:

(a) Determination of the factors necessary for satisfying the expectations of interested parties;
(b) Selection of the approach to, and methodology for, the assessment;

(c) Assessment of the satisfaction of the expectations of interested parties;
(d) Analysis of the data.

3.9. The results of the assessment of satisfaction of the expectations of interested parties should be used as an input for the process of continual improvement of the management system.

ORGANIZATIONAL POLICIES

3.10. Reference [1] states in para. 3.7 that:

> "Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization."

3.11. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Developing the policies

3.12. The policies of the organization should be stated as succinctly as possible, to enable them to be effectively communicated, understood and consistently implemented. In addition, the following key information should be communicated effectively for each policy:

(a) The meaning and purpose of the policy;
(b) The values and beliefs that relate to the policy;
(c) The commitment of senior managers to its implementation;
(d) The plans, standards, procedures and systems relating to its implementation and the measurement of performance;
(e) Additional factual information to promote the involvement and commitment of individuals;
(f) Performance reports;
(g) Comments and ideas for improvements;
(h) How lessons learned will be applied.

3.13. Written policy statements should set the direction for the organization:

(a) By demonstrating senior managers' commitment;
(b) By setting each policy in context with other business objectives;
(c) By making a commitment to continual improvement in performance.

3.14. The key tasks of senior management with regard to policies should include:

(a) Specifying and devising the policies of the organization;
(b) Establishing strategies to implement each policy and integrating these strategies into general business activities;
(c) Specifying a structure for planning, measuring and assessing each policy;
(d) Specifying a structure for implementing each policy and its supporting plans;
(e) Agreeing plans for improvements and for reviewing progress, to develop both the management system and the policies;
(f) Pursuing the policy objectives.

Implementing policies

3.15. The processes for implementing each policy and the structure within which the policy is implemented should be clear. Individuals should know which parts of the processes are relevant to them, so as to understand the major risks in the activities at the installation and how they are controlled.

3.16. In order to understand and implement policies at the installation, managers at all levels should have:

(a) Leadership skills;
(b) Communication skills;
(c) Skills in training, instruction, coaching, knowledge management and problem solving;
(d) An understanding of the risks within the manager's own area of responsibility;
(e) Knowledge of relevant legislation and appropriate methods of compliance;
(f) Knowledge of the planning, measuring and assessment processes at the installation.

3.17. Some managers in key positions may provide specific input to the policies of the organization. This would apply to those managers who devise and develop the management system, who investigate accidents and other incidents, who take part in review and audit activities or who are responsible for implementing emergency procedures.

3.18. To understand and implement the policies of the organization, every individual should have:

(a) An overview of the principles underlying each policy;
(b) Detailed knowledge of the arrangements relevant to the individual's own job and safety implications thereof;
(c) Communication skills and problem solving skills, to allow effective participation.

3.19. The system of performance appraisal should be used to identify any lack of understanding by individuals or any failure to implement the policies of the organization. Such a lack of understanding could arise, for example, because an individual has not absorbed formal on the job training or information provided as part of their induction. Training is necessary in different situations and at various stages. Training should cover:

(a) The induction of new personnel, including part-time and temporary personnel;
(b) Improving the performance of individuals;
(c) Job changes, promotions or delegations of authority allowing someone to deputize;
(d) The introduction of new equipment, technology or procedures;
(e) Follow-up actions after the investigation of an incident.

3.20. A single integrated policy or an integrated set of policies should be developed that includes as a minimum the following topics:

(a) Safety (including nuclear safety and the health and safety of individuals);
(b) The environment;
(c) Quality;
(d) Change management;
(e) Security.

Safety, health and environmental policy

3.21. Since policies on safety, health and the environment are similar in content and nature, some organizations choose to combine them into one policy. The combined safety, health and environmental policy:

(a) Should state the importance of protecting the safety, the health and the environment of personnel, contractors and the public.
(b) Should confirm that excellence in performance in the areas of safety, health and environmental protection is an integral part of the business and is essential to commercial success.
(c) Should state, as primary goals, that no harm should result from activities carried out by the organization and that the organization should be respected and trusted by the personnel, by the public and by interested parties.
(d) Should state clear policy objectives and proposed means of:
    — Eliminating injuries and health issues at work and minimizing radiation exposures;
    — Preventing incidents and maintaining effective arrangements for emergency preparedness and response;
    — Reducing pollution as far as practicably feasible, minimizing radioactive discharges, minimizing radioactive waste and other waste and using natural resources in a sustainable way, for the purpose of environmental protection;
    — Ensuring the safe disposal or storage of radioactive waste and other waste;
    — Achieving and maintaining a strong safety culture;
    — Learning lessons from events, implementing corrective actions and seeking out and using good practices;
    — Ensuring that the activities and products of the organization are in compliance with applicable legislation and that its practices meet the relevant requirements and applicable standards of performance.
(e) Should specify how the safety, health and environmental policy will be developed and improved by, for example:
    — Consulting individuals on matters of common interest;
    — Listening to and responding to interested parties;
    — Openly reporting, at least once a year, on performance in meeting the objectives of the safety, environmental and health policy;
    — Working with interested parties, the nuclear industry and contractors to improve safety, environmental and health activities;

— Informing, instructing, training and developing individuals who work at the installation and ensuring that competent advice on safety, environmental and health matters is available;
— Auditing the management system and, as a result, adjusting the objectives and targets of the safety, environmental and health policy where necessary;
— Maintaining a high level of performance of activities, in particular by ensuring that the activities are adequately resourced and are carried out by suitably qualified and experienced individuals, with priority given to safety at all times.

(f) Should state which specific legal requirements the policy has been developed to meet.

(g) Should specify the process for reviewing new legislation on safety, environmental and health matters and for ensuring that the organization can comply with it.

Policy for quality

3.22. The policy for quality:

(a) Should specify the organization's expectations in relation to quality.

(b) Should set the expectations of the management for organizational performance and for the performance of individual employees.

(c) Should express the management's support of each individual in carrying out their assigned work.

(d) Should promote an objective of continual improvement.

(e) Should create a working environment that promotes quality and continual improvement throughout the installation.

(f) Should ensure that individuals have the necessary responsibilities and authorities to carry out their work.

(g) Should state a commitment that products and processes will be of the required quality.

(h) Should establish the management's responsibility for ensuring that individuals understand and accept their functions and obligations in applying the policy for quality.

(i) Should specify the key documents that govern levels of performance, such as:
— Other policy statements;
— Statutes and regulations;
— The description of the management system;
— National and international codes and standards.

Policy for change management

3.23. Organizations should promulgate a policy for promoting and managing change that encompasses their vision and values. This policy for change management:

(a) Should give priority to safety;
(b) Should address all types of change;
(c) Should introduce the process for change management;
(d) Should state that only approved changes will be implemented;
(e) Should promote effective communication.

Security policy

3.24. Details of the security policy are not provided here because of the nature of its content. The content of the security policy is governed by the security requirements of the Member State (see footnote 3).

PLANNING

3.25. Reference [1] states in paras 3.8–3.11 that:

> "Senior management shall establish goals, strategies, plans and objectives[10] that are consistent with the policies of the organization.
> "Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.
> "Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization.
> "Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary."

[10] These goals, strategies, plans and objectives are sometimes collectively referred to as a 'business plan'.

3.26. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

RESPONSIBILITIES AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.27. Reference [1] states in paras 3.12–3.14 that:

> "Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved.
> "An individual reporting directly to senior management shall have specific responsibility and authority for:
> — Coordinating the development and implementation of the management system, and its assessment and continual improvement;
> — Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;
> — Resolving any potential conflicts between requirements and within the processes of the management system.
> "The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system."

3.28. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

3.29. The individual with specific responsibility for the development and implementation of the management system should be specified. This individual should ensure that those persons responsible for each process (the process owners) provide a periodic report on the status of their processes to enable reports on the performance of the management system to be prepared.

3.30. Techniques such as benchmarking (internal and external) should be used to identify potential improvements in the management system. Also, the individual with specific responsibility for the assessment and for continual improvement of the management system should be aware of, and if possible

should be involved in, developments in national and international standards, and should be aware of practices in other organizations, so as to identify potential improvements.

4. MANAGEMENT OF RESOURCES

PROVISION OF RESOURCES

4.1. Reference [1] states in para. 4.1 that:

> "Senior management shall determine the amount of resources necessary and shall provide the resources[11] to carry out the activities of the organization and to establish, implement, assess and continually improve the management system."

4.2. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Resources provided by suppliers and partners

4.3. Work may be contracted out to external organizations for reasons of economy or because another organization is more competent to perform the work. This should be done on the basis of an established management strategy for suppliers. This strategy should clearly specify whether goods or services are simply acquired from suppliers or whether the organization and the supplier are partners.

[11] 'Resources' includes individuals, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.

4.4. In either case, the organization should know and should have a clear understanding of the products and services with which it is supplied. 'Intelligent customer capability'[12] should be retained by the organization in order to ensure the organization can exercise control over the work, so as to maintain the ultimate responsibility for its safe and effective execution.

4.5. It may be beneficial to maintain an approved list of suppliers whose performance has been verified by means of selection criteria and/or experience. However, the inclusion of a supplier on an approved list should not diminish the organization's responsibility to ensure that goods and services are as specified in procurement documentation.

4.6. In the case of a partnership between the organization and the supplier, consideration should be given to the way in which learning could best be achieved to the advantage of both organizations and to maximize the future benefits of continuing the relationship. This may include partners in project initiation phases such as development and review. Partnerships should be managed with account taken of any regulations regarding competition.

4.7. When contracts are awarded for work to be carried out at the installation by individuals from other organizations, the organization should ensure that there is no conflict between the work practices and standards of the supplier and those at the installation.

Managing information and knowledge

4.8. Reference [1] states in para. 4.2 that "The information and knowledge of the organization shall be managed as a resource."

4.9. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

4.10. Knowledge management is an integrated, systematic approach to identifying, acquiring, transforming, developing, disseminating, using, sharing and preserving knowledge that is relevant to achieving specified objectives.

[12] An 'intelligent customer capability' is the capability of the organization to have a clear understanding and knowledge of the product or service being supplied.

Knowledge management consists of three fundamental components: (i) individuals, (ii) processes and (iii) technology. Knowledge management focuses on individuals and organizational culture to stimulate and nurture the sharing and use of knowledge; on processes or methods to find, create, capture and share knowledge; and on technology to store knowledge and make it accessible and to allow individuals to work together without needing to be in the same place. Individuals are the most important of these components, because managing knowledge depends on the willingness of individuals to share and reuse knowledge.

4.11. With regard to information, the full information needs of those carrying out tasks and the ways in which the information is to be provided to the user should be considered in formulating the instructions for each task. The day to day responsibility for ensuring that such information is used effectively lies with the immediate supervisors of the individuals performing tasks. An example of a good practice is the use of pre-job and post-job briefings that include the review of instructions, the review of potential hazards, tool checks, reports on experience of performing the same or similar tasks, and the possible impacts of any other work being undertaken in the vicinity. Information on any unexpected or unusual occurrences while carrying out the work should be preserved and shared.

4.12. Information relating to safety should not be regarded as intellectual property but rather should be shared freely within the nuclear community. Sharing may be achieved through the contribution of information to databases, the sharing of reports, participation in conferences and seminars and benchmarking visits.

4.13. For an organization to be able to provide critical information, it should manage pertinent knowledge so that it is easily accessible to those who may need it for carrying out their tasks. An organization should have an integrated, systematic approach to identifying, capturing, managing and sharing its knowledge and, in so doing, enable groups of individuals to acquire 'new' knowledge collectively to help achieve the objectives of the organization. Such a knowledge management system helps an organization to gain insight and understanding from its own experience.

4.14. Knowledge management should be used to capture knowledge (both tacit and explicit) from individuals before they leave the organization, so that it can be retained and transferred to others who need the knowledge for the performance of their jobs or tasks. The organization should assess any risk that

is posed by the loss of critical knowledge and should take mitigatory action if necessary. The organization should have the knowledge base necessary to facilitate the assimilation of new workers and to enhance the skills and knowledge of existing workers.

HUMAN RESOURCES

4.15. Reference [1] states in paras 4.3 and 4.4 that:

> "Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.
> "Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."

4.16. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

4.17. The organization should maintain a human resources plan that deals with both numbers of staff and competence levels. The human resources plan should include a model that covers, for example, the demographics of the organization's personnel and the projected use of contractors and off-site work. The organization should consider the effects of ageing on its workforce and should establish a detailed plan to ensure that sufficient competent staff remain available. Account should be taken in the plan of the lead time necessary to recruit and train key personnel such as reactor operators.

INFRASTRUCTURE AND THE WORKING ENVIRONMENT

4.18. Reference [1] states in para. 4.5 that:

> "Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met."

4.19. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Managing material assets

4.20. Registers of all significant material assets should be maintained. For each material asset or type of asset there should be a strategy or plan that specifies how that asset will be preserved, maintained, enhanced or replaced, with account taken of the entire lifetime of the asset, so as to preserve the contribution of that asset to safety. Appropriate treatment of all material assets at the end of their useful lifetimes should be a major factor in asset management.

4.21. Inventories of material such as consumables and spare parts should be maintained at appropriate levels, with due recognition of the fact that safety takes priority over economic considerations.

4.22. The process for specifying the provision of infrastructural assets should include consideration of the possibility that such assets may be deliberately damaged or stolen. Appropriate security arrangements should be put in place to ensure that the contribution of such assets to safety would not be compromised.

4.23. Some material assets, such as supplies of chemicals or gases, may present a risk to the health and safety of individuals or to the environment through their use or their presence on-site. Arrangements should be in place to identify, manage and reduce such risks. The long term effects of using items should be assessed for the possibility that they cause repetitive stress injury, or that the use of display screens and other equipment causes eye strain or results in bad posture.

Replacing old technologies

4.24. The organization should actively seek opportunities to replace with better and more modern technologies those components of its systems that are prone to human error or to mechanical failure leading to poor performance. When replacing old technologies, the organization should be able to demonstrate that the new technology will not compromise safety.

4.25. In particular, care should be taken to identify and manage situations in which the original suppliers of material assets no longer provide or support the installed systems or components. When replacements of original systems and components become necessary and the original supplier no longer exists, an 'equivalent component replacement' process should be established.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. Reference [1] states in paras 5.1–5.5 that:

> "The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved.
> "The sequence and interactions of the processes shall be determined.
> "The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.
> "The development of each process shall ensure that the following are achieved:
> — Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.
> — Hazards and risks are identified, together with any necessary mitigatory actions.
> — Interactions with interfacing processes are identified.
> — Process inputs are identified.

— The process flow is described.
— Process outputs (products) are identified.
— Process measurement criteria are established.

"The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities."

5.2. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

5.3. Every organization involved in research and development, site evaluation, design, construction, operation and decommissioning for nuclear installations should specify, develop, implement, maintain and improve all the processes that are necessary for it to achieve its goals, strategies, plans and objectives. This section provides recommendations on processes that are generic to research and development and to all stages in the lifetime of a nuclear installation. Further recommendations and guidance on processes that are specific to research and development activities and to each stage of the lifetime of the nuclear installation are provided in Appendices II–VIII.

Process model

5.4. Many organizations have a structured approach to developing their processes in order to achieve integrated management of the installation and to ensure that they address safety issues when making commercial decisions.

5.5. A major component of the management system is the process model that incorporates the hierarchy of the processes of the organization. In some Member States, the individual in the most senior position in the organization appoints a management system manager with responsibility for controlling the process model of the organization and for formulating a standardized approach to describing and controlling processes in order to ensure that there is consistency and continuity between the various processes.

5.6. The following process model is provided as an example of the levels of processes within an organization. There are many alternative models and terms that could be used to describe the levels of processes in an organization. In this example there are three types of process: (1) core processes (sometimes

referred to as key processes), (2) supporting processes and (3) management processes.

(1) Core processes

Core processes produce the output that is critical to the success of the organization. In the following example there are three main types of core process. These are (a) operation processes, (b) maintenance processes and (c) technical support processes.

(a) Operation processes describe how the organization:
  — Operates equipment and systems:
    • To meet planned operational needs;
    • To respond to off-normal conditions;
    • To prepare equipment for maintenance.
  — Monitors (including sampling and testing) equipment and systems (including system fluids) to confirm that they are performing as expected.
  — Develops monitoring programmes, analyses the results and makes adjustments as necessary.

(b) Maintenance processes describe how the organization:
  — Repairs, overhauls and adjusts equipment so that it works correctly throughout its service life.
  — Carries out inspections and diagnostic testing to determine whether and when maintenance is necessary.
  — Implements maintenance programmes, analyses the results and makes adjustments as necessary.
  — Arranges work planning and scheduling to enable maintenance to take place.

(c) Technical support processes describe how the organization:
  — Develops monitoring programmes, analyses the results and makes adjustments as necessary.
  — Develops maintenance programmes, analyses the results and makes adjustments as necessary to optimize plant and/or equipment performance.
  — Develops management programmes for plant and/or equipment life, including monitoring of age related degradation mechanisms and planning of necessary overhauls, refurbishments or replacements to restore equipment conditions.

— Monitors and assesses new developments in technology and replaces equipment and parts, as necessary, to minimize risks due to technological obsolescence.
— Develops and implements design changes to structures, systems and components (including software).
— Maintains the design basis and basis for the safety analysis (safety case).
— Carries out activities relating to reactor physics and core management.

(2) Supporting processes

Supporting processes provide the infrastructural services necessary to perform all of the core processes and management processes effectively. Typically, there are many supporting processes covering such activities as:

(a) Providing training;
(b) Providing for personnel safety, radiation protection and fire protection;
(c) Carrying out contamination control;
(d) Providing for emergency preparedness and response arrangements;
(e) Providing for security of the installation;
(f) Providing for environmental monitoring and environmental protection;
(g) Providing information technology support;
(h) Procuring goods and services;
(i) Providing documentation and records;
(j) Obtaining and maintaining regulatory licences and permits.

(3) Management processes

Senior management primarily uses these processes to describe how it sets and communicates expectations and how it exercises control:

(a) To direct and manage the business of the installation;
(b) To provide human resources;
(c) To provide financial resources;
(d) To manage external relationships and interfaces;
(e) To assess and improve the performance of work;
(f) To assess and improve the effectiveness of work processes.

Management processes should be such as to ensure that the management of the organization makes adjustments as necessary to its plans and objectives. Management processes also cover the management of important relationships outside the installation.

PROCESS MANAGEMENT

5.7. Reference [1] states in paras 5.6–5.10 that:

> "For each process a designated individual shall be given the authority and responsibility for:
> — Developing and documenting the process and maintaining the necessary supporting documentation;
> — Ensuring that there is effective interaction between interfacing processes;
> — Ensuring that process documentation is consistent with any existing documents;
> — Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
> — Monitoring and reporting on the performance of the process;
> — Promoting improvement in the process;
> — Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.
>
> "For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified.
>
> "For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.
>
> "Each process shall be evaluated to ensure that it remains effective.
>
> "The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.
>
> "The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes."

5.8. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

GENERIC MANAGEMENT SYSTEM PROCESSES

5.9. Reference [1] states in para. 5.11 that "The following generic processes shall be developed in the management system."

Control of documents

5.10. Reference [1] states in paras 5.12 and 5.13 that:

> "Documents[13] shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.
> "Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves."

5.11. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

Control of products

5.12. Reference [1] states in paras 5.14–5.20 that:

> "Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.

[13] Documents may include: policies, procedures, instructions, specifications and drawings (or representations in other media), training materials and any other texts that describe processes, specify requirements or establish product specifications.

"Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.

"The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.

"Products shall be provided in such a form that it can be verified that they satisfy the requirements.

"Controls shall be used to ensure that products do not bypass the required verification activities.

"Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product.

"Products shall be handled, transported, stored, maintained and operated as specified, to prevent their damage, loss, deterioration or inadvertent use."

5.13. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. They describe the processes used at nuclear installations to control products.

Inspection and testing

5.14. The inspection process may require inspections to be performed by the organizational unit responsible for the work, by another department or by an external organization that is independent of the installation. Individuals should ensure that their own work has been performed correctly by self-checking. However, individuals should not be permitted to inspect their own work when determining acceptance.

5.15. Managers should ensure that inspections are properly planned. Planning should address such aspects as product characteristics, inspection techniques, hold and witness points, acceptance criteria and the organization or individuals responsible for conducting the inspections.

5.16. Appropriate tests should be conducted to demonstrate that products perform as intended. All testing should be conducted using established and

proven test requirements and acceptance criteria. Further recommendations and guidance on testing equipment and testing are provided in Refs [8, 9].

5.17. Arrangements should be established to hold products or to stop further work until the required inspections and tests have been completed and the corresponding reports have been received and verified by designated individuals. These arrangements should state what should be done if inspections and tests give negative results.

5.18. The plans for inspection and testing should identify the sequential inspection and testing activities that are necessary to demonstrate conformance with requirements, the means by which conformance is to be verified and the relevant acceptance criteria.

5.19. The following types of information should be included in the inspection and testing plans:

(a) General information, such as the name of the installation, the product or system reference, the procurement document reference, the document reference number and status, associated procedures and drawings.
(b) A sequential listing of all inspection and testing activities; all products to be inspected and tested should be identified and referenced in the plan.
(c) The procedure, work instruction, specification or standard (or the specific section, if appropriate) that should be followed in respect of each operation, inspection or test.
(d) Reference to the relevant acceptance criteria.
(e) Specification of who is to perform each inspection and test and provision for recording that each inspection and test has been performed satisfactorily.
(f) Specification of hold points beyond which work may not proceed without the recorded approval of designated individuals or organizations.
(g) Specification of witness points where an assigned individual or organization can check activities but where the work need not be stopped if the inspector is not present.
(h) Specification of hold points for inspection and testing by an external organization that is independent of the installation, e.g. the regulatory body or a third party inspector.
(i) The type of record to be prepared for each inspection or test.
(j) The number of products to be inspected or tested when multiple products or repeat operations are involved.

(k) The individuals or organizations that have authority for the final acceptance of the product.

5.20. Test requirements, including testing frequency and acceptance criteria, should be specified. Unless otherwise stated, the test requirements should be subject to the approval of the organization responsible for the specification of the product or system to be tested. Required tests should be controlled. Tests may include:

(a) Prototype qualification tests;
(b) Production tests;
(c) Proof tests prior to installation or handover of equipment in the installation;
(d) Construction tests;
(e) Pre-operational or commissioning tests;
(f) Operational tests.

5.21. Testing requirements and acceptance criteria should be based on the design documents or other pertinent documents. Testing should verify that the safety function of a product has been maintained. Appropriate testing of computer software should be completed before reliance is placed upon the software for operations.

5.22. Testing instructions should specify the test objectives and should make provision for ensuring that prerequisites for the given test have been met, that adequate equipment is available and is being used, that necessary monitoring is performed and that suitable environmental conditions are maintained.

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

Measuring and testing equipment

5.24. Reference [1] states in para. 5.15 that:

> "Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision."

5.25. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

5.26. A process should be established for the control and, where necessary, calibration of tools, gauges, instruments and other measuring, inspection and testing equipment used for activities important to safety at the installation.

5.27. A process should be established for the control of equipment that is out of calibration, including its segregation to prevent its further use and the identification and evaluation of any consequences of its use for previous measurements made since the last calibration date.

5.28. Tools, gauges, installed instrumentation and other measuring, inspection and testing equipment (including testing software and devices) should be of the proper range, type, accuracy and measuring precision.

5.29. The selection, identification, use, calibration requirements and calibration frequency of all measuring, inspection and testing equipment should be specified. The responsibility for the control of measuring and testing equipment should be specified. Arrangements should include:

(a) Specification of the measurements to be made and the accuracy required, and the specific measuring and testing equipment to be used.
(b) Identification, calibration and adjustment of all measuring and testing equipment and devices that could affect product quality, at prescribed intervals or prior to use, against certified equipment having a known and valid relationship to nationally or internationally recognized standards. If no such standards exist, the basis used for calibration should be documented.
(c) Establishment, documentation and maintenance of calibration procedures, including details of the type of equipment, its unique identification number, its location, the frequency of checks, the check method, the acceptance criteria and the actions to be taken when results are unsatisfactory.
(d) Verification that the measuring and testing equipment has the required accuracy and precision.
(e) Identification of measuring and testing equipment with a suitable indicator or approved identification record to show its calibration status.
(f) Maintenance of calibration records for measuring and testing equipment.

(g) The review and documentation of the validity of previous measurements if measuring and testing equipment is found to be out of calibration. Operation records or maintenance records can be used as a source of information to identify the testing equipment that was used.
(h) Controls to ensure that environmental conditions are suitable for the calibrations, measurements and tests being carried out.
(i) Controls to ensure that the handling, preservation, storage and use of calibrated equipment are such that its accuracy and fitness for use are maintained.
(j) Protection of measuring and testing equipment from adjustments that may invalidate its accuracy.
(k) Methods for adding measuring and testing equipment to, and removing it from, the calibration programme, including the means to ensure that new or repaired products are calibrated prior to their use.
(l) A process to control the issue of measuring and testing equipment to qualified and authorized individuals.

5.30. Testing hardware, such as jigs, fixtures, templates or patterns, and testing software used for inspections should be checked prior to their use in production and in the installation. They should be rechecked at prescribed intervals and account should be taken of any recommendations of the manufacturer/supplier. The extent and frequency of these checks should be established and records should be maintained as evidence of control. Such testing hardware that has been approved for use should be properly identified.

Control of records

5.31. Reference [1] states in paras 5.21 and 5.22 that:

> "Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.
> "Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record."

5.32. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

Purchasing

5.33. Reference [1] states in paras 5.23–5.25 that:

> "Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.
> "Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.
> "Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents."

5.34. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Commercial grade products

5.35. Certain products 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 product to be supplied.

5.36. Relevant technical data and trial information regarding the product should be requested from the manufacturer as necessary. Where appropriate, a commercial grade product may need to undergo confirmatory analysis or testing to demonstrate the adequacy of the product to perform its intended function.

5.37. When a commercial grade product is proposed for any safety function, a process should be used to determine the product's suitability; this is sometimes referred to as a 'dedication' process in some States. This process should identify whether the following activities are required:

(a) A thorough technical evaluation of critical characteristics such as reliability and failure modes.
(b) Verification of compliance of the product with requirements that are safety significant.

(c) Determination of specific tests, inspections and verification activities to ensure the capability of the product to meet requirements for any critical characteristics.
(d) Performance of tests and acceptance of results on the basis of criteria. The critical characteristics required for any safety function should be included as acceptance criteria in the procurement documents.
(e) The need to conduct verification or inspection of the product at the supplier's facility prior to authorization for delivery.
(f) Evaluation of the capability of, and the controls applied by, the suppliers of the product.
(g) Retention of records and documents that substantiate the product's conformity and history.

Communication

5.38. Reference [1] states in paras 5.26 and 5.27 that:

> "Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties.
> "Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization."

5.39. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

Managing organizational change

5.40. Reference [1] states in paras 5.28 and 5.29 that:

> "Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.
> "The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."

5.41. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations. Reference [10] provides further guidance.

PROCESSES COMMON TO ALL STAGES

5.42. The following processes are common to all stages in the lifetime of a nuclear installation. The guidance provided should be used with account taken of the stage in the lifetime of the installation, the size and structure of the organization and the nature of the activities to be carried out.

Project management

5.43. Project management can be described as managing a project in accordance with the agreed scope, schedule, cost and quality requirements, and dealing with all the challenges and risks encountered from the pre-planning phase to the completion of the project. This is achieved by performing various planned tasks in sequence and by deploying resources effectively and efficiently.

5.44. The success of a project depends on its project manager leading a team of dedicated individuals to achieve its objectives. The characteristics of an effective project manager include:

(a) Understanding the requirements of the project and the results to be achieved;
(b) Understanding the technologies and resources necessary to manage the project;
(c) Ability to plan, organize, lead and control the project;
(d) Being a good and effective communicator who can ensure that the project team remains well informed of the expectations on it and the status of the project;
(e) Ability to deal with uncertainties and risks and to take good decisions in a timely manner;
(f) Ability to communicate and negotiate effectively with interested parties;
(g) Energy, enthusiasm, resolve and intellectual acuteness to deal with emerging issues.

5.45. To perform effectively, the project manager and the team should have authority over all elements of the project, including:

(a) Making all necessary organizational, commercial and technical decisions;
(b) Specifying the organizational structure, functions, responsibilities and accountabilities of the team so as to achieve the goals of the project in accordance with the specified requirements;

(c) Selecting and managing all contractors in accordance with any limitations of the organization, such as financial authorizations;
(d) Controlling the funding, scheduling and quality of the project;
(e) Meeting statutory and other mandatory requirements;
(f) Meeting and possibly exceeding the requirements of those authorizing the project (sometimes referred to as the customer or project sponsor).

5.46. The manner in which a project is organized should be carefully determined on the basis of the project's scope and complexity. For smaller projects or groups of smaller projects, a functional and/or matrix approach should be considered.

5.47. For long term and complex projects, the use of a dedicated project organization should be considered. Such an organization can provide in-depth and sustained control of the project internally and externally, especially when interfacing with the customer or project sponsor. Other advantages of such an organization include:

(a) Complete line authority over the project;
(b) Improved communication and shorter reaction time;
(c) Better control of budgets and schedules.

5.48. In an organization that is responsible for several projects, however, the necessary attention should be paid to minimizing duplication of effort, facilities and personnel and to promoting technical exchange of expertise between different projects through effective coordination and communication.

5.49. Ensuring project quality and 'doing it right first time' reduce reworking and costs and save time. The presence of the following factors will strongly influence the outcome of the project:

(a) A clear and well-documented management system covering all the performance functions, including management processes, core processes and supporting processes;
(b) Effective planning coupled with regular monitoring, reporting and 'troubleshooting' of impending or emerging issues;
(c) Effective management of interfaces, including the interface between projects and the line organization;
(d) A documented process for the monitoring and resolution of non-conformances;

(e) Regular and frequent assessments and audits and effective methods of managing corrective actions;
(f) A learning culture;
(g) Initial and ongoing training and the provision of feedback from experience.

5.50. Conducting comprehensive and frequent internal assessments and audits encourages a team approach. Consideration should be given to such internal assessments and audits, which serve as an important mechanism for reviewing work processes in a constructive way to identify problems and promote early solutions. In addition, they serve to enhance the morale of the project organization and to ensure that it is always prepared for external assessments.

5.51. If a project is contracted to an external organization, project management activities should commence during contract negotiations and discussions and should continue to the end of the project and the fulfilment of the contract.

5.52. Key activities performed in the pre-project phase include: development of the plan for project implementation; description of the project; definition of the scope of the project, the roles of participants and the work structure; negotiation of supporting contracts; specification of the performance required of the client and of the contractor; specification of scheduling requirements; selection of contractors and suppliers; definition of the high level breakdown of project activities consistent with the project scope (work breakdown structure); and setting the initial budget.

5.53. Key activities performed in the project implementation phase include: preparation of the organizational structure and the mobilization plan; documentation of applicable processes; and establishment of various functions relating to the project, including, for example, management of supplies and materials, construction, engineering, change control, administration, training, inspection and testing, quality assurance, project planning, scheduling and control, budget and cost control, and information management and communications.

5.54. Key activities performed in the project termination phase include negotiations with the client to close all open commercial and technical issues and to address outstanding plant performance warranties as well as equipment, material and workmanship warranties as specified in the contract.

5.55. Appropriate methods and checkpoints should be used to ensure that project plans succeed. This includes measuring and evaluating progress and taking timely corrective actions to achieve or exceed predefined targets for each milestone and for cost and quality. Performing the work on schedule, meeting quality requirements and minimizing rework will ensure effective control over cost.

5.56. All projects are inherently risky ventures. Factors that contribute to risk include:

(a) Poorly defined scope and goals or objectives;
(b) Poorly defined project and technical requirements;
(c) Lack of qualified resources;
(d) Poor estimating;
(e) Lack of management support;
(f) Inadequate work breakdown or poor planning;
(g) Unrealistic scheduling;
(h) Poor methodology for change control;
(i) Poor methodology for control of corrective actions;
(j) Unproven equipment and facilities;
(k) Poor information management and/or configuration management.

5.57. A risk management plan to define the methodology and tools for identifying and evaluating risk should be prepared. Budgets should be prepared with contingency provisions, with account taken of the accuracy of the estimates, the potential for cost escalation and/or exchange fluctuations for foreign currency, and historical experience with similar projects.

5.58. The project manager should have the necessary authority to utilize any funding or provision set aside for dealing with unexpected problems or changes to the project (sometimes referred to as contingency funding).

5.59. The manner in which the project is controlled will depend on its size and complexity. Many organizations establish a project steering committee to control projects. The project steering committee may consist of:

(a) A manager with overall responsibility for the project;
(b) A representative of the interests of the users of the products or results of the project;
(c) Main or key supplier(s) which represents the interests of those responsible for product development;

(d) A project manager who runs the project from day to day on behalf of the project board.

5.60. The project steering committee should initiate the project and plan the different stages, agree on the points at which the project passes from each stage to the next, and monitor progress at these points. The project steering committee should resolve any major issues that have the potential to affect costs or the planned schedule or quality, and should agree on, and implement, any associated corrective action(s), while at the same time addressing commercial issues.

5.61. When a project is completed, it should be reviewed against its original intent to determine its success. For example:

(a) Did the project achieve its objectives?
(b) Did it realize the expected benefits claimed for it in the original proposal?
(c) Did it operate within its scope?
(d) Did the products or results of the project meet the relevant criteria?
(e) Was the project completed within the schedule outlined in the project plan?
(f) Was the project completed within the budget?
(g) Has the project been adequately documented and have the necessary records been generated, maintained and handed over, as necessary?

Work planning and control

5.62. The process for planning and controlling work, which is used in design, construction, commissioning, operation and decommissioning, should be used to ensure that work at the nuclear installation is properly planned and is completed in a safe and efficient manner.

5.63. The work planning and control process should list all requests for work and should arrange them in accordance with their description, assigned priority, initiation date and configuration requirements. The system should track the status of all work requests, in particular those that are on hold awaiting planning, spare parts or materials, or because of other constraints. The system should be capable of tracking the completion of testing prior to the return of any item to service.

5.64. Work planning:

(a) Should identify the safety significance of the work processes;
(b) Should identify and schedule the work necessary to operate and maintain the installation;
(c) Should describe the required performance objectives of the work by referencing clear, concise and unambiguous work instructions that include any inspection and testing requirements;
(d) Should identify any requirements that are part of the work process, such as requirements for radiation protection and fire protection;
(e) Should ensure that the work is authorized to be carried out;
(f) Should identify any workplace hazards and specify how they are to be mitigated;
(g) Should provide any safety documents, such as isolation permits for systems or items;
(h) Should specify requirements for isolation and tagging;
(i) Should identify any equipment or system needs to enable the work to be carried out, e.g. pump to be in standby mode;
(j) Should clarify the personnel requirements to carry out the work safely and specify any special training needs that are a prerequisite for doing the work;
(k) Should identify the status of work;
(l) Should specify any reviews required upon completion of the work;
(m) Should identify the required records, such as records of work completion, spare parts used and equipment used;
(n) Should identify any specific requirements relevant to the lifetime stage (see Appendices III–VIII);
(o) Should take account of lessons learned from previous experience.

Assessment of workplace risk

5.65. In addition to the risk assessments carried out in the planning and control process, assessments of workplace risk (sometimes referred to as 'point of work' risk assessments) should be carried out for all activities performed by individuals at the installation or by contractors' personnel that may pose a particular risk of injury, harm or damage.

5.66. To carry out an adequate workplace risk assessment, the workplace should be visited and account should be taken of: the route for getting to and from the workplace; other work (including routine operations) being

undertaken in the area; and any new requirements emanating from emergency arrangements, changes to procedures, training and supervision.

5.67. In recognition of differing types of risk, there are different types of workplace risk assessment that can be used and which should be documented and used as an input to work planning and control. For example:

(a) *Area assessment*: This covers the risks relating to the equipment, services or conditions in the workplace, rather than those relating to the actual task being carried out. It concerns, for example, lighting, floors, traffic routes and fire precautions.
(b) *Task assessment*: In planning work, some risks will be associated directly with the activity to be undertaken and other risks will be associated indirectly through work or activities in adjacent work areas. These risks need to be assessed as an integral part of the work planning process. Risks should be considered at a sufficiently early stage so that the results of the assessment may be used to influence the work methods to be adopted.

5.68. Additional risk assessments may also be required when there is a special, more demanding hazard, such as working in confined spaces or opening flanges on acid lines. States have differing regulations in respect of such assessments.

5.69. The results of workplace risk assessments should be communicated to the work teams concerned and to others who may be affected. This includes personnel who are new to the organization, contractors and visitors who may be affected by the work being carried out.

5.70. Workplace risk assessments can be communicated by means of:

(a) Pre-job briefings before the work is undertaken, for one-off jobs or work that is performed infrequently;
(b) Training for individuals on plant, process or maintenance operations;
(c) Inclusion of findings in operating instructions or instructions for safe systems of working (e.g. through work permits);
(d) Warning notices;
(e) Team briefings and site briefings;
(f) Induction training or on the job training;
(g) Notices and personnel handbooks;
(h) Information provided in documentation on point of work assessments;
(i) Information on work planning and control documents.

5.71. Communication of the workplace risk assessment should be such as to ensure that anyone involved directly or incidentally in a job is made aware of any hazards and risks to their health and safety, and knows and understands the procedures that are in place to control or reduce those hazards and risks.

5.72. Regular planned reviews should be carried out to confirm the validity of workplace risk assessments. Post-job briefings can be used to capture information on issues relating to human performance, performance and risks, for lessons to be learned. When there has been a significant change, such as the introduction of new equipment, substances, procedures or working conditions, or as a result of any proposed corrective or preventive actions, a risk reassessment may be required. A record of completed workplace risk assessments should be retained (in either paper or electronic format) at least until the next review. Workplace risk assessments that have been carried out to support working instructions should be archived together with the instructions.

Safety of personnel

Industrial safety

5.73. A process that reflects the national industrial safety regulations should be established for all individuals, suppliers and visitors, and the process should refer to the rules and practices for industrial safety that are to be adopted. The process should include arrangements for the effective planning, organization, monitoring and review of the preventive and protective measures for industrial safety.

5.74. The organization should provide support, guidance and assistance in the area of industrial safety for personnel at the installation. Personnel at a nuclear installation should understand how the industrial safety programme affects their individual work practices.

5.75. Data on industrial safety at the installation should be monitored. Examples of items to be monitored include working time lost owing to industrial accidents (sometimes referred to as ‘lost time accidents’), other accidents leading to individuals needing medical attention, industrial safety non-conformances, near misses and modifications resulting from concerns about industrial safety.

5.76. The underlying causes of industrial accidents and problems relating to industrial safety should be identified and corrected. Results of cause analyses

should be used to identify opportunities for improving industrial safety. Lessons learned from investigations and from operational experience in the nuclear industry and sometimes from other industries should be used to improve performance.

5.77. Relevant information on industrial safety should be obtained and screened. Relevant material and any required actions should be incorporated into the installation's working practices and instructions and industrial safety practices and should be communicated within the installation.

Radiation protection

5.78. A process should be established and implemented for each working group, work area and activity to ensure that radiation doses are kept within the relevant limits and are kept as low as reasonably achievable. Further recommendations and guidance are provided in Refs [11, 12].

Control and supervision of contractors

5.79. A process should be developed to control and supervise contractors who are carrying out work at a nuclear installation. Contractors should perform work under the same controls, and to the same working standards, as the personnel of the installation.

5.80. When using contractors, the organization should control and supervise their actions to ensure that safety is not compromised and that there are no hazards, either immediate or potential, or risks. Such hazards may result in an immediate danger to the contractors' workers or to workers around them, or the hazard may be latent or inherent defects that could be manifested later.

5.81. The organization should ensure that contractors are competent to carry out the work assigned to them. Contractors who perform work at the installation should receive appropriate training in the procedures and practices of the installation to enable them to carry out their work safely. Adequate time should be allocated for such training. The organization may have to take responsibility for this training in relation to radiation protection, industrial safety practices at the installation, emergency preparedness and response arrangements, and systems for obtaining permits for work. The training of contractors should be to the same standard as the training of the installation's personnel for the same or equivalent tasks.

5.82. The control and supervision of contractors should ensure that contracted work is carried out to an adequate standard. For work that may be significant to safety, the organization should oversee the work to ensure that the work carried out and the end product meet the relevant safety standards, e.g. contractors carrying out the preparation and review of the safety analysis report, or design, construction, commissioning, modifications or maintenance work. In such situations, the organization should:

(a) Set standards for the contracted work;
(b) Evaluate completed work for acceptability (including a technical evaluation or review, where appropriate);
(c) Make arrangements to cover the interfaces between the installation and the contractors, between different contractors, and between contractors and subcontractors.

5.83. To be able to control and supervise its contractors, the organization should have the necessary expertise and capability, sometimes referred to as 'intelligent customer capability' (see footnote 12). The concept of the 'intelligent customer' relates to the organization rather than the capabilities of individual personnel. As an 'intelligent customer', in the context of safety, the organization should know what is required, should fully understand the need for a contractor's services, should specify requirements, should supervise work and should technically review the output before, during and after the work.

Design

5.84. The design process requires the use of sound engineering and scientific principles and appropriate design standards. The design process is subject to the relevant requirements of Ref. [13] or [14] for the type of installation concerned, and the recommendations and guidance provided in Refs [12, 15–28] apply as appropriate.

5.85. The following recommendations and guidance apply in developing the design process or processes:

(a) All structures, systems and components that are important to safety, including software for instrumentation and control, should be first identified and then classified on the basis of their function and their significance to safety, in accordance with the recommendations and guidance provided in Refs [12, 15–28], as appropriate.

(b) Design requirements, inputs, processes, outputs, changes, records and organizational interfaces should be controlled.

(c) Design inputs should be correctly translated to design outputs. Design inputs include all requirements for the design, such as the technical bases for the design (the design basis), performance requirements, reliability requirements and requirements for safety and security.

(d) The design outputs include specifications, drawings, procedures and instructions, including any information necessary to implement or install the designed system or product.

(e) Design changes should be justified and should be 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 for repair. Changes should be subject to configuration control and design control measures and should be subject to approval by the original design organization or by an alternative, technically qualified body.

(f) Interfaces among all organizations involved in the design should be identified, coordinated and controlled. Control of interfaces includes the assignment of responsibilities among, and the establishment of procedures for use by, participating internal and external organizations.

(g) Design inputs, processes, outputs and changes should be verified. Individuals or groups performing design verification should be qualified to perform the original design. Those carrying out verification should not have participated in the development of the original design (but they may be from the same organization). The extent of verification should be based on the complexity, the associated hazards and the uniqueness of the design. Some typical design verification methods include design review, carrying out calculations by an alternative method and qualification testing. Previously proven designs should not be subject to verification unless they are intended for different applications or the performance criteria are different.

(h) Computer programs used in design should be validated through testing or simulation prior to use, if they have not already been proven through previous use.

(i) Tests used to verify or validate design features should be conducted with due consideration of the conditions that simulate the most adverse operating conditions.

(j) Design verification is usually completed before the design output is used by other organizations, or is used to support other work such as procurement, manufacturing, construction or research and development. In specially controlled circumstances, the installation of unverified parts

of the design may be permitted to proceed to a point where replacing or modifying the design would not necessitate extensive demolition or rework.

(k) Design records, including the final design, calculations, analyses and computer programs, and sources of design input that support design output, are normally used as supporting evidence that the design has been properly accomplished.

5.86. The design process should include the following activities; recommendations and guidance on these activities are provided in paras 5.87–5.140:

(a) Design initiation, specification of scope and planning;
(b) Specification of design requirements;
(c) Selection of the principal designer;
(d) Work control and planning of design activities;
(e) Specification and control of design inputs;
(f) Review of design concepts and selection;
(g) Selection of design tools and computer software;
(h) Conducting conceptual analysis;
(i) Conducting detailed design and production of design documentation;
(j) Conducting detailed safety analyses;
(k) Defining any limiting conditions for safe operation (sometimes referred to as the safe operating envelope);
(l) Carrying out design verification and validation;
(m) Configuration management;
(n) Management of the design and control of design changes.

Design initiation, specification of scope and planning

5.87. The design process is initiated in support of a project for the construction of a new nuclear installation or other nuclear structures, systems and components as needed. The overall specification of the scope and the initiation of design activities should be carried out only after a review of the contracts, work orders and other such high level documents that require an organization to perform design activities. The planning and timing of design activities and milestones should support the overall plan for the project in question. The operating organization of the nuclear installation remains responsible for the installation's safety and for complying with nuclear regulatory requirements even when design activities are contracted to a design organization. The

organization should ensure that it selects a design organization that can undertake the design function and all related activities.

Identifying design requirements

5.88. The design organization should establish all the key requirements for the design after conducting a review of applicable contracts, codes and standards, regulatory requirements, and laws and regulations.

5.89. For the design of specific structures, systems and components, the applicable design parameters may also be covered in related design documents such as design requirements, design specifications, and safety standards and guides on design.

Selection of the principal designer

5.90. The organization should select the person (often referred to as the principal designer) who will have the responsibility for specifying the design requirements and for approving the design output on its behalf.

5.91. The responsibilities of the principal designer should include:

(a) Definition of the base requirements and specifications;
(b) Involvement in design reviews;
(c) Involvement in design verification;
(d) Approval of the detailed design;
(e) Review and approval of design changes at all stages;
(f) Control of interfaces;
(g) Review of relevant applications for non-conformances.

Work control and planning of design activities

5.92. Design activities should be carried out in a logical planned sequence to ensure that the installation as designed can be safely sited, constructed, commissioned, operated and decommissioned.

5.93. The design of the nuclear installation and of its structures, systems and components should be organized in discrete elements and work assignments that clearly specify the scope of the design, the activities for planning the design activities and the activities for preparing design documents.

5.94. Design planning should take place at the earliest opportunity, before the commencement of design activities. Plans should specify the activities to be performed in manageable elements (sometimes referred to as a work breakdown structure).

5.95. Plans used in design should include the following, where appropriate:

(a) The scope of the work, including work carried out by other organizations;
(b) All key interfaces with national and other relevant authorities, the design customer and other parties;
(c) The design methods, including consideration of human factors;
(d) Software requirements (software to be developed or software codes to be validated for use);
(e) Testing requirements, including qualification tests, prototype tests and seismic tests;
(f) Requirements for the review, verification and validation of the design;
(g) The production of design output documents such as maintenance manuals and operating procedures or instructions;
(h) Resource requirements, including, for example, the disciplines of specialists, such as evaluating structural integrity and the resources required for design reviews;
(i) Any specific training requirements;
(j) A schedule of activities, specifically identifying those critical to the success of the design project (sometimes referred to as being on the critical path);
(k) Points at which checks of the design process will take place and the frequency of such checks.

5.96. In addition to general planning requirements, the following aspects should also be considered in design planning where applicable:

(a) Procurement of components and materials;
(b) Availability of components and materials;
(c) Qualification of suppliers;
(d) Preparation and planning of tests;
(e) Acceptance and use of previously proven designs and components.

Specification and control of design inputs

5.97. All relevant inputs that may affect the design directly or indirectly should be considered. The design input documentation[14] should define the requirements to be met by the design. Design input documents are normally prepared, reviewed and approved by the organization.

5.98. Establishing, determining and selecting design inputs will vary with each different design. Basic sources of design inputs are identified in contractual requirements and, by taking into account customer input and commercial considerations (including cost and marketability), design inputs can also be derived from:

(a) Basic inputs that are available in the early stages of the design process, as specified in relevant contracts and documents defining high level design requirements;
(b) Derived inputs that become available after the conceptual and detailed design progresses to a certain level.

5.99. The design inputs may include the following parameters, on the basis of their applicability to each particular installation and design activity:

(a) Basic inputs (independent of the conceptual design):
  — Function of the installation, structure, system or component.
  — Location and interfacing requirements.
  — Performance requirements such as capacity, rating and output.
  — Operational requirements under relevant conditions, such as startup, normal operation, anticipated operational occurrences, abnormal operation, accident and emergency, shutdown, standby and consideration of the frequency of events.
  — Environmental conditions, including wind, snow loading, consequences of rain and flooding and seismic events, and physical conditions, such as conditions of temperature and humidity, the presence of airborne and other chemicals, and conditions of radiation, corrosion and erosion.

[14] Design input documentation includes design requirements, design specifications, design guides and standards, documents on the analysis basis, documentation of technical specifications and flow sheets.

— Safety considerations, including risks to individuals, potential to cause physical damage, fire hazards and radiation hazards.
— Failure considerations, including consequences for safety, limiting the consequences of failure, the effect of failures on plant functions and on adjacent structures, systems and components, the function of standby equipment and the effects of adjacent failures.
— Standards, including mandatory and contractual codes and standards, and national and other relevant requirements.
— Security considerations.
— Safeguards considerations.
— Human factor considerations.
— Usability of equipment.
— Feedback from research and development.
— Consideration of previous designs and feedback of experience and lessons learned from purchasing, fabrication, construction, installation, commissioning, operation and decommissioning.

(b) Derived inputs (dependent on the conceptual design):
— Design requirements for specific disciplines, including:
  • Structural aspects: loading, pressures, stress, supports and bracing;
  • Mechanical aspects: vibration, speed and lubrication;
  • Electrical aspects: voltage, power, regulation and insulation;
  • Hydraulic and pneumatic aspects: flow, pressure, temperature, fluids, velocities, and suction and discharge heads;
  • Chemical aspects: fluid chemistry, corrosion and erosion;
  • Control and instrumentation: controls, alarms, ranges, stability and readability;
  • Metallurgical and material aspects: protective coatings, welding, galling, wear, erosion and creep.
— Fabrication requirements, including constructability, size and weight, fabrication processes, quantity, interchangeability and spare parts.
— Installation requirements, including shipping, storage, installation, proof tests and running in plant at reduced loads.
— Commissioning requirements, including accessibility, tests and testing equipment.
— Operational requirements, such as resource needs and the need for procedures and instructions.
— In-service requirements, including reliability, redundancy, accessibility, serviceability, maintenance and inspection.
— Engineering input data, including validity of reference data, test reports, analyses and in-service reports.

— Decommissioning requirements, including dismantling and decontamination.

5.100. Sufficient detail should be provided in the design input documents to allow them to serve as a reference basis for making decisions, performing verification and validation for the conceptual and detailed design, evaluating design changes and setting up tests and criteria for commissioning.

Review of design concepts and selection

5.101. The responsible design organization may examine one or more design concepts to evaluate the suitability and adequacy of various options in order to select the preferred approach. All design concepts selected in this manner should be evaluated and documented and should be subject to the approval of the organization.

5.102. Such an evaluation of design concepts may include consideration of the feedback of previous experience from design, procurement, manufacturing, construction, installation, commissioning, licensing and operation. The preferred design concept should be specified, documented and justified with supporting information.

Selection of design tools and computer software

5.103. The design tools and computer software used in design, safety analysis, plant control, calculations and data management should be selected on the basis of their appropriateness and adequacy for application and use. All such tools and software should be suitably qualified on the basis of applicable codes and standards. Tools and software used by the various design organizations should be compatible to the maximum extent possible.

5.104. Where computer software is used for analysis and for process control, appropriate measures should be provided for its verification and validation. Further recommendations and guidance are provided in Ref. [15].

Conducting conceptual analysis

5.105. The need for a conceptual design analysis should be evaluated. Such an analysis, when required, should be prepared on the basis of selected design concept(s). This is generally done for new, complex and first of a kind design of systems, structures or components that are critical to safety. Conceptual

analysis documents may require submission for regulatory approval, depending on the applicable laws and regulations.

5.106. The need for conceptual analysis of the safety and environmental aspects should be determined and when required such analysis should be prepared on the basis of optimum or preferred design concept(s).

Conducting the detailed design and production of design documentation

5.107. Calculations, analyses and studies should be documented in sufficient detail and should be controlled in such a manner that subsequent users of the design, in the various stages of the lifetime of the installation, can understand the design and make informed decisions. Inputs, assumptions, modelling, test and development work and results, safe operating parameters and envelopes, key acceptance criteria and parameters for commissioning tests, for example, should all be documented.

5.108. Design activities should ensure that specified requirements are correctly translated into design outputs, such as:

(a) Basic design of the installation;
(b) Design computer codes;
(c) Design specifications;
(d) Functional specifications.

5.109. A suite of design documentation should be developed by establishing an overall 'baseline' listing of all key design documents on the basis of the requirements of the customer and of national requirements. This listing should cover the design documents needed for the various activities at the installation in all stages, such as for procurement and manufacturing, construction and installation, commissioning, operation, maintenance and decommissioning.

5.110. The baseline listing should include the following:

(a) Design requirements and specifications;
(b) National and other relevant codes, standards, classifications and other criteria;
(c) Requirements for traceability;
(d) Requirements for purchasing, installation and maintenance;

(e) Critical characteristics of the design for which confirmation in commissioning is necessary;
(f) Operating limits and reliability and maintainability requirements for systems or equipment.

Conducting detailed safety analysis

5.111. Safety analysis is an important part of the design process that is carried out to examine the various postulated conditions, accidents and events that may affect the performance and operation of equipment, structures, systems and components at the installation. The necessary types and the extent of safety analysis should be evaluated in the light of the governing codes and standards and regulatory requirements and, if required, the safety analysis should be prepared on the basis of the selected design concepts.

5.112. In some States, safety analyses are documented in reports such as preliminary safety analysis reports and final safety analysis reports and in probabilistic safety analyses. These reports are updated as required. All analyses should cover the purpose, methods, assumptions, input and sources, computer modelling information, details of test and development work, results and key references. The selected tools for the safety analyses, such as computer programs, should be verified and validated to confirm their suitability and adequacy for the types of analysis being performed.

Defining any limiting conditions for safe operation

5.113. Design analysis and safety analysis should establish an 'envelope' of configurations and operating limits for the plant, equipment, systems, structures and components that are acceptable for safe operation.

Carrying out design verification and validation

5.114. Design verification is the process by which a design is evaluated to ensure compliance with the prescribed requirements. Design verification should be performed throughout the various design phases, including the phases of conceptual design, detailed design and safety analysis, to ensure that each design phase has reached a satisfactory level of completion before going on to the next phase.

5.115. Individuals who did not perform the design activity or make decisions concerning the design being verified should normally carry out the design verification.

5.116. The designer's direct supervisor, or a qualified delegate, should be responsible for confirming that the design work is correct, that the design meets the requirements, and that the verification activities have been properly completed. Those individuals carrying out verification and validation should have access to sufficient background information and supporting information to gain an understanding of the design intent.

5.117. At the start of any design activity, the design organization should specify the activities to be carried out to verify each design or revisions to the design. Formal design documents (including design verification documents) are normally subject to verification.

5.118. The nature and extent of design verification should be based on the following criteria:

(a) Importance to safety of the plant, equipment, structure, system or component;
(b) Exposure to economic risk;
(c) Complexity of the design;
(d) Consideration of human factors;
(e) Degree of standardization;
(f) Technical developments;
(g) Similarity to previously proven designs.

5.119. When previously finished and verified designs are to be used for a new application, the design verification programme may be limited to confirming that:

(a) The application of the design is correct;
(b) The analyses and design calculations are still valid.

5.120. Acceptable design verification methods should include various methods of review, such as:

(a) Carrying out calculations using an alternative method;
(b) Verification by testing;
(c) Review of the design by a group of peers.

5.121. The resulting verification output documents should themselves be reviewed to confirm their adequacy, validity and relevance to the design being verified.

5.122. Design reviews are generally conducted by a group of experts in the subject matter, led by a senior designer who has considerable experience in, and a broad knowledge of, the subject. Typically, a design review involves a number of disciplines and interfacing organizations. A single individual could also conduct a design review.

5.123. At appropriate stages of the design, formal verification reviews of the design process should be planned, conducted and documented. Participants in these reviews should include representatives of organizational units of the design organization concerned with the design stage under review and other individuals as necessary. Reviews may range from reviews by individuals to reviews by many organizations.

5.124. The objective of the design review is to provide assurance that the output documents will be correct and will fully address the requirements (e.g. functional, safety and regulatory requirements, and requirements of industry codes and standards) of the design specification.

5.125. The principal designer should determine the scope and extent of the review. As part of the review, it should be established that procedures have been followed and that designated individuals have participated in the review, and that the results have been adequately documented and checked prior to the release of any design documents to the customer or organization sponsoring the design project.

5.126. The design review should be such as to anticipate and identify potential problem areas and inadequacies, and corrective actions should be initiated to ensure that the final design meets the design intent.

5.127. In the design review, certain basic questions should be addressed. These questions should include, but should not be restricted to, the following:

(a) Have design inputs been correctly selected and incorporated?
(b) Have the original design requirements and safety requirements been met?
(c) Is the design output information complete?

(d) Have any assumptions been made, are they adequately described and what is their basis?
(e) Has an appropriate design methodology been used and have designated design standards been followed?
(f) Have design procedures been followed?
(g) Is the design output reasonable in comparison with the design input?

5.128. Verification or certification, where required, of design specifications, design or stress reports, seismic qualification reports and environmental qualification reports, including those prepared by suppliers, should be carried out in accordance with the applicable codes and standards.

5.129. Design calculations should be verified to check their validity. Alternative analyses may be performed using simplified calculations and assumptions to obtain approximate results. The results of such analyses should be reviewed and the acceptability of the original calculations should be justified. Alternative analyses, assumptions and results should be documented.

5.130. Qualification testing is used to verify the design of a system or component, or a specific design feature of a prototype or a production unit, by operating the item under controlled conditions and measuring and evaluating its performance. The organizations performing qualification testing should have a programme for qualification testing that meets the requirements of applicable standards.

5.131. Test requirements should be identified in a test specification document. Test results should be included in a test report. Test reports should be reviewed for their validity and relevance to the test requirements against the acceptance criteria specified in the test specification document.

5.132. Where computer programs and their associated documentation are part of the design output, such as computer programs for controlling the operation of safety systems or for monitoring or displaying reactor operation, they should be subject to a set of verification and validation tests. For example, verification and validation should be carried out to ensure that any software or hardware failures would not lead to the failure of a safety function. Software development plans, design verification plans or quality plans should specify verification and validation requirements, as appropriate. Applicable national standards and international standards should be specified and followed. Test documentation for software verification and validation should provide information on, or should reference documents containing information on:

(a) The test methods to be used;
(b) The equipment used for the verification of computer programs;
(c) The inputs to be processed;
(d) The output acceptance criteria.

5.133. The manager of the design organization should ensure that the design is adequately verified by confirming that all planned verification activities have been completed before the approval of any design documents. This is normally carried out by reviewing evidence that verification activities have been completed.

5.134. The adequacy of the design methods and the design verification methods applied to all major designs as defined in the applicable design verification plan should be confirmed. Validation of the design of equipment, structures, systems and components should be carried out in the commissioning stage. Design validation could also be carried out throughout the various design phases, including the conceptual design, detailed design and safety analysis phases. Validation should be conducted on any subsequent changes to the design of systems and on new systems by using methods such as task based validation and user centred validation. The designer should document all the key requirements such as performance, functional and control parameters, safety assumptions and objectives that need to be confirmed in commissioning. The design documents should include the relevant information for commissioning tests and the acceptance criteria to be followed by the commissioning organization.

Management of the design 'baseline' and control of design changes

5.135. Once the design of a structure, system or component, or of the installation, is complete, configuration processes and change control processes should be applied to the design. These processes should be used to ensure that designed equipment is in place, is properly installed and documented and is confirmed to be operational, and that its operational status is known at any particular time.

5.136. The design organization should also provide records of design changes that it has introduced in the course of the design activities. All changes should be reviewed by, and should be subject to the approval of, individuals who have information and knowledge of the requirements and the intent of the original design.

5.137. Design changes, whether initiated by the designers in the organization or elsewhere at the installation, or by outside groups such as contractors, consultants, national or other relevant authorities or other interested parties, should be identified (with the reasons for them) and should be documented, reviewed, evaluated, verified and, where appropriate, validated. Documents affected by the change should be identified. If the change is approved, the affected documents should be revised and approved and then released. Activities affected by the change should be verified.

5.138. Permanent and temporary changes made at the construction, commissioning and operation stages should be documented, verified and approved before they are implemented.

5.139. Concessions provided to fabricators, installers, construction forces and commissioning or operational groups that permit deviations from the design should be controlled. The controls include methods for the identification of concessions and for the resolution, approval, issuing and filing of concessions.

5.140. The design baseline should be identified, documented and maintained. The change control process should be used to ensure that changes to the design baseline are identified, reviewed, approved and documented.

Configuration management

5.141. Configuration management is fundamental to safe operation. Configuration management is the process of identifying and documenting the characteristics of the systems and components (including computer systems and software) at an installation and ensuring that consistency is maintained between the design requirements, the physical configuration and the configuration documentation of the installation and its systems and components. For example, after maintenance is carried out, the installation systems and components should be returned strictly to their design configuration.

5.142. The principal concern relating to inadequate configuration management is the loss of the ability to perform safety actions when these are needed. Not having the right information available at the right time and in the right format for use by engineering and operations personnel can lead to human errors with potential consequences for safety as well as economic consequences. In many cases, the effort required to respond to and to correct

these errors is greater than the effort required to maintain the plant and its structures, systems and components in their design configuration.

5.143. It is assumed that every organization has already knowingly or unknowingly employed the concept of configuration management. The extent of the application of configuration management and its status may be different at different installations, depending on the management's experience of and awareness of configuration management.

5.144. Configuration management should be used to ensure that the construction, commissioning, operation, maintenance and testing of the installation are in accordance with the design requirements as established in the design documentation, and that this consistency is maintained, where appropriate, throughout all stages of the lifetime of the installation, particularly when changes are made.

5.145. It is recognized that there are three elements in configuration management that should be consistent with each other: (i) design requirements, (ii) configuration documentation for the installation and (iii) the physical configuration. These elements are illustrated in Fig. 2.

(a) Design requirements are technical requirements. They are derived from standards, regulatory requirements and the design process, they impose limits on the final design, including the consideration of margins, and they are reflected in the design documentation.
(b) The configuration documentation for the installation is the set of all documents that contain information on the configuration, recording how the plant and its structures, systems and components are designed, operated and maintained. Configuration documentation should be traceable to installed equipment. It can be categorized as either:
    — Design information;
    — Information on the operational configuration; or
    — Other information on the configuration considered necessary for procurement, operation, maintenance and training activities.
(c) Physical configuration applies to the installed and subsequently commissioned structures, systems and components and to their operational configuration.

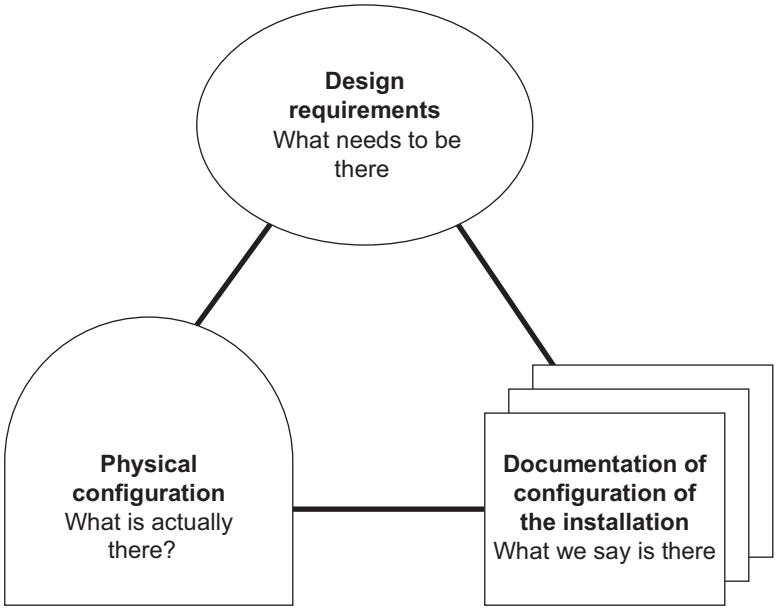

FIG. 2. Consistency model for configuration management.

5.146. The configuration management process should include:

(a) Programme planning;
(b) Criteria on the scope of the physical configuration;
(c) Criteria on the scope of the configuration documentation for the installation;
(d) Concepts and terminology;
(e) Information system for configuration control;
(f) Configuration audits and assessments;
(g) Training on configuration management.

5.147. The process of configuration management should be used to ensure that responsibilities are specified, including responsibilities for the design bases, the safety analysis bases, the design processes, operation, maintenance and the change processes. This description of responsibilities should specify clearly who is responsible for each activity, including the interfaces and transfer of responsibilities, and for documents and related information. The responsibilities of the following organizations should also be specified in the configuration management process:

(a) The original or principal designer (if involved);
(b) The suppliers (if involved);
(c) The design organization in charge of modifications to the design (if not the same as the original designer);
(d) The construction, commissioning, operating and decommissioning organizations (including maintenance, training and operations);
(e) Any corporate or company level organizations or departments (if involved).

Plant modification

5.148. A process should be established and implemented to control modifications to the structures, systems and components and to any associated software. Further guidance is provided in Refs [29, 30].

Maintenance

5.149. A process should be established and implemented to control maintenance of the systems, structures and components of the installation. Further recommendations and guidance are provided in Refs [8, 9].

Housekeeping and cleanliness

5.150. Housekeeping and cleanliness should be considered an essential process to provide a clean workplace and to encourage a high standard of workmanship. The process should include establishing, maintaining and enforcing standards for housekeeping and cleanliness that:

(a) Prevent the contamination of items and individuals;
(b) Minimize the risk of injury;
(c) Reduce the risk of occurrence of conventional accidents such as fires;
(d) Protect open systems and equipment from contamination with foreign material during maintenance and modification;
(e) Control the movement of materials, equipment, tools and individuals into and out of work areas;
(f) Ensure that cleanliness inspections are performed immediately prior to reassembly of systems or components;
(g) Encourage individuals to leave an area as clean as or cleaner than it was before they carried out activities in it.

Handling and storage

5.151. It should be ensured by means of a process for handling and storage that only the correct items are used at the installation. For this purpose, items should be identified. Physical means of identification should be used to the extent possible and the identification should be transferred to each part of an item that is to be subdivided.

5.152. Provision should be made for preventing damage, deterioration or loss of items. For this purpose, items should be stored in a manner that provides for their ready retrieval and protection. Storage should be controlled to prevent the deterioration of degradable material, such as elastomer seals, O-rings and instrument diaphragms.

5.153. Maintenance should be performed on certain items held in storage, such as large pumps and motors. Such maintenance should include periodically checking energized heaters, periodically changing desiccants, rotating shafts on pumps and motors, and changing oil on rotating equipment, and other maintenance requirements as specified by the vendor.

5.154. Items removed from or placed into storage, including surplus material returned to storage, should be promptly documented so that the store inventory is kept accurate. The store record system should indicate the locations of materials and parts in all designated storage areas. Access to storage areas should be controlled.

5.155. The handling and storage process should include arrangements for shelf life management. For example, an item whose shelf life has expired should be discarded unless an engineering evaluation is conducted and engineering approval is obtained prior to use of the item.

5.156. For critical, sensitive, perishable or high value items, special arrangements, such as the provision of protective enclosures, an inert gas atmosphere and moisture and temperature control, should be specified and put in place. These measures may also be applied to installed items that are subject to extended out-of-service conditions.

5.157. The handling and storage process should also cover field storage of consumables such as lubricants and solvents to ensure that they are properly stored and identified.

5.158. Storage practices should be adopted to ensure that:

(a) Corrosive chemicals are well segregated from equipment and metal stock;
(b) Flammables are properly stored;
(c) Radioactive material is properly controlled;
(d) Stainless steel components are protected from halogens, sulphur and direct contact with other metals, in particular carbon steel;
(e) Relief valves, motors and other equipment are stored on their bases;
(f) Containers (boxes, barrels and crates) are stacked to reasonable heights and in accordance with instructions of the vendor and storage instructions;
(g) Parts, materials and equipment are repackaged or protective caps are reinstalled to seal items on which previous packaging or protective caps have deteriorated or been damaged or lost while in storage;
(h) Elastomers and polypropylene parts are stored in areas where they are not exposed to light;
(i) Machined surfaces are protected;
(j) Equipment internals are protected from the ingress of foreign material;
(k) Material, equipment and storage facilities are properly protected from rodents;
(l) There is suitable segregation of safety related and non-safety-related components.

5.159. Items removed from storage should be protected. In the handling of items, factors such as weight, size, certification and regular inspection of hoisting or lifting equipment, chemical reactivity, radioactivity, susceptibility to physical shock or damage, electrostatic sensitivity, sling location, balance points and method of attachment should be considered. Special handling tools and equipment should be provided, controlled and inspected periodically as necessary, to ensure safe and adequate handling.

Inventory management

5.160. The inventory management process should be designed to ensure that spares and other consumable items are available when required for use so that safety is not compromised. To develop the inventory management process, the organization should first establish an inventory register and ensure that the procurement process will be suitable to maintain stocks at an acceptable level. This can be achieved by:

(a) Forecasting demand;
(b) Understanding lead times for the manufacture and procurement of spares and consumable items;
(c) Monitoring spares and the issue and usage of consumables;
(d) Establishing minimum stock levels and minimum stock reorder levels;
(e) Taking historical information into consideration.

5.161. The organization may choose to arrange to obtain spares at the time of procurement of the original products. The spares should meet the same requirements as the original products and should meet additional requirements to ensure their protection in long term storage. The factors to be considered in determining the quantities of spares to be kept in storage should include the following:

(a) Numbers and safety significance of products liable to failure;
(b) Any special nature of the manufacturing process that might prevent the subsequent manufacture of the products;
(c) Uncertainties in the supply of spares;
(d) Anticipated delivery periods and shelf lives;
(e) Delays caused by importing spares from other countries;
(f) Geographical isolation of the installation from qualified manufacturers;
(g) Obsolescence.

5.162. For items which are obsolete or where an identical item cannot be obtained, an evaluation should be performed on any replacement item considered to be equivalent, to ensure that the original design requirements have not been compromised.

Identification and labelling of structures, systems and components

5.163. A process should be established and implemented to ensure that structures, systems and components are uniquely and permanently labelled to provide individuals with sufficient information to identify them accurately.

5.164. Identification and labelling of components is developed in the design stage, implemented and confirmed in the construction and commissioning stages and maintained in the operation and decommissioning stages. Identification and labelling of structures, systems and components should not be compromised by the activities conducted during the lifetime of the installation. Necessary user friendly improvements should be made, on the basis of feedback from experience, and the design configuration should be

updated as part of the design modification process. Detailed recommendations and guidance are provided in Ref. [31].

Radioactive waste management

5.165. The generation of radioactive waste in commissioning, operation and decommissioning should be minimized and provision should be made for safe handling, treatment and segregation as necessary, and for storage, transport and disposal of liquid, solid and gaseous radioactive waste. Requirements for the predisposal management of radioactive waste are established in Ref. [32].

5.166. The control process for radioactive waste should be such as to ensure that the waste generated is within authorized limits and conditions; the process should include, for example:

(a) Identifying the source;
(b) Defining the waste streams;
(c) Segregating the waste;
(d) Characterizing the waste;
(e) Carrying out treatment and conditioning;
(f) Using appropriate methods of packaging and transport;
(g) Using correct methods of storage and disposal;
(h) Maintaining inventories;
(i) Preventing unauthorized access;
(j) Generating and keeping records such as waste package specifications and waste package data sheets.

5.167. Further recommendations and guidance on radioactive waste management are provided in Refs [12, 13, 33–35].

5.168. The organization should ensure that the transport of radioactive waste to a licensed repository satisfies regulatory requirements and that the final waste packages meet waste acceptance criteria for disposal.

5.169. Reference [36] establishes the requirements for the safe transport of radioactive material.

Protection of the environment

5.170. The organization should develop a process that identifies the activities, products or services that may have a significant impact on the environment and put in place controls to reduce or eliminate their impact.

5.171. The organization should determine its objectives and targets for the protection of the environment on the basis of the nature, scale and impact of its activities, products and services and with regard to past, present and planned activities.

5.172. The process for managing the protection of the environment should cover:

(a) Emissions to air and water;
(b) Impact of the process for radioactive waste management;
(c) Contamination of land;
(d) Contamination of water resources;
(e) Use of raw materials and natural resources;
(f) Other local environmental and community issues.

5.173. The process for managing the protection of the environment should cover the environmental impact of all the installation's activities at all stages of its lifetime. Environmental aspects should also be considered as relevant in all other management processes.

5.174. Further recommendations and guidance on radioactive discharges to the environment and on the identification and monitoring of toxic releases to the environment are provided in Refs [5, 11, 12, 37].

Regulatory interface

5.175. The organization should establish a process to ensure that regulatory and statutory requirements are identified and to describe how they are implemented (see Ref. [5]). The organization should also ensure that interface arrangements are established with all relevant regulatory bodies. For example, such arrangements would include meetings (their types, frequency and terms of reference) and reporting and communication routes. The information needs of the regulatory bodies should also be specified in the interface arrangements. Further recommendations and guidance are provided in Ref. [38].

Information technology

5.176. A process should be established to ensure that controls are applied throughout all stages of the lifetime of an information technology system; that is, the acquisition and supply of a new information technology system and its development, operation and maintenance.

5.177. Change controls should be applied to information technology to ensure that:

(a) Only properly authorized changes are permitted;
(b) Appropriate individuals are consulted throughout the changes;
(c) All possible risks have been considered and mitigating actions taken;
(d) Needs for information technology at future stages in the lifetime of the installation are taken into account.

5.178. Configuration management systems provide a mechanism for identifying, controlling and tracking the versions of software items and their associated documentation. Configuration management systems may be paper based or may be implemented using software tools, or a combination of both techniques may be used.

5.179. Plant control software that could affect the safe and reliable operation of the installation, such as computer codes and data used in computerized protection and control systems, should be verified and validated. Installed plant control software should be subject to periodic checking to ensure the continued integrity of computer programs. Further recommendations and guidance are provided in Ref. [15].

Protection against fires

5.180. The organization should establish and implement a fire prevention and protection process to protect individuals and items. The fire prevention and protection process should be appropriate to the stage in the lifetime of the installation. Further recommendations and guidance are provided in Refs [5, 21, 39].

Accounting for, and control of, nuclear material and radioactive material

5.181. The inventory of nuclear and other radioactive material at the installation should be well established, maintained and periodically verified by

a specially designated unit within the organization. The accounting for, and control of, nuclear material and radioactive material is subject to internationally agreed requirements.

Security

5.182. The organization should establish, maintain and operate physical protection systems [40] and appropriate security arrangements to prevent individuals from intentionally carrying out unauthorized actions that could jeopardize safety at the installation, and to prevent sabotage and theft of nuclear material and radioactive material. Guidance on nuclear security is issued in the IAEA Nuclear Security Series.

5.183. The organization should establish and implement a nuclear security plan to prevent individuals from carrying out unauthorized actions, which could jeopardize safety. The plan should be periodically revised, with account taken of the modified design basis threat and the stage in the lifetime of the installation.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

MONITORING AND MEASUREMENT

6.1. Reference [1] states in para. 6.1 that:

> "The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement."

6.2. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Management oversight

6.3. Managers normally perform oversight reviews and assess the performance of activities through their day-to-day line management activities. Other, more structured mechanisms include:

(a) *Line management monitoring*: In order to become proactive and to maintain control over emerging problems, line managers and supervisors should be aware of what is going on in their areas of responsibility and should assess actual performance against expected results. Line management monitoring necessitates that managers be individually involved in assessing the performance of work, posing informed and probing questions and reviewing the results of work completed. To achieve these objectives, line managers and supervisors:
   — Should observe the work being carried out to ensure that the applicable standards are being met;
   — Should be visibly present and available and should listen to suggestions and complaints from personnel;
   — Should examine trends in performance indicators;
   — Should review the results and lessons to be learned from self-assessments, independent assessments, observation and surveillance programmes;
   — Should carry out pre-job briefings and post-job briefings where necessary;
   — Should coach and mentor individuals to improve their performance.

(b) *Reviewing the achievement of goals, strategies, plans and objectives*: A series of planned and systematic reviews (sometimes referred to as accountability reviews) should be carried out to assess the progress of individuals or functional units in their achievement of the goals, strategies, plans and objectives relevant to them. Managers at an appropriate level should review the effectiveness of the performance of each individual or functional unit. The reviews should be carried out to a predetermined frequency and schedule to enable a continuous view of performance to be obtained and communicated to individuals. Such reviews should cover historical performance and future plans relating to the goals, strategies, plans and objectives that are described in each department's plan. Such reviews will commonly address the following:
   — Direction and planning, including the setting of objectives and associated targets;
   — Endorsement of strategies;

— Accomplishment of strategies, plans or project proposals;
— Measurement of performance against set plans and targets using established performance indicators;
— Failures of control (e.g. significant incidents);
— Proposed ideas and initiatives for improvements;
— Human resource issues such as staffing levels, individual performance and the performance of training.

Recommendations and/or decisions on actions reached as a result of these reviews should be tracked through to completion.

(c) *Oversight meetings*: These should be held to enable managers to obtain oversight and to take any immediate, corrective action. Typically, these meetings are:

— Operational meetings: These are meetings for key functions in the installation, normally taking place daily, to review the operational status of the installation and to ensure that resources are allocated to support day-to-day operational needs.
— Management team meetings: The purpose of these meetings is to make decisions and set the direction for the installation on the basis of feedback from internal and external sources. The meetings focus on making optimal decisions with respect to achieving the goals, strategies, plans and objectives for the installation as identified in the business plan. This is a primary means of achieving agreement and commitment by all participants.
— Nuclear safety oversight meetings: The purpose of these meetings is to ensure that the management continually maintains an awareness of, and responds appropriately to, nuclear safety issues. The meetings evaluate past, present and future nuclear safety issues at the installation and allow decisions concerning actions to be taken to maintain or to enhance high levels of nuclear safety.
— Corporate oversight: Corporate oversight ensures that the management system at the installation meets the management needs of the corporation. Corporate oversight may also be used in determining whether there is a need to develop specific management programmes for new initiatives or lifetime stages, e.g. major refurbishment or decommissioning, and in initiating independent external assessments of programmes at the installation.

SELF-ASSESSMENT

6.4. Reference [1] states in para. 6.2 that:

> "Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture."

6.5. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Self-assessment by senior management

6.6. The input to self-assessment by senior management should include information on:

(a) Safety related results and trends and performance indicators;
(b) Overall performance, including safety, health, environmental, security, quality and economic considerations;
(c) Analysis of current performance, such as feedback from peer evaluations, surveillance and results of technical reviews;
(d) Adequacy of the management system of the organization;
(e) Effectiveness of management procedures and work instructions;
(f) Organizational issues, such as levels of authority and responsibility, interfaces, communications and policies for recruitment, training and promotion;
(g) Results of staff surveys and assessments of safety culture;
(h) Effect of regulatory and statutory requirements and any changes to them;
(i) Strategic planning, the purpose or 'mission' of the organization and the safety objective;
(j) Feedback from experience.

6.7. Management self-assessment should enhance safety at the installation and should contribute to the organization's quality improvement process.

Self-assessment by managers and individuals

6.8. Examples of self-assessment techniques for managers and personnel include the following:

(a) Observation by managers of operating crews performing on simulators and in training activities in which weaknesses in performances are documented for further action;
(b) Reviews of work backlogs and rates of maintenance rework;
(c) Event investigations and critiques of maintenance activities (post-work reviews performed to identify areas for improving these activities in the future);
(d) Inspections of systems or equipment and document reviews;
(e) Industrial safety inspections;
(f) Questionnaires, staff surveys and other feedback mechanisms;
(g) Evaluation of operating experience at the installation, in the organization and industrywide;
(h) Researching information to identify opportunities for improving performance.

6.9. The self-assessment process should be used to evaluate programmes, processes and performance areas against specific criteria by the most appropriate technique identified above. Self-assessments may be carried out periodically (e.g. every two years).

6.10. Self-assessments may be planned (proactive) or may be initiated in response to situations that indicate the need for a closer review of performance (reactive), such as:

(a) Events;
(b) Visits to, or review of information from, other installations to consider possible performance related issues;
(c) New regulatory requirements.

6.11. Self-assessments are typically performed by teams, but they may occasionally be performed by an individual. Self-assessments should be properly organized (e.g. some form of guidance should be used to ensure completeness and consistency). Self-assessments generally necessitate planning, scheduling, preparation, acquisition of resources and reporting. Self-assessment is different from self-checking, which is a continuous personal responsibility in the conduct of work.

6.12. Schedules for self-assessments should include:

(a) Long range planning in which all self-assessments are specified to avoid scheduling self-assessments and other work for which there are insufficient personnel or other resources available;

(b) The use of other planned activities, including other forms of evaluation;
(c) Flexibility to allow any changes necessary to include new self-assessments;
(d) Communication of plans to the appropriate individuals in time to permit sufficient planning.

6.13. Among the skills to be considered in selecting individuals to participate in self-assessments should be:

(a) Technical expertise in the area being assessed;
(b) Ability in applying the techniques of interviewing, observing and analysing;
(c) Open-mindedness and the ability to accept different approaches.

6.14. Self-assessment assignments should also involve the participation of less experienced individuals to increase their knowledge.

6.15. In preparing for and conducting self-assessments, the following should be considered:

(a) Information from professional organizations;
(b) Information obtained from national or international standards;
(c) Feedback from external groups, such as regulatory bodies, the IAEA and industry organizations.

6.16. For each function within the installation, self-assessments of programmes, processes and performance should routinely be conducted. Independent assessments should be carried out periodically to evaluate the self-assessment process and its performance.

6.17. Teams or individuals conducting self-assessments should communicate closely with those being assessed to help ensure their understanding and to promote their acceptance of the results.

6.18. Potential issues should be kept under discussion to promote understanding of the issues and acceptance by the individuals who will be responsible for correcting the weaknesses identified.

6.19. Managers should verify that issues for resolution that are identified in the self-assessment process are promptly entered into the corrective action programme or other tracking systems, to ensure that the resolution of issues is

timely and is prioritized on the basis of their potential consequences for safety and reliability.

6.20. When managers determine that an issue identified in a self-assessment does not need further action, the reasons for this decision should be documented and communicated to the person who identified the issue. This should be done with care and sensitivity so as not to discourage the identification of possible issues in the future.

6.21. Results of self-assessments should be communicated to the groups and individuals who are affected by the actions to be taken. Managers should periodically review the results of ongoing self-assessment activities with individuals to improve their performance. Typical methods of communication include use of the following:

(a) Group meetings;
(b) Special newsletter articles;
(c) Performance indicators posted in the workplace;
(d) Company intranet sites or computer databases.

6.22. Self-assessment results should be reviewed by (or shared with):

(a) The manager being evaluated;
(b) The groups being evaluated;
(c) Other groups that can use the information to improve their performance.

6.23. Indicators of the effectiveness of the self-assessment process include:

(a) Recurrence (repetition) of issues from previous self-assessments;
(b) Trends in performance indicators in areas where corrective actions have previously been implemented;
(c) Critiques by team members of the effectiveness of self-assessments;
(d) Comparison of the results of different self-assessments to check their effectiveness;
(e) Feedback on the usefulness of the results from managers whose areas of responsibility were evaluated;
(f) Comparison of the results of self-assessments with the results of independent assessments or group assessments, or information from external feedback, as available;
(g) Benchmarking of performance with that of other departments or external organizations to determine whether self-assessment activities reflect best

industry practices and standards and to identify additional opportunities for improvement.

INDEPENDENT ASSESSMENT

6.24. Reference [1] states in paras 6.3–6.6 that:

> "Independent assessments shall be conducted regularly on behalf of senior management:
> — To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
> — To determine the adequacy of work performance and leadership;
> — To evaluate the organization's safety culture;
> — To monitor product quality;
> — To identify opportunities for improvement.
>
> "An organizational unit shall be established with the responsibility for conducting independent assessments.[15] This unit shall have sufficient authority to discharge its responsibilities.
>
> "Individuals conducting independent assessments shall not assess their own work.
>
> "Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them."

6.25. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

Types of independent assessment

6.26. The following types of independent assessment are typically used by organizations.

[15] The size of the assessment unit differs from organization to organization. In some organizations, the assessment function may even be a responsibility assigned to a single individual or to an external organization.

Peer evaluation

6.27. Peer evaluation is a critical examination of specific safety related subjects by individuals from another organization or other organizations to identify areas for improvement and to promote good practices. The evaluation team should consist of experts in all areas of the evaluation to promote the sharing of experience and to develop relationships between the peers and individuals at the installation under evaluation.

6.28. Senior managers should consider developing, on the basis of best international practice, a set of performance indicators, objective standards and criteria against which performance could be evaluated. For an installation, objective standards and criteria that specify performance requirements in areas such as operation, maintenance, chemistry, engineering, radiation protection, protection against fires and emergency planning should be considered and developed. In some States, such objective standards and criteria are sometimes referred to as performance objectives and criteria.

6.29. Peer assessment is both objective, in that it compares actual performance against the objectives and criteria, and subjective, in that it uses the collective knowledge of the peers to identify areas for improvement and to promote good practices.

6.30. In the evaluation, the work should be observed and a judgement should be made on the basis of the methods used and the results achieved. A written report of issues identified and good practices observed should be presented to the management of the installation. The management should develop an action plan to implement any improvements identified as necessary and to ensure that information on good practices is made known to others at the installation.

Technical review

6.31. 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.

6.32. Different techniques may be used, such as inspection and testing, as well as emergency drills and exercises.

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

6.34. Those who are requested to perform a technical review should be able to demonstrate their qualifications and competence in the area of work being assessed.

ASSESSMENT OF SAFETY CULTURE

Self-assessment of safety culture

6.35. The self-assessment of safety culture should include the entire organization. Several different self-assessment tools should be used to determine the status of the safety culture of the organization. Possible self-assessment tools include interviews, focus groups, questionnaires, observations and document reviews. The safety culture should be assessed on the basis of its characteristics (see paras 2.14–2.21) and attributes (see Appendix I). These characteristics and attributes should all be covered when developing interview questions, items for inclusion in a questionnaire or issues for discussion in focus groups.

6.36. A designated team representing all organizational levels and functions at the installation should carry out the self-assessment. A specialist in safety culture should be included in the team for ensuring that appropriate assessment tools are developed and applied, as well as for carrying out an analysis of the results (including a statistical analysis of the results of questionnaires) and their interpretation. The self-assessment team should receive training in how to develop the assessment tools and in the steps to be considered in the assessment process. Focus groups may be used to obtain an impression of the organization's safety culture. The focus groups should compare the characteristics and attributes of safety culture with current practices to identify strengths and areas for improvement. The focus groups should include cross-functional representatives and/or representatives from an organizational unit. There should be enough focus groups to obtain a realistic assessment of the entire organization.

6.37. The self-assessment team should summarize the results and identify areas for improvement and may suggest actions to be taken. The results should be reported to the management at an appropriate level; one that is responsible for

the implementation of improvement actions. A follow-up assessment should be performed, account being taken of the time needed for improvement actions to have their full effect on the safety culture.

Independent assessment of safety culture

6.38. The independent assessment of safety culture should follow a similar approach to that used for the self-assessment and should also include all characteristics (see paras 2.14–2.21) and attributes (see Appendix I) of safety culture. The independence and qualification of the members of the assessment team should be considered crucial for the success of the assessment. The team should be staffed with sufficient diversity of experience and should include specialists in behavioural science, with knowledge of statistical methods of analysis.

6.39. The independent assessment team should aim at identifying strengths and areas for improvement and may recommend or suggest actions to be taken. The results should be reported to the management at an appropriate level; one that is responsible for the implementation of improvement actions. Similarly, as for the self-assessment, a follow-up assessment should be performed, account being taken of the time needed for improvement actions to have their full effect on the safety culture.

MANAGEMENT SYSTEM REVIEW

6.40. Reference [1] states in paras 6.7–6.10 that:

> "A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished.
> "The review shall cover but shall not be limited to:
> — Outputs from all forms of assessment;
> — Results delivered and objectives achieved by the organization and its processes;
> — Non-conformances and corrective and preventive actions;
> — Lessons learned from other organizations;
> — Opportunities for improvement.
> "Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.

"The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes."

6.41. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS

6.42. Reference [1] states in paras 6.11–6.16 that:

"The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.

"Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization. The impact of non-conformances shall be evaluated and non-conforming products or processes shall be either:

— Accepted;
— Reworked or corrected within a specified time period; or
— Rejected and discarded or destroyed to prevent their inadvertent use.

"Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorization. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.

"Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential non-conformances shall be determined and taken.

"The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level in the organization.

"Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices."

Non-conformance control

6.43. The generic recommendations that were developed to provide a means of meeting these requirements are provided in Ref. [2]; there are no supplementary recommendations.

Corrective actions

6.44. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

6.45. The process of determining and implementing corrective actions is an important way of improving safety, reliability and performance as well as helping to prevent incidents. The process for corrective actions should require corrective actions to be evaluated using risk assessment techniques to ensure that any risks are identified and mitigated.

6.46. All forms of assessment, such as independent assessments, external assessments, assessments by the regulatory body and self-assessments, together with feedback from operating experience, are methods for the identification of issues, and they provide input to the corrective action process. The process can also be used to track issues that have been identified by any other means.

6.47. Some organizations use a single, formal, installation-wide corrective action process to track, select, evaluate, trend and resolve all issues; other organizations report and track issues using tracking systems of various types. These other types of tracking system are typically managed at the departmental level and are separate from the installation-wide corrective action process. Such tracking systems are periodically reviewed to ensure that important issues that should be dealt with at the level of the installation-wide corrective action process are not being reported at an inappropriate level. The monitoring of such tracking systems by management helps to ensure that they are used as intended and that they do not reduce the effectiveness of the corrective action process.

6.48. Issues reported in the corrective action process should be reviewed promptly for their possible effect on safety, reliability and operability and to determine whether they meet the threshold criteria for reporting to the regulatory body. To ensure consistent results, it is often beneficial to have a

defined, consistent review process that is monitored by management. The possibility of generic issues should be considered in the review of issues.

6.49. Issues should be evaluated, on the basis of their significance, to determine their cause(s). The corrective action process should include a formal definition of what constitutes a significant issue and, if recurrence is unacceptable, the process should specify where techniques for evaluating root causes should be applied. Evaluation of significant issues should be initiated immediately to prevent the loss of evidence and the loss of memory of the circumstances.

6.50. Evaluation of issues of lower significance should be focused on correcting the immediate (or apparent) cause and may not need to address the root cause. For very simple issues, the cause may be obvious and more detailed analysis to determine corrective actions may not be necessary. For such issues of lower significance, corrective actions may remedy the immediate issue but may not prevent its recurrence. If similar issues occur, trending may identify common issues, which would benefit from root cause analysis. Where a trend is identified, it should be documented as a significant issue and treated accordingly.

6.51. Individuals should be trained in the techniques of root cause analysis for reviewing significant issues, using a well-defined method to identify root causes, contributory causes and corrective actions needed to prevent recurrence. Any root cause evaluation should include a review that is broad enough to help ensure that the corrective actions will prevent recurrence, not only where the issue arose originally, but also in other places where it could arise.

6.52. Contributory causes may include not only errors made by individuals, but also leadership and organizational factors or behaviours.

6.53. Individuals who identify issues should be provided in a timely manner with information on corrective actions that have been taken or are planned. This will help to motivate personnel to continue using the corrective action process. The information may be provided directly to the individuals or by means of easy access to an information management system. Feedback should also be provided if a reported issue is determined to be invalid or not worthy of additional corrective actions in order to explain to the individual why this decision has been taken.

6.54. Trending should be used to identify categories of issues such as those associated with procedures, human performance and equipment. Trend coding

can be used to assist in trend analysis, provided that it is applied consistently and in the knowledge that the number of trend codes is limited.

6.55. Consistently trending issues of a given type (such as errors in procedures) in the entire organization may help to identify weaknesses that exist in more than one part of the organization.

6.56. The corrective action process should be reviewed periodically to assess the effectiveness of the performance of processes against the expectations of the management. The reviewer should consider any outstanding or unresolved issues and their agreed corrective actions and should verify that their priorities are appropriate and that underlying issues with common causes are being addressed.

Preventive actions

6.57. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

6.58. Managers should periodically analyse available information such as non-conformance reports, audit reports, maintenance reports, operating logs, registers of significant events and plant safety reviews. The analysis should be used for seeking out trends to identify problem areas for which root cause analysis is required, to confirm that appropriate actions have been taken to prevent repetition of the non-conformances and to enhance safety and performance.

6.59. Information on incidents, events or quality related issues available from other organizations in the nuclear industry (i.e. operational experience feedback) should be assessed to provide input for the development and implementation of suitable preventive measures.

6.60. The implementation of preventive actions may proceed in stages. In such cases, each stage should be clearly defined and the means of verification to ensure that the actions have been effective should be specified. Preventive actions should be evaluated by means of risk assessment techniques to ensure that any risks are identified and reduced. Prior to their implementation, all proposed actions should be agreed, documented and authorized.

Reporting of events

6.61. Criteria should be established for the selection of the significant events and the issues with equipment that are to be reported to the utility, to the regulatory body and to other national and international bodies.

6.62. Significant events and equipment issues meeting these criteria, or of generic interest, should be reported to such off-site organizations and bodies in a timely manner.

Improvement

6.63. Reference [1] states in paras 6.17 and 6.18 that:

> "Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.
> "Improvement plans shall include plans for the provision of adequate resources. Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked."

6.64. The following recommendations have been developed to provide a means of meeting these requirements for nuclear installations. They are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2].

6.65. Continual improvement of the processes of an organization may lead to enhanced safety and efficiency benefits such as cost reductions and shorter cycle times within the activities of a process. Shorter cycle times could include reducing the time waiting for approvals or eliminating unnecessary interactions between departments or functions.

6.66. To introduce continual process improvements effectively, the following recommendations apply:

(a) There should be long term commitment to improvement and engagement by senior management throughout the entire organization.
(b) All personnel of the organization who use the processes are actively encouraged and expected to contribute to continual process improvement.

(c) The organization should have in place an approach to process management (see Section 5).
(d) The organization should identify the systems and processes that are working well in order to maintain and extend good practices and to reinforce correct behaviour.
(e) Management should use information from processes as an input to managing the installation.
(f) The processes should be aligned with the objectives of the organization through the organization's business plan.
(g) The information on process performance should be used to identify and prioritize the processes that require improvement.

6.67. A structured approach to continual improvement should be used that is focused on the ways in which an organization can improve its processes. It is recognized that there are many different approaches and methods available commercially for improving processes.

6.68. Process improvements may affect nuclear safety or conventional safety. All changes to the installation and its processes should be properly evaluated for their effects on safety and the implementation of changes should be effectively controlled, with additional safety measures taken if necessary during the period of change.

6.69. Figure 3 depicts the cycle of continual improvement of the management system and shows how it relates to the aspects of measurement, assessment and improvement, as well as to other aspects of the management system.

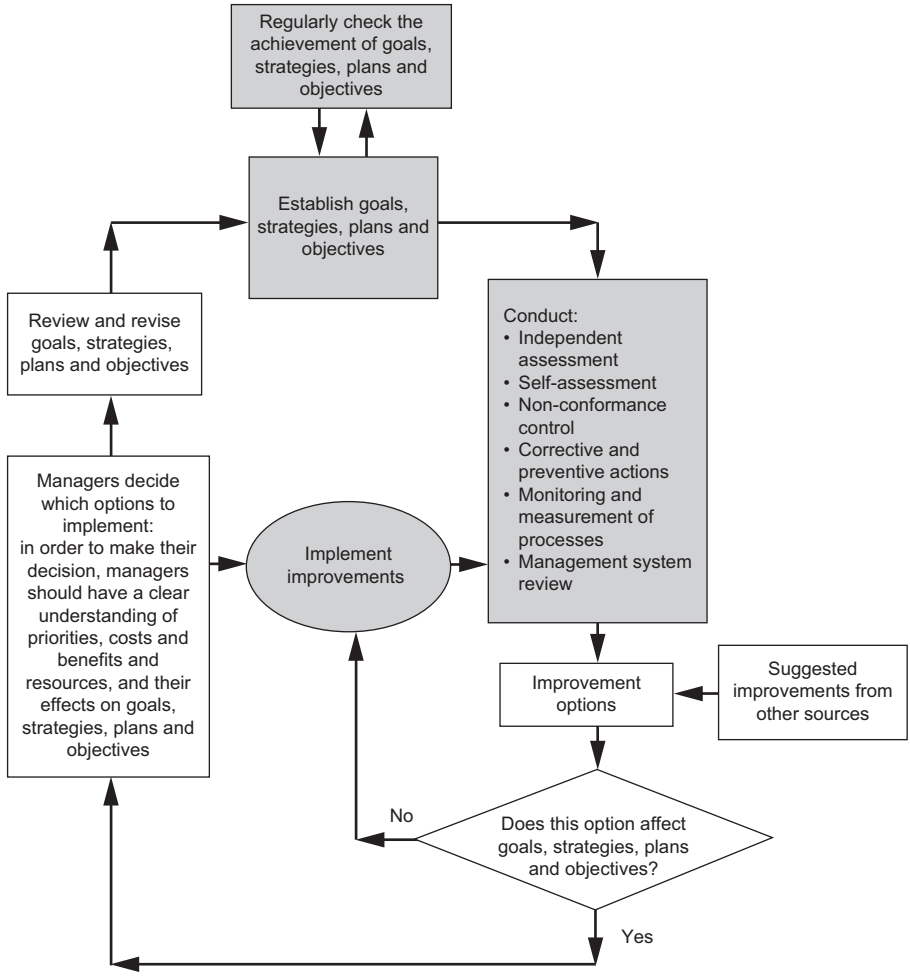

FIG. 3. The continual improvement cycle. The shaded boxes denote requirements for the management system [1]. The start box is the 'establish goals, strategies, plans and objectives' box.

Appendix I

ACHIEVING THE ATTRIBUTES OF A STRONG SAFETY CULTURE

I.1. The framework identified in Ref. [2] consists of a set of five key characteristics. Each of the characteristics has a number of attributes that have been identified as essential for achieving a strong safety culture. The attributes are reproduced from Ref. [2] in this appendix for the sake of completeness; the activities that could demonstrate each attribute and therefore aid with the implementation of a strong safety culture follow them.

(1) SAFETY IS A CLEARLY RECOGNIZED VALUE

Attributes

(a) The high priority given to safety is shown in documentation, communications and decision making:
- The safety policy required by Ref. [5] or [13] or [40], depending on the type of installation concerned, should be documented and should be communicated to personnel.
- The rationale for significant decisions relating to safety should be communicated regularly to personnel.
- Decisions that affect safety should be made in a timely manner.
- Multiple methods should be used to communicate the importance of safety throughout the organization.
- Key decisions relating to safety should be periodically revisited and assumptions and conclusions should be challenged in the light of new information, operating experience or changes in circumstances.

(b) Safety is a primary consideration in the allocation of resources:
- Resource allocation should be in line with the stated priorities and goals, strategies, plans and objectives of the organization.

(c) The strategic business importance of safety is reflected in the business plan:
- Goals, strategies, plans and objectives relating to safety should be clearly identified and integrated into the business plan.

(d) Individuals are convinced that safety and production go hand in hand:
- Managers should be especially sensitive to decisions that may seem to place production or other factors above safety and should take care to explain such decisions to personnel.

— Managers and supervisors should regularly communicate the importance of ensuring safety while meeting requirements for production and performance.

(e) A proactive and long term approach to safety issues is shown in decision making:
— In strategic and long range planning, account should be taken of known and potential safety issues.
— The priorities of, and incentives for, senior management should not be concerned exclusively with short term goals, strategies, plans and objectives.

(f) Safety conscious behaviour is socially accepted and supported (both formally and informally):
— The performance appraisal process should recognize and reward safety conscious behaviour.
— Peers should encourage each other to engage in safety conscious behaviour.

(2) LEADERSHIP FOR SAFETY IS CLEAR

Attributes:

(a) Senior management is clearly committed to safety:
— Senior managers should treat supervisors as a crucial part of the management team as they translate safety culture into practice and should give them their full support.
— Senior corporate managers should periodically visit operating installations to assess at first hand the effectiveness of management.

(b) Commitment to safety is evident at all levels of management:
— Managers should establish clear expectations of performance in areas that affect safety and these should be documented where appropriate.
— Managers should adhere strictly to policies and procedures in their own conduct and should not expect or accept special treatment.
— Managers should not tolerate or ignore substandard performance in relation to safety for any reason.
— Managers should exhibit a sense of urgency in remedying significant weaknesses or vulnerabilities.

(c) There is visible leadership showing the involvement of management in safety related activities:
— Managers should be able to recognize conditions of degraded safety (physical or organizational).

— Managers should individually note performance and inspect conditions in the field by walking around the installation and observing and listening to individuals, and should intervene vigorously to remedy safety issues ('walk, look, listen and fix').
— Managers should ensure that situations adverse to safety are remedied.
— Supervisors should spend time observing and coaching individuals at their workplaces and should encourage and reinforce expected behaviour.
— Supervisors should discuss safety issues frequently with their teams or work groups.
— Managers should visit personnel at their workplaces.

(d) Leadership skills are systematically developed:
— Managers and supervisors should be selected and evaluated with due consideration of their demonstrated ability to foster a strong safety culture.
— Skills in change management should be taught to individuals in leadership roles.
— A succession plan that includes aspects of safety culture should be put in place for developing future managers.

(e) Management ensures that there are sufficient competent individuals:
— Personnel should only perform work for which they are trained and qualified.
— A systematic approach should be taken to training and qualification.
— Attendance at training by personnel should be given a high priority.
— Staffing levels should be consistent with the demands of ensuring safety and reliability.

(f) Management seeks the active involvement of individuals in improving safety:
— Managers should actively seek dissenting views and diverse perspectives and should encourage open and frank discussion to support independent thinking.
— Managers should encourage the raising of concerns by personnel and should take action or else explain why no action was taken.
— Where practicable, managers should involve personnel in decision making and activities that affect them, for example, by involving individuals in writing their own procedures and instructions.
— Individuals should feel that their opinion matters and should be able to cite instances of their input leading to positive change.

(g) Safety implications are considered in change management processes:
  — Processes for change management and control should be put in place so that account is taken of the possible effects on safety of changes to procedures and equipment and other managed changes.
  — Personnel should be informed of impending changes in ways that uphold trust within the organization.

(h) Management shows a continual effort to strive for openness and good communication throughout the organization:
  — Supervisors should respond to individuals' questions openly and honestly and should maintain good relations with personnel.
  — Managers should ensure that open communication is valued and preserved.
  — Managers should visit personnel at their workplaces and, where possible, should hold open meetings to explain issues and decisions in context.
  — Managers and others who may influence the behaviour of personnel should encourage a questioning attitude.
  — Management has the capability to resolve conflicts as necessary.
  — When necessary, fair and impartial methods should be used to resolve conflicts and to settle disputes.

(i) Relationships between managers and individuals are built on trust:
  — Managers should carry out what they undertake to do in their communications.
  — Personnel should adhere to the management system.
  — Managers should be able to be trusted by personnel to act professionally when personnel raise safety concerns or report near miss events.
  — Managers should ensure that safety consciousness prevails in the working environment throughout the organization.
  — Managers should ensure that communication is not stifled in the organization and should take prompt action to counter any such effect.

(3) ACCOUNTABILITY FOR SAFETY IS CLEAR

Attributes

(a) An appropriate relationship with the regulatory body exists that ensures that the accountability for safety remains with the licensee:
  — Complete and accurate information should be provided to the regulatory body.

— The regulatory body should be consulted to obtain any necessary clarification of, and guidance on, regulatory matters.
— The licensee should be seen by the regulatory body to be open and timely in its reporting and interactions.

(b) Roles and responsibilities are clearly defined and understood:
— The organization is required to define and to document functions and responsibilities for all aspects of safety that are under its control, see Refs [13, 40–42].
— Individuals should understand their functions and responsibilities for safety and how their work may affect safety.
— Individuals should know where to obtain help with safety related issues and should seek clarification if necessary.
— When contractors are engaged, their functions and their responsibilities for safety should normally be specified in contractual documents. The individuals affected in the organization and in the contractor organization should be made aware of these arrangements.

(c) There is a high level of compliance with regulations and procedures:
— Personnel should adhere to regulations and procedures and instances of non-compliance should be avoided.
— Management's expectations for the use of procedures (i.e. when procedures are to be in the hands of the user and are to be used) and adherence to procedures (i.e. the degree of compliance expected) should be clear and made well known to personnel.
— Managers and supervisors should inspect workplaces frequently to ensure that procedures are being used and being followed in accordance with expectations.
— Personnel should be encouraged to review procedures and instructions critically in use and to suggest improvements where appropriate.

(d) Management delegates responsibility with appropriate authority to enable clear accountabilities to be established:
— Accountable behaviour should be positively reinforced by managers and peers.
— Individuals should help each other to fulfil their accountabilities.
— Accountability should be perceived positively and not negatively as a way to apportion blame.
— If possible, the accountability for every operational decision should be clear before its execution.
— The way authority is exercised should not discourage individuals from maintaining open communication or reporting concerns or unusual observations.

(e) ‘Ownership’ for safety is evident at all organizational levels and for all personnel:
  — Individuals should have their own targets in relation to safety and should continually seek improvement.
  — Individuals should take care of safety in their own working environment.
  — Supervisors should promote good safety practices.

(4) SAFETY IS INTEGRATED INTO ALL ACTIVITIES

Attributes:

(a) Trust permeates the organization.
(b) Consideration of all types of safety, including industrial safety and environmental safety, and of security is evident.
(c) The quality of documentation and procedures is good:
  — Procedures should be controlled, clear, understandable and up to date and should be easy to find, use and revise.
  — Documentation should be comprehensive, easy to understand and easily accessible.
  — Responsibilities for preparing documentation and the scope of reviews should be clearly defined and understood.
(d) The quality of processes, from planning to implementation and review, is good:
  — Work should be preplanned (including plans for contingencies) to ensure that all safety functions are effective at all times and to ensure that safety is not compromised.
  — Individuals should follow the approved plans and should seek proper approvals before deviating from the approved plans.
  — Work should be planned in sufficient detail to allow personnel to work effectively and efficiently (e.g. resources should be matched to demands, and spares and tools should be available when needed).
(e) Individuals have the necessary knowledge and understanding of the work processes:
  — Individuals should have a good understanding not only of their own work processes, but also of how these processes interact with other processes.
(f) Factors affecting work motivation and job satisfaction are considered:

— Individuals and their professional capabilities, values and experience should be considered the organization's most valuable strategic asset for safety.
— The reward system should be aligned with safety policies and should reinforce the desired behaviour and outcomes.
— Recognition should be given to individuals and teams for exemplary performance.
— Individuals should take pride in their work and should feel that their tasks and performance are important contributors to the success of the organization.
— Managers should be trained and should have appropriate knowledge of the factors influencing human performance.

(g) Good working conditions exist with regard to time pressures, workload and stress:
— The scheduling of work on safety critical tasks at night should be avoided.
— Shift schedules should be based on up to date knowledge of best solutions with regard to human performance and capabilities.
— Records of overtime should be kept, trended and acted upon. Planned overtime should be kept within regulated limits.
— Managers should be sensitive to stress affecting individuals under their control by, for example, undertaking stress awareness training.
— The physical working environment should be conducive to high standards of safety and performance (e.g. standards of housekeeping, provision of equipment and tools, including response equipment, and guarding and signposting of hazards).
— Individuals should be consulted about the ergonomics and the effectiveness of their working environment.
— Human factor specialists should be made available to the organization.

(h) There is cross-functional and interdisciplinary cooperation and teamwork:
— Multidisciplinary teams (drawn from different work groups and different levels) should be used when appropriate to develop solutions to problems.
— Individuals should interact with openness and trust and should routinely offer support to each other.

(i) Housekeeping and material conditions reflect commitment to excellence:
— Managers should not accept long standing problems with items of equipment, systems or processes as 'the way things are'. Managers

should pay careful attention to resolving such problems, even if the solutions are challenging and expensive.
— There should be a process for identifying long-standing issues concerning equipment or processes. For example, each issue could have an action plan for its solution.

(5) SAFETY IS LEARNING DRIVEN

Attributes:

(a) A questioning attitude prevails at all organizational levels:
— Individuals should notice and should be able to question unusual signs and occurrences and should seek guidance when in doubt.
— Individuals at all levels should be encouraged to ask detailed questions in meetings.
— Management should be questioning of its own attitudes and views and should actively seek independent views.
(b) Open reporting of deviations and errors is encouraged:
— The organization should have a variety of established processes to allow and encourage individuals to report abnormal conditions, concerns and events, including near misses.
— Recognition should be given to individuals and to teams who report abnormal conditions, concerns and events, including near misses.
— Individuals should be comfortable raising safety concerns without fear of retribution.
— Managers should ensure that matters raised are acted upon and that feedback on the outcome is given.
(c) Internal and external assessments, including self-assessments, are used:
— Various oversight forums and processes, including self-assessment, should be used to review, evaluate and enhance the safety performance of the organization.
— The number and types of oversight mechanism should be periodically reviewed and adjusted.
— Oversight should be viewed positively and constructive use should be made of external or independent opinions.
— Periodic safety culture assessments should be conducted and used as the basis for improvement [5].
— Senior managers should be periodically briefed and should initiate actions on the basis of the results of oversight activities.

(d) Organizational experience and operating experience (both internal and external to the installation) are used:
  — Processes should be in place to obtain, review and apply available internal and external information that relates to safety, including information on experience from other industries.
  — Reports on operating experience should be reviewed and actions should be taken to ensure that the organization learns and applies the relevant lessons.
  — There should be no indications of an attitude of "it couldn't happen here".

(e) Learning is facilitated through the ability to recognize and diagnose deviations, to formulate and implement solutions and to monitor the effects of corrective actions:
  — Personnel should be able to have confidence in the corrective action process and should be able to point to examples of problems that they have reported and which have been solved.
  — Checks should be made to see that corrective actions taken address the real and underlying cause(s) and solve the problem.
  — There should be a low rate of repeat events and errors.

(f) Safety performance indicators are tracked, trended and evaluated, and acted upon:
  — The causes of safety significant events and adverse trends should be identified and acted upon in accordance with an established time frame.
  — The organization should use measures and targets in order to explain, maintain and improve safety performance at all levels.
  — Results with regard to safety performance should regularly be compared with targets and the results of the comparison should be communicated to personnel.
  — Action should be taken when safety performance does not match its goals, strategies, plans and objectives.
  — The pitfalls of focusing on too narrow a set of safety performance indicators should be recognized.
  — The organization should be alert to detect and respond to possible indications of a declining safety performance.

(g) There is systematic development of individual competences:
  — Individual development programmes, including succession planning, should be put in place.
  — Managers and supervisors should be selected and evaluated on the basis of their demonstrated ability to foster a strong safety culture.
  — Appraisals of individual development should be carried out to determine the training needs and development needs of individuals.

Appendix II

MANAGEMENT SYSTEM FOR R&D ACTIVITIES FOR A NUCLEAR INSTALLATION

II.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for R&D activities. For R&D activities, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1];
(b) Takes into account the generic recommendations provided in Ref. [2];
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix.

II.2. R&D activities should be performed in a manner that provides assurance that safety requirements have been adequately taken into account. This should be accomplished by conducting the R&D activities in a manner that meets the requirements for the management system [1].

II.3. The starting point for R&D may 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 various technologies that could be used.

II.4. R&D organizations (e.g. the operating organization of a research reactor) should consider whether the recommendations provided in Appendices III–VIII apply to their installations.

MANAGEMENT SYSTEM

II.5. For success in R&D activities, management at all levels:

(a) Should cultivate and sustain an environment that encourages creativity, intellectual stimulation, innovation and collaboration.
(b) Should demand good work practices as the only acceptable way of performing and supporting R&D.
(c) Should avoid overloading researchers with administrative tasks by providing adequate administrative support;

(d) Should ensure that intellectual property rights are preserved and protected.

II.6. Management of the R&D activities should ensure that functions, responsibilities, authorities and interfaces are clearly specified and understood, particularly between the functions of: (a) managing the resources necessary to support research work, (b) performing the research and (c) carrying out assessments over the course of the R&D activities. These relationships can be complex because some researchers may have additional individual functions to carry out at different times. In every case, however, the functions of performing research and carrying out assessments should be so organized that they are clearly independent.

II.7. The requirements for the management system may be implemented for R&D activities important to safety by developing a plan for each R&D project (the R&D plan).

II.8. Some researchers may be working at universities or at other institutions that share an interest in the R&D project. In such cases, agreed methods of collaboration should be adopted.

II.9. Management should assign a principal investigator or 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 or researcher may subsequently assign some or all of the work to other researchers, engineers or technicians. When work is assigned, a description of the functions, responsibilities and authorities for the work should be described in the R&D plan.

II.10. The management of the organization responsible for the R&D activities should ensure that the functions, responsibilities and authorities for reviewing and approving R&D plans are specified. Reviewers should consider, for example, the technical direction of the work, user requirements, assumptions, resources and implications of the schedule.

II.11. Senior managers of the organization responsible for the R&D activities should review possible alternative activities and should document their decisions, justifying the choice of a specific direction and the rationale for disregarding alternatives.

II.12. Prior to the application of the results of any R&D activities, the organization or the licensee should ensure that the results of the work have been properly validated, the safety implications have been assessed and that approval has been obtained, if required, from the regulatory body.

II.13. Interfaces should be described in the R&D plan and arrangements between the organizations performing work should be agreed upon. For example, the following interfaces should be addressed:

(a) Organizational interfaces at the start of the R&D activities;
(b) Interfaces between internal and external organizations during the R&D activities;
(c) Interfaces with similar R&D activities;
(d) Interfaces at the end of the R&D activities, such as those relating to the use and the application of the results.

GRADING

II.14. When developing the structured approach to grading the application of the requirements for the management system (see Section 2), the following aspects could be considered:

(a) The intended end use of the knowledge, data, technological process or technological product that will result from the R&D activities, in particular in terms of its effects on safety;
(b) The nature and quantities of the materials to be used and the degree to which the work poses risks or hazards to personnel, the public and the environment;
(c) The capability to demonstrate, test or repeat the results;
(d) The scale and technical complexity of the activity and the installations to be used;
(e) Whether a new concept, a proven concept or an extension to a new application is involved;
(f) The managerial complexity of the activity, i.e. the involvement of many interested parties with different objectives and responsibilities;
(g) The impact that missed or delayed milestones will have on the schedule, the ease or difficulty of recovery of the schedule, the loss of key individuals, delays in recruiting new personnel and delays in receiving critical equipment or making it functional;

(h) The extent to which other work depends on the results of the R&D activities;
(i) The desired performance or the expectations for the results.

RECORDS

II.15. Managers of the R&D activities should establish requirements for ensuring that all appropriate aspects of R&D activities are adequately documented and recorded. This includes work from the initial conception and design of the R&D plan through to the conduct of the research and analysis of the results.

II.16. Laboratory and work notebooks and other recording methods should be used.

II.17. Entries in laboratory notebooks should be traceable to the work performed and developed to an adequate level of detail and should be correct, complete and legible.

II.18. All laboratory notebooks, other records and data from the R&D activities should be retrievable and should be protected from loss or damage.

TRAINING AND QUALIFICATION

II.19. Training should be provided to a degree that is commensurate with the hazards associated with the work being performed and with its importance to safety. The principal investigator or researcher performing or assessing R&D activities for a nuclear installation should have a basic knowledge of nuclear safety.

PROCESS IMPLEMENTATION

II.20. Processes to be implemented during R&D activities will be dependent on the type and nature of the research activity. The following recommendations apply as appropriate.

PLANNING AND PREPARATION FOR R&D ACTIVITIES

II.21. The principal investigator or researcher should prepare an R&D plan that includes a written description of the proposed R&D activities. The plan should describe the content and extent of the R&D activities to be performed and the possible results, hypotheses and calculated predictions. The level of detail in the plan should only be as complex as the R&D project demands and should be such as to ensure that a qualified peer could replicate the work.

II.22. The R&D plan should incorporate the requirements and expectations of the user and should reference applicable technical standards. It should also describe or refer to the environmental, safety, health and regulatory requirements that apply, the way in which they will be met and the way in which funding and other resources will be made available for decommissioning at the end of the project. The plan should include details of the expected or intended effects of the results on safety.

II.23. The R&D plan should describe the purpose of the work. It should also specify criteria that can be used to assess the success or failure of the work and to indicate when it is completed. Hold points should be included at which management (and/or peers) can review and consider these criteria.

II.24. The R&D plan should provide a brief historical overview of the work. This should include references to publications that describe previous experiments, theories and feedback from the users of the products of previous R&D activities or technological developments that have led to the work described in the R&D plan.

II.25. The R&D plan should contain a description of the basic conditions and of the relevant components of the experimental equipment and 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 used should also be included.

II.26. The R&D plan should describe how support personnel and technical personnel who have the necessary education, experience and skills would be assigned to perform the work.

II.27. The principal investigator or researcher should ensure that the R&D plan is reviewed and approved by the organization. The R&D plan should

describe dependences 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 coordinated.

II.28. 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, personnel, graduate students, post-doctoral fellows, budgets and equipment.

II.29. The R&D plan should specify milestones for, and products and results of, 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.

II.30. The R&D plan should describe the requirements for the installation and the equipment for carrying out the work and should include:

(a) An explanation of how the installations will be used, the necessary location and gross floor area and a brief description of the probable impact on the installation's services;
(b) A statement of whether or not major modifications to existing installations will be necessary to perform the work;
(c) A statement of whether outdoor work is necessary and, if so, its location and expected environmental impact;
(d) A description of the means of collecting and processing samples and if published techniques are to be used, they should be referenced;
(e) Identification of equipment and materials already in place for performing the work and details of new equipment and materials that will need to be procured;
(f) Preparation of commissioning procedures for new equipment.

II.31. Sound scientific and engineering practices should be applied to the design and construction of the equipment and apparatus described in the R&D plan. The design and configuration of the equipment and apparatus should be documented. For requirements on design, see Ref. [5] or [13] or [14], depending on the type of installation concerned. For further recommendations on design, see Ref. [2].

II.32. Sound scientific and engineering 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 can be achieved.

CONDUCTING R&D ACTIVITIES

II.33. All work performed as a part of the R&D plan should follow sound scientific and engineering principles to ensure that its goals are achieved.

II.34. The principal investigator or researcher should ensure that all relevant documentation is available in a language that is appropriate to the users.

II.35. The items associated with the R&D plan should be properly stored and shelf life limitations should be observed.

II.36. In the commissioning of equipment, apparatus or prototypes, the requirements for calibration and performance for testing, measurement and diagnostic equipment and apparatus should be defined to a level of detail that will ensure that the goals of the R&D may be achieved. Requirements for calibration and performance for testing, measurement and diagnostic equipment and apparatus should be maintained throughout the activities for data gathering.

II.37. In the operation stage and the data gathering stage of R&D activities, the principal investigators or researchers should ensure that the systems and subsystems of the experimental equipment and apparatus are functioning as intended. This includes, for example:

(a) Visually or computationally monitoring the apparatus to ensure that systems are operating properly and are correctly calibrated, for example, by checking power supplies and devices that use gases and fluids;
(b) Ensuring that the proper materials and chemicals are being used;
(c) Monitoring performance against safety requirements;
(d) Monitoring the rates at which data are gathered to ensure that they are appropriate;
(e) Ensuring that the data that will enable the researcher(s) to achieve the research objectives are being recorded.

II.38. Individuals performing R&D activities and support work should evaluate their own performance and should look for ways to improve the quality of their work.

DATA ANALYSIS AND REPORTING

II.39. When analysing data for acceptability, researchers should define:

(a) The assumptions and the methods used;
(b) The results obtained and the manner in which the results have been used, so that competent experts can evaluate the way in which the data were interpreted;
(c) The methods used to identify and to minimize uncertainties in measurements;
(d) The analytical models used;
(e) Whether the results of the R&D activities have been documented adequately and can be validated.

II.40. The final reports should describe, for example:

(a) The results obtained and their range of application and validation;
(b) The relationship of the results to previous publications, experiments, theories or technological developments;
(c) A description of the apparatus and its operation and a description of data gathering activities;
(d) A description of any significant problems that occurred in operation or in data gathering activities;
(e) A description of issues relating to data analysis;
(f) A summary of the work performed, including conclusions, recommendations and a description of any possible consequences for safety objectives.

II.41. The management for the R&D activities should review and approve the final research report.

II.42. Deviations from the expectations recorded in the R&D plan should be recorded and analysed to determine whether they are true non-conformances or whether they are improvements that actually benefit the R&D project. For further recommendations on the control of non-conformances and corrective actions, see Ref. [2].

Appendix III

MANAGEMENT SYSTEM FOR SITE EVALUATION FOR A NUCLEAR INSTALLATION

III.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for site evaluation for a nuclear installation. For the site evaluation stage, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1].
(b) Takes into account the generic recommendations provided in Ref. [2].
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix.
(d) Meets the requirements established in Ref. [41] or [42] or [43], depending on the type of installation concerned.
(e) Takes into account the recommendations provided in Refs [44–49], as appropriate, when developing the processes and the organizational structure. These Safety Guides provide recommendations on the activities that should be described in the management system processes for the site evaluation stage.

III.2. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

(a) The intended end use of the knowledge and data that result from site evaluation activities, in particular, in terms of their consequences for safety;
(b) The capability to demonstrate, test or repeat results;
(c) The scale and technical complexity of the site evaluation activity, whether it is a new or proven concept or a model that is being applied or an extension of a new application;
(d) The managerial complexity of the activity and the involvement and coordination of multiple disciplines, work units or internal and external organizations, with divided or contingent objectives and responsibilities;
(e) The extent to which other site evaluation work, or later work, depends on the results of the site evaluation activities;
(f) The expectations for, or the desired use or application of, the results.

Appendix IV

MANAGEMENT SYSTEM FOR THE DESIGN OF A NUCLEAR INSTALLATION

IV.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for the design of a nuclear installation. For the design stage, the organization should develop and implement a management system that:

(a) Meets the requirements established Ref. [1].
(b) Takes into account the generic recommendations provided in Ref. [2].
(c) Takes into account the recommendations provided in the body text of this publication, in particular paras 5.84–5.140, and in this appendix.
(d) Meets the requirements established in Ref. [13] or [14] or [44], depending on the type of installation concerned.
(e) Takes into account the recommendations provided in Refs [15–27], as appropriate, in developing the processes and the organizational structure. These Safety Guides provide extensive recommendations on the activities that should be described in the management system processes for the design stage.

IV.2. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

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

Appendix V

MANAGEMENT SYSTEM FOR THE CONSTRUCTION OF A NUCLEAR INSTALLATION

V.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for the construction of a nuclear installation. For the construction stage, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1];
(b) Takes into account the generic recommendations provided in Ref. [2];
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix.

V.2. The organization should develop and implement a management system that describes the overall arrangements for the management, performance and assessment of the nuclear installation during construction.

V.3. The organization should formally appoint an individual to be responsible for construction activities.[16]

V.4. The individual appointed should have access to the necessary resources within the construction organization to discharge the following responsibilities:

(a) Ensuring that construction work and work at the installation is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of the relevant requirements;
(b) Ensuring that construction work and work that is undertaken at the installation, including work by contractors, is coordinated, carried out and completed in accordance with planned programmes;
(c) Controlling access to the construction site.

V.5. Interface arrangements should be agreed between the construction organization, suppliers and other organizational units performing the work.

[16] The individual formally appointed to be responsible for construction activities may be the head of the construction organization.

The interface arrangements should be specified in writing and should be included in procurement documents. Interfaces that should be considered include, for example, those of:

(a) The construction organization with suppliers.
(b) The construction organization with operating personnel or the operating organization.
(c) Suppliers with subsuppliers.
(d) The construction organization with the principal designer.
(e) The construction organization with the site evaluation organization.
(f) The construction organization with the owner of the installation (if the construction organization is not the owner or a part of the owner, or the licensee).
(g) The construction organization with the commissioning organization (usually interfaces are organized at the level of the organization rather than at the level of personnel, even though personnel perform the activities at the interface).
(h) The construction organization with the organization for operations. This type of interface arises where construction activities may interfere with the operations of installations on the same site. In particular, it is relevant for connections to, and the use of, common systems such as the emergency water supply and waste treatment.
(i) The construction organization with the regulatory body.

GRADING

V.6. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

(a) The qualification of special construction processes such as non-destructive testing and the qualification of the personnel that will carry them out;
(b) The necessary level of detail and the need for inspection and test plans;
(c) The level of traceability;
(d) The level of in-process controls and the need for hold or witness points;
(e) Purchasing.

PROCESS IMPLEMENTATION

V.7. The processes for the construction stage should be determined by reviewing the scope of construction activities derived from the specifications for the design of structures, systems and components, procurement documents and drawings, and construction work plans and schedules.

V.8. The examination of specifications, documents and drawings, and plans and schedules should identify what on-site fabrication, installation, and inspection and testing activities have been specified.

V.9. The construction organization should confirm the adequacy of construction methods with reference to the principal designer where necessary.

V.10. The principal activities of the personnel in the construction organization should include, as a minimum:

(a) Controlling and supervising suppliers both on-site and off-site;
(b) 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 with regard to the applicable industrial safety requirements;
(c) Preparing safety related working procedures, including industrial safety procedures, to issue to the personnel of both the construction organization and the contractors, and establishing that both the construction organization and the contractors' industrial safety arrangements on the construction site comply with the applicable requirements.
(d) Monitoring the industrial safety policies and activities of all personnel on the construction site to ensure compliance with statutory and regulatory requirements;
(e) Planning and monitoring the progression of work to fulfil the construction programme, including, where appropriate, coordinating the activities of suppliers responsible for constructing interfacing structures, systems and components;
(f) Ensuring that suppliers' work is carried out in accordance with procedures, specifications and drawings, that quality requirements are specified and implemented and that inspections and tests at the suppliers' facilities are appropriate and in accordance with inspection and test plans and associated surveillance schedules;

(g) Carrying out maintenance on equipment that could deteriorate during construction, such as dehumidification of electrical equipment and preservation of critical surfaces that could rust;
(h) Carrying out inaugural inspection of systems or components that will later be subject to in-service inspection;
(i) Carrying out adequate housekeeping activities to protect open equipment against foreign material intrusion and contamination;
(j) Arranging the controlled handover of completed works from one supplier to another or to the construction organization;
(k) Obtaining baseline data for comparative purposes in in-service inspection;
(l) Ensuring that relevant regulatory requirements are incorporated into work related documents.

HANDOVER AND TRANSFER OF RESPONSIBILITIES

V.11. Provisions should be made by the construction organization to control and coordinate the handover of completed works from one supplier to another and from the construction organization to the organization responsible for commissioning the nuclear installation in order to maintain the integrity of the completed works. These provisions should include the following three steps:

(1) An orderly transfer from the construction organization to the commissioning organization of responsibilities for systems, structures and components and their related records should be planned and implemented.
(2) Documentation relating to the items transferred should be reviewed by the construction organization for completeness and accuracy. Any non-conformances or incomplete items should be identified and the issues resolved and it should be ensured that the status of such items is clear and does not have the potential to affect safety during commissioning activities. Termination points identifying the boundaries of transferred systems and equipment, or transferred parts of systems and equipment, should be clearly identified in transfer documentation.
(3) When the construction and commissioning organizations are satisfied that the transfer can be accomplished, a joint check should be carried out by both organizations of the transferred items and the associated documents. Both parties should sign formally to indicate the transfer of responsibilities.

PLANNING OF CONSTRUCTION ACTIVITIES

V.12. Construction activities should be planned. Computer aided planning is desirable. The plan should specify:

(a) The activities to be performed, in manageable units;
(b) The planned sequential order and duration of these activities;
(c) The resources allocated for each activity.

V.13. Whereas the construction organization should retain the responsibility for coordinating and planning the overall construction of the nuclear installation, 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.

V.14. Account should be taken in planning for on-site fabrication, installation, inspection and testing of structures, systems and components important to safety, of needs for:

(a) The identification, preparation and control of procedures and work instructions;
(b) Special equipment or materials;
(c) Competent personnel;
(d) Inspection hold points or hold points for the regulatory body;
(e) Environmental considerations;
(f) The validation at the end of construction of records that will be transferred to the commissioning or operating organization to be maintained for the lifetime of the installation.

STARTUP MEETING

V.15. Following the award of subcontracts in the construction stage, 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 on, for example:

(a) Interface arrangements;
(b) Methods of communication;
(c) Documents and information to be submitted;
(d) Housekeeping;

(e) Site security;
(f) Site training;
(g) Industrial safety (especially in the use of non-destructive testing and in construction activities);
(h) The management system;
(i) Oversight and supervision of subsuppliers.

The meeting should also finalize the arrangements that the supplier will make to satisfy these requirements.

CONTROL OF DESIGN INFORMATION

V.16. Lines of communication and arrangements should be established for the issue of design information among the organizations involved in design. Prior to issue, the construction organization should ensure that the information being issued reflects the prevailing conditions at the site. Particular attention should be paid to the design information required at any off-site fabrication facility.

V.17. A process should be established to address queries from the supplier with regard to the design information issued. If the query may have an implication for safety in operation, it should be addressed to the principal designer for a response.

V.18. Changes to the design documentation made on-site during the construction activities that have an impact on the design information (e.g. on drawings, specifications or instructions) should be reviewed, designated for action, approved and validated by the owners' representatives with design responsibilities and/or the principal designer. Original design documentation should be updated for design corrections or clarifications. A complete set of 'as constructed' drawings that includes approved changes from the baseline design should be provided at the end of the construction phase. This set of drawings should be part of the handover package.

CLEANLINESS DURING CONSTRUCTION

V.19. A process should be developed and implemented to ensure that structures, systems and components are built in accordance with the specified requirements for cleanliness. This includes putting in place the controls

necessary to protect sensitive mechanical, electrical and control equipment from internal and external contamination by dirt, dust and other foreign material. Particular attention should be paid to excluding foreign material from piping systems by controlling the openings of such systems during installation.

V.20. Piping systems should be flushed to confirm that the systems meet the requirements for cleanliness before being put into service.

V.21. When procuring items for the installation, it should be ensured that the requirements for cleanness are included in the procurement documentation so that the items arrive on the site with an acceptable standard of cleanness.

V.22. To preserve items being constructed or installed, measures for performing housekeeping, cleaning and preservation should be established. These should include:

(a) Methods and techniques for control of the site area, individual structures and systems, the facilities, and the material and equipment being incorporated into the installation.
(b) Methods for the control of environmental conditions and individuals' 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 and maintenance.

CONTROL OF ITEMS

V.23. Items should be controlled from receipt to storage, handling and use, to prevent their abuse, misuse, damage, deterioration or loss of identification. Where possible, items that arrive at the construction site should be visually inspected before unloading to verify that there is no damage.

V.24. After items have been received, an inspection should be carried out to ensure that the relevant specifications are fulfilled such that:

(a) The item is configured correctly;
(b) Identification and marking are adequate;
(c) Manufacturing documentation is available as required;
(d) Protective covers and seals are intact;
(e) Coatings and preservatives have not been damaged;
(f) No physical damage has been sustained;

(g) Cleanliness is of the correct standard;
(h) Inert gas blankets and the condition of desiccants, where relevant, have not been compromised;
(i) Necessary tests of hardware characteristics have been performed.

STORAGE

V.25. 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.

V.26. Storage areas should be established and controlled, with account taken of aspects such as:

(a) Access;
(b) Cleanliness and housekeeping practices;
(c) Requirements for fire protection;
(d) Identification and marking of items;
(e) Protective requirements relating to coatings, preservatives, covers and sleeves;
(f) Prevention of physical damage;
(g) Removal from, and return to, storage;
(h) Environmental control (such as control of temperature and humidity);
(i) Preventive maintenance;
(j) Security;
(k) Items that have a limited shelf life or service life;
(l) Physical and chemical characteristics of items;
(m) Safety grades.

V.27. Inspections should be performed as necessary to ensure that the specified conditions are maintained and that any non-conformances are dealt with. These inspections may need to be continued in the commissioning and operation stages. Handover arrangements should be established.

HANDLING

V.28. All items should be properly handled, with account taken of aspects such as:

(a) Weight;
(b) Size;
(c) Susceptibility to damage by shock;
(d) Surface finish;
(e) Prescribed handling points;
(f) Orientation;
(g) The handling equipment and any tests required for it;
(h) Vulnerability to degradation by static discharge;
(i) Preservation of coatings;
(j) Maintenance of environmental conditions.

V.29. The use of items such as special cartons, containers, protective devices, hoists, manipulators and transport vehicles should be considered where handling operations are, by their 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 national regulations and standards.

V.30. Items that the construction organization has procured for issue to the contractor should be stored and maintained in such a manner as to ensure that there is no deterioration of the item and that it can fulfil its design function. Where appropriate, records for the item should be transferred from the contractor in the handover package.

VERIFICATION OF CONSTRUCTION WORK

V.31. The construction organization should establish methods and schedules for verification that specify the level of inspection and verification required.

V.32. Before offering an item or service for acceptance, the supplier should verify that all specified procurement requirements have been satisfied. Acceptance by the purchaser should not absolve the supplier from its responsibility to provide products fit for purpose, nor should it preclude the subsequent rejection of any product.

V.33. Construction activities carried out by contractors and suppliers should be performed on the basis of inspection and test plans, which should be submitted to the organization for approval. As appropriate, depending on the complexity of the work and the importance for the safety of the system, hold points and witness points should be established in the inspection and test plan

by the organization to assess the activities concerned and verify their acceptability. A plan should be prepared by the organization to ensure that all design requirements and regulatory requirements are met during construction activities.

V.34. The process should include arrangements to verify the completion of construction and installation activities. This verification should be formally documented by the use of a check sheet or a similar means that records the checks to be carried out to confirm that structures, systems and components have been constructed and installed to the specified requirements.

V.35. A typical check sheet includes:

(a) Identification of the structure, system or component;
(b) Description of the checks to be carried out and how the results will be verified;
(c) The date and time of the check;
(d) Any special tools or calibrated equipment used;
(e) A list of deficiencies and outstanding items or work;
(f) Confirmation that specified documentation and records are available and complete;
(g) Confirmation by all parties that the check has been carried out.

Appendix VI

MANAGEMENT SYSTEM FOR THE COMMISSIONING OF A NUCLEAR INSTALLATION

VI.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for the commissioning of a nuclear installation. For the commissioning stage, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1];
(b) Takes into account the generic recommendations provided in Ref. [2];
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix;
(d) Meets the requirements established in Ref. [13] or [41] or [42], depending on the type of installation concerned;
(e) Takes into account the recommendations provided in Refs [50, 51], as appropriate, in developing the processes and the organizational structure for the commissioning stage.

VI.2. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

(a) The level of detail of, and the need for, inspection plans and test plans;
(b) The level of traceability;
(c) The level of in-process controls and the need for hold points or witness points;
(d) Qualification of the commissioning processes and procedures and of the personnel who will carry them out;
(e) Details of all commissioning phases, with related tests and milestones specified;
(f) The compilation of the as-found test procedures with all related documentation to form the package for handover to the operations department;
(g) The requirements on handover of the commissioned systems to the operations personnel;
(h) The involvement of operations personnel in the commissioning stage;
(i) The final acceptance test of the organization.

Appendix VII

MANAGEMENT SYSTEM FOR THE OPERATION OF A NUCLEAR INSTALLATION

VII.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for the operation of a nuclear installation. For the operation stage, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1].
(b) Takes into account the generic recommendations provided in Ref. [2].
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix.
(d) Meets the requirements established in Ref. [13] or [41] or [42], depending on the type of installation concerned.
(e) Takes into account the recommendations provided in Refs [5, 8, 9, 11, 12, 29–31, 37, 39, 50–58], as appropriate, in developing the processes and the organizational structure for operation. These Safety Guides provide extensive recommendations on the activities that should be described in the management system processes for the operation stage. In particular, the recommendations in Ref. [31] should be considered.

VII.2. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

(a) The need for, and the level of detail in, operating instructions;
(b) The types of installed equipment requiring calibration;
(c) The levels for reporting of, and the authorities for, non-conformances and corrective actions;
(d) The need for formal shift operating logs;
(e) Testing, surveillance and inspection activities;
(f) Equipment to be included in plant status control;
(g) Controls applied to the storage of, and records for, spare parts;
(h) The need to analyse the history of items in the installation;
(i) The need to carry out condition monitoring;
(j) The need to carry out comprehensive and periodic self-assessments;
(k) The need for feedback from operating experience, both internal and external.

Appendix VIII

MANAGEMENT SYSTEM FOR THE DECOMMISSIONING OF A NUCLEAR INSTALLATION

VIII.1. The recommendations in this appendix are supplementary to, and should be read in conjunction with, the generic recommendations provided in Ref. [2]. The recommendations are specific to the management system for the decommissioning of a nuclear installation. For the decommissioning stage, the organization should develop and implement a management system that:

(a) Meets the requirements established in Ref. [1].
(b) Takes into account the generic recommendations provided in Ref. [2].
(c) Takes into account the recommendations provided in the body text of this publication and in this appendix.
(d) Meets the requirements established in Ref. [59].
(e) Takes into account the recommendations provided in Refs [60–62], as appropriate, in developing the processes and the organizational structure for the decommissioning stage. These Safety Guides provide extensive recommendations on the activities that should be described in the management system processes for the decommissioning stage.

VIII.2. When developing the structured approach to grading the application of the management system requirements (see Section 2), the following could be considered:

(a) The need for, and the level of detail of, decommissioning documents;
(b) The management of waste from decommissioning;
(c) The review and approval of decommissioning documents;
(d) The type and level of detail of training of the personnel carrying out decommissioning activities;
(e) The controls applied to the dismantling of the plant, the removal of equipment and demolition.

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Annex

EXAMPLE OF A METHODOLOGY FOR GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

A–1. This annex provides an example (Fig. A–1) from a Member State of a methodology for grading the application of management system requirements and some explanation of how this methodology can be used.

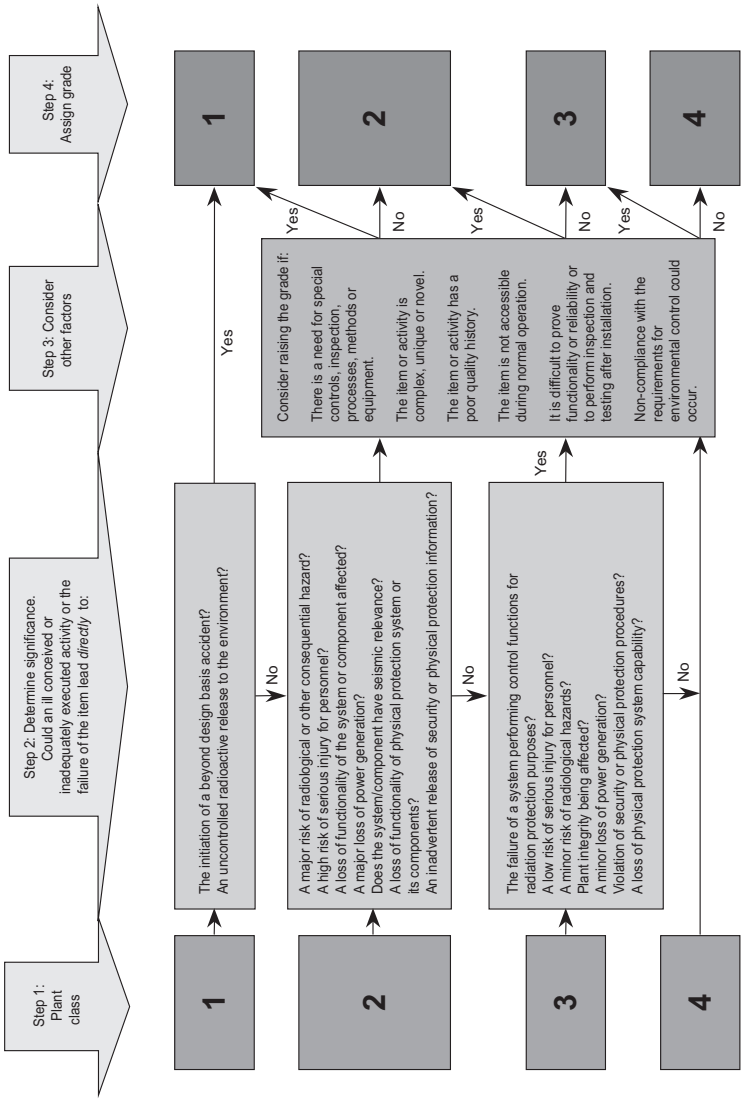

FIG. A–1. Method for grading the application of management system requirements in operation. Each organization should quantify and define the terms (major, minor, high, low, etc.) used in step 2 of its grading method on the basis of risks and hazards and the magnitude of the risks (potential impacts) associated with the safety, health, environmental, security, quality and economic aspects of each product or activity.

A–2. Using the methodology in Fig. A–1, a grade is assigned to the item, service or process. The grade assigned may be either alphabetic or numeric; the example in Fig. A–1 uses a numeric identifier with the number "1" used to identify an item, service or process assigned the highest safety significance. When taking into account the other factors shown in Fig. A–1 (step 3), it is possible to assign a grade lower than 1 to an item, service or process that is in a system classified as class 1, or to assign a higher grade to an item, service or process in a system with a classification that is lower than class 1. The plant classification is normally specified in the original design documents for the installation.

A–3. Grade 1 should be selected for items, services and processes of major safety significance and potential major commercial risk, while Grade 4 at the other end of the scale should be selected when the safety significance and the risk of environmental impacts and the commercial risk are only minor. The safety significance of the item, service or process should always be the most important factor in the assignment of a grade.

A–4. The next stage is to specify the degree of application of the management system requirements corresponding to each of the four grades. The criteria used in specifying the application of the requirements for activities should be developed so as to achieve varying degrees of control, verification, measurement and record keeping and to maintain confidence that items or services satisfy the relevant requirements. Examples of such controls include written instructions and checklists, quality plans and independent hold point inspections.

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA
ISBN 978–92–0–103409–0
ISSN 1020–525X