Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

**Eidgenössisches Nuklearsicherheitsinspektorat ENSI**
**Inspection fédérale de la sécurité nucléaire IFSN**
**Ispettorato federale della sicurezza nucleare IFSN**
**Swiss Federal Nuclear Safety Inspectorate ENSI**

# The Organisation of Nuclear Installations

## Guideline for Swiss Nuclear Installations

**ENSI-G07**

**July 2013 Edition**

# The Organisation of Nuclear Installations

July 2013 Edition

**Guideline for Swiss Nuclear Installations** **ENSI-G07/e**

# Contents

Guideline for Swiss Nuclear Installations ENSI-G07/e

# 1 Introduction

The Swiss Federal Nuclear Safety Inspectorate (ENSI) is the regulatory authority for nuclear safety and security of the nuclear installations in Switzerland. ENSI issues guidelines either in its capacity as regulatory authority or based on a mandate in an ordinance. Guidelines are support documents that formalise the implementation of legal requirements and facilitate uniformity of implementation practices. They further concretise the state-of-the-art in science and technology. ENSI may allow deviations from the guidelines in individual cases, provided that the suggested solution ensures at least an equivalent level of nuclear safety or security.

# 2 Subject and scope

This Guideline stipulates the requirements for the organisation of nuclear installations in the operational and post-operational phase.

It includes references to other ENSI Guidelines as follows:

The requirements for the training and qualification of personnel at nuclear installations are stipulated in Guidelines ENSI-B10 and ENSI-B13.

The requirements for the emergency response organisation at nuclear installations are covered by Guideline ENSI-B12.

Guideline ENSI-B11 stipulates the organisational provisions for conducting emergency exercises.

The requirements for periodic reporting and the obligation to give notice of organisational changes are set out in Guidelines ENSI-B02 and ENSI-B03.

In this document, the term “safety” is used as a synonym for “nuclear safety and security”.

# 3 Legal framework

This Guideline refers to the following basic requirements of the Nuclear Energy Ordinance dated 10 December 2004 (732.11):

a. Article 7, letter a, of the Nuclear Energy Ordinance

b. Article 10, paragraph 1, letter j, of the Nuclear Energy Ordinance

c. Article 30 of the Nuclear Energy Ordinance

d. Article 31 of the Nuclear Energy Ordinance

e. Article 32, paragraph 3, of the Nuclear Energy Ordinance

f. Article 36 of the Nuclear Energy Ordinance.

The Ordinance on the Qualifications of Personnel in Nuclear Installations dated 9 June 2006 (732.143.1) is also taken into consideration as a legal basis.

# 4 Basic requirements

## 4.1 Responsibility

The licence holder bears the responsibility for the safety of its nuclear installation as per Article 22 of the Nuclear Energy Act (732.1). This responsibility cannot be transferred to third parties.

The licence holder must designate the holder of the position for technical operation of the installation (as per Article 30, paragraph 4, of the Nuclear Energy Ordinance). The holder of this position is responsible for decisions regarding safety. The licence holder must make the necessary powers and resources available to the holder of the position for technical operation of the installation. Responsibility for decisions regarding safety cannot be transferred to third parties.

The licence holder and the holder of the position for the technical operation of the installation must clearly understand their relationship of dependency, and must ensure that this does not have any adverse impact on safety.

As a fundamental principle, safety has the utmost priority; precautions must be taken to prevent any impairment of safety. The licence holder and the holder of the position for technical operation of the installation must show how they accommodate the importance accorded to safety, and how they meet their responsibilities. The licence holder and the holder of the position for technical operation of the installation must lay down clear requirements for safety and must apply them as benchmarks for decision making and problem solving. As one of their corporate goals, they must define and communicate safety objectives and strategies in a manner that enables them to be understood, easily monitored and tracked by staff in the nuclear installation. They must endeavour to improve safety on a continuous basis and must also motivate the employees to do so, and involve them in this process. When taking account of the interests of third parties, it must be ensured that the safety of the nuclear installation is not impaired.

The holder of the position for the technical operation of the installation must:

a. establish and apply an effective management system (see section 4.2),

b. ensure that effective safety leadership is implemented at all hierarchical levels (see section 4.3), and

c. ensure and foster a good safety culture (see section 4.4).

Assessments of whether the measures regarding the assumption of responsibility for safety are appropriate and are implemented must be carried out on a regular basis; such assessments must be more frequent than those performed in connection with the Periodic Safety Reviews. Any improvement measures that may be required must be introduced.

## 4.2 Management system

All conditions and processes relating to the installation and its operation which are relevant to safety must be clearly and coherently stipulated in the management system, with an appropriate level of detail and with binding force. Methods to prevent errors and to enable learning from experience must be integrated into the system. In the management system the nuclear installation must be described as a socio-technical system consisting of three components: humans, technology and organisation. When considering this system, account must be taken not only of its individual components and their interactions, but also of external influences on the system (of an environmental, social, political and cultural nature).

The proviso governing the description of conditions and processes relating to the installation and its operation in the management system is that the safety of the nuclear installation must always be guaranteed. Consideration must also be given to the organisation's reaction to the occurrence of unforeseen or unforeseeable conditions or sequences of events.

In keeping with a graded approach, the outlay on safety relating to conditions, processes, activities and products must be adapted in line with their importance and complexity, the relevant hazard or risk potential, and the potential consequences of incorrect execution or failure. Clearly comprehensible methods must be used to determine the outlay on safety precautions.

In order to guarantee their quality, all activities must be described in compliance with the principle of the management cycle (planning, execution, control, improvement) and must be geared to processes, as per Article 31 of the Nuclear Energy Ordinance.

Line managers at all levels must apply the management system, must ensure that it is implemented by their own and third-party personnel, and must provide support for such personnel to achieve this purpose.

The management system must be adapted as necessary in case of changes in the nuclear installation (see section 7.8).

The effectiveness of the management system must be verified on a regular basis. In case of divergences, or if the system is not effective, remedial measures must be defined and implemented. These measures must be monitored and their effectiveness must be reviewed once they have been completed.

The management system must meet the requirements stated in IAEA Safety Standard GS-R-3 (see section 8).

The management system must be certified by an accredited body.

## 4.3 Effective leadership

In addition to meeting the requirements specified in the management system, line managers at all levels have a special function as role models in respect of safety. They must be aware of this role-model function and must utilise it to enhance the effectiveness of their leadership.

## 4.4 Safety culture

Measures for the purpose of observing, assessing and fostering a good safety culture must be incorporated in the management system.

It is necessary to promote a working atmosphere that encourages trust, cooperation and open communication, and one which attaches value to the communication of problems.

Consideration must be given to cultural aspects in connection with the organisation's own staff and third-party personnel, and efforts shall be made to encourage the positive development of the culture in the nuclear installation.

# 5 Resources

The licence holder must provide the holder of the position for technical operation of the installation with the necessary resources he requires in order to assume and carry out his responsibilities (see section 4.1).

Appropriate resources and the necessary own personnel must be transparently determined and made available in order to

a. establish and apply an effective management system, and to review it on a regular basis,

b. enable effective leadership in respect of safety at all hierarchical levels, and

c. promote a good safety culture.

If external staff are required for the aforementioned activities (staff acting on behalf of the organisation as per Article 13 of the Ordinance on the Qualifications of Personnel in Nuclear Installations), this requirement must be transparently determined and the staff must be made available.

## 5.1 Infrastructure, resources and working conditions

For the organisation's own staff and for external staff:

a. Infrastructure as appropriate to their activities must be made available.

b. Suitable facilities for communication and information must be provided.

c. The required financial and material resources must be made available.

d. Working conditions, working material and specified requirements commensurate with human characteristics and capabilities must be made available.

e. Information must be made available as required for an understanding of the remit and its performance, including aspects of relevance to safety.

It must be ensured that the statutory requirements and relevant regulations on safety at work and health protection are observed in respect of the assigned personnel.

## 5.2 Personnel

Tasks and activities of relevance to safety must only be carried out by qualified and suitable personnel.

When new staff are recruited or when staff take on new functions, attention must be paid to the requirements for qualifications and aptitude as stated in the Ordinance on the Qualifications of Personnel in Nuclear Installations. A suitable selection process must be applied in order to guarantee that posts are filled by qualified and suitable individuals.

The minimum levels for personnel subject to mandatory approval and for recognised radiation protection staff must be determined transparently, and an appropriate staffing level for safety-related activities must be planned for the long term. If staffing levels are reduced, proof must be furnished that the safety of the installation continues to be guaranteed.

The requirement for the organisation's own qualified and suitable staff to undertake special scientific and technical tasks must be determined transparently. Such staff must be made available, and it must be ensured that they retain their professional expertise. As the minimum, these technical and scientific tasks include:

a. Updating and reviewing the safety analysis report

b. Drafting and reviewing the plant design

c. Updating and reviewing the Technical Specification

d. Updating and reviewing the Ageing Management Programme (AMP)

e. Updating and reviewing the deterministic and probabilistic safety analyses

f. Processing operational and project experience, including events and incidents in particular

g. Considering the latest developments in work science and ergonomics when setting up and modifying workplaces, work materials and working processes.

It must be ensured that external staff are qualified and suitable for their assignments (as per Article 13 of the Ordinance on the Qualifications of Personnel in Nuclear Installations). External staff are obliged to comply with the safety standards of the nuclear installation.

## 5.3 Knowledge

The knowledge available to a nuclear installation must be regarded and treated as a resource. A knowledge management system must be set up and applied in order to ensure that

a. the necessary knowledge is actively applied in the event that it is required in the nuclear installation,

b. organisational learning and its promotion are supported in the nuclear installation.

In this regard, resources and methods must be made available and utilised, especially in order to

a. select, collect, organise, document, evaluate, update, safeguard and distribute knowledge,

b. build up and continue to develop learning skills.

# 6 Organisational structure

The licence holder and the holder of the position for technical operation of the installation must ensure that the organisational structure they select

a. fulfill the requirements of Article 30 to Article 41 of the Nuclear Energy Ordinance,

b. supports effective management,

c. favours the promotion of a good safety culture.

## 6.1 Job descriptions and deputisation arrangements

Job descriptions must be available for positions of relevance to safety. These descriptions shall define the functions, tasks and authorities of the postholders, as well as their responsibilities.

Deputisation arrangements must be guaranteed for positions of relevance to safety. It must be ensured that the deputy is always able to take over the tasks of the postholder.

The job descriptions for staff subject to mandatory approval must take account of the requirements stated in the Ordinance on the Qualifications of Personnel in Nuclear Installations, and of deputisation in the absence of the specialist radiation protection employee.

## 6.2 Officers

Appropriately qualified individuals must be appointed to carry out tasks of particular relevance to safety. They must have direct access to the holder of the position for technical operation of the installation.

## 6.3 Committees

### 6.3.1 Safety Committee

A Safety Committee must be set up to advise the holder of the position for technical operation of the installation on significant issues of relevance to safety.

As the senior and independent monitoring body, the Safety Committee must assess the safety aspects of safety-relevant documents and of changes to the installation, selected internal and external events, near-misses, test programmes and emergency exercises before and after they take place.

The Safety Committee must not be consulted as an authoritative quality assurance body.

In addition to the holder of the position for technical operation of the installation, the heads of important organisational units must be members of the Safety Committee. Moreover, an independent external specialist on safety must be co-opted in nuclear power plants. It must be possible for issues entered on the agenda of the Safety Committee to receive suitable expert treatment by co-opting additional specialists in the appropriate subjects. Meetings of the Safety Committee must take place at regular intervals, and minutes must be kept. Minority opinions must be recorded.

### 6.3.2 Committee to analyse events as per Article 30, paragraph 3, of the Nuclear Energy Ordinance

If there is any possibility that the causes of events and findings stem from human factors, integral analyses of such events and findings must be carried out by a committee (see section 7.7).

A specialist in work and organisational science must be a member of this committee.

This committee must, in turn, be appropriately represented on the Safety Committee.

# 7 Process-related requirements

## 7.1 Shift operation

Regulated shift operation must be guaranteed for working processes which take place continuously and which require alternating staff. The staffing levels and the form of shiftwork must be arranged so that the necessary processes for the safety of the installation and its operation are guaranteed at all times, and so that stipulated requirements for the presence of staff (as per the power plant regulations) can be met. Formal procedures must be applied for this purpose, and consideration must be given to the state of the art of work and organisational science relating to shiftwork.

The tasks of the shift groups for operational management in power plants are based on Articles 6, 7 and 10 of the Ordinance on the Qualifications of Personnel in Nuclear Installations.

Regulations must be in place to govern the operation of shifts and, in particular, shift handovers.

When work is handed over, it must be ensured that information required to understand current conditions and to continue procedures is passed on in an appropriate manner, and that all parties concerned are appropriately informed in case of divergences from planned work.

## 7.2 Stand-by service and specialist technical support

A technical support service provided by stand-by engineers (stand-by service) must be ensured in nuclear power plants so that the shift supervisor on duty can always call in qualified technical assistance if safety-relevant issues arise. During power operation, it must be possible for the duty stand-by engineer to reach the deployment location within 15 minutes of being summoned. During periods of Planned Maintenance Outage (PMO), the engineer must arrive on site within 60 minutes.

The tasks of the stand-by engineer are based on Article 8 of the Ordinance on the Qualifications of Personnel in Nuclear Installations.

Appropriate specialist and technical support must be guaranteed for the organisation’s own staff and for external staff who are integrated into the operating processes.

## 7.3 Decision making

In case of safety-relevant decisions (including, in particular, decisions in uncertain or unsafe situations or when unexpected problems arise), a suitable process must ensure that decision making is geared to safety aspects.

The licence holder and/or the holder of the position for technical operation of the installation must stipulate when, how and by whom decisions on processes are to be taken. Decisions must be transparently documented.

Prior to decisions on safety issues, the licence holder and/or the holder of the position for technical operation of the installation must ensure that appropriate investigations and consultations take place so that all the relevant safety aspects are taken into account. Safety-related decisions must be reviewed in the appropriate manner.

## 7.4 Documentation and records

Regulations must govern the creation, updating, review, approval and communication of documents. The requirements for documentation and records are stated in Article 41 of the Nuclear Energy Ordinance.

## 7.5 Quality management

The quality of the installation and its operation as necessary for safety purposes must be guaranteed. Quality requirements and measures to fulfill them must be stipulated in the management system.

Safety-relevant reviews must be carried out in the form of independent reviews (independent verifications). In particular, this requires that the reviews be carried out by qualified individuals who were not involved in the development of the matters under review, and it must be ensured that such reviews are not adversely affected by relationships of dependency between the participating individuals or by conflicts of interest.

Safety-relevant information compiled by external contractors must be reviewed internally before it is communicated to ENSI. The requirements for safety-relevant reviews must be taken into account for this purpose.

ENSI must not be regarded as an agency with a mandate to review quality.

## 7.6 Safety reviews

The licence holder must systematically review the safety of the nuclear installation. For this purpose, suitable methods must be applied which take account of the human, technological and organisational factors, and of the interactions between these factors.

Internal reviews must be conducted on a regular basis. Nuclear power plants must also undergo peer reviews by recognised external organisations.

The measures derived from the reviews, together with the decisions and reasons that have led to them, must be recorded and communicated within the nuclear installation.

The results of the reviews must be reconciled with the operational documentation (as per Annex 3, of the Nuclear Energy Ordinance).

## 7.7 Operating experience

It must be ensured that operating experience is recorded to the appropriate extent and is evaluated to determine potential for improving safety, and that adequate operating experience feedback takes place. Systematic methods must be applied for these purposes.

It must also be ensured that the organisation's own staff and external staff are obligated and motivated to pass on information that may be of significance for safety to units or reporting systems set up for this purpose. The conditions required to achieve these objectives must be guaranteed.

Likewise, it must be ensured that events are processed promptly, in accordance with Guideline ENSI-B03. When events are analysed, it must be guaranteed that the human, technological and organisational components of the system and their interactions are taken into account. Particular consideration must be given to concealed safety-relevant errors, precursor events and potential trends that could detract from safety. Knowledge derived from events must be collated and subjected to overall evaluation. Once potential for improvement has been identified, it must be exploited by means of appropriate measures, whose effectiveness must then be verified. Experience gained must be communicated within the nuclear installation.

Events involving participation by external contractors must be integrated into the analysis of events.

External operating experience and the state of the art of science and technology must be tracked and examined to identify their relevance for the organisation's own nuclear installation. Safety-relevant knowledge gained from the organisation's own operating experience must be made available in a suitable form to concerned external parties or specialist organisations in the nuclear energy sector, at both national and international level.

It must be guaranteed that potential conflicts of interest are taken into account when recording and analysing operational experience and feedback thereof.

## 7.8 Change management

It must be ensured that technical and organisational changes are justified, and that their impact on safety is adequately examined prior to their implementation. Consideration must be given here to the impact on human, technological and organisational factors, and on the interactions between these factors. An appropriate formal procedure must be applied, with the inclusion of plant knowledge, operating experience and the state of the art of science and technology.In case of permanent or longer-term temporary changes in the installation, the following aspects in particular must be ensured:

a. Consideration must be given to the impact of a change on regulations, operation, maintenance, training, the plant simulator, safety analyses and also on organisational structures and procedures.

b. The change process must take appropriate and detailed account of the sub-steps of planning, production, installation, testing and commissioning.

c. The state of the art of work science and ergonomics must be taken into account at the interface between humans and technology.

d. In case of changes which influence operation, maintenance or other safety-relevant activities, simulation must be deployed to validate and verify that human characteristics and capabilities are taken into account.

In connection with all changes, appropriate safety assessments must be undertaken to furnish proof of compliance with safety-related requirements and specifications.

In case of organisational changes-, it must (in particular) be ensured that the following employee-related aspects are taken into account:

a. Appropriateness of the scope and speed of the change

b. Motivation of the affected employees to accept and support the change

c. Support for the affected employees so that they become accustomed to the new situation.

It must be ensured that the implementation of a change is monitored in such a way as to allow an intervention at any time if the change process diverges from the expected course, or if new knowledge about a given measure becomes available.

It must be ensured that temporary changes are identified as such, that their duration is limited, that they are monitored and the necessity for them is verified at regular intervals, and that their number is kept as low as possible. Likewise, it must be ensured that affected members of the organisation's own staff and external staff are made aware of the existence of temporary modifications and of their impact on the nuclear installation.

Suitable configuration management must be introduced when changes take place. A systematically structured documentation concept must be defined and implemented for this purpose. It must also be guaranteed that the planning and implementation documents and the documentation instructions are always coordinated with each other.

Modified plant components may only be commissioned after the relevant training measures and the necessary adaptations to the documentation have been completed to the appropriate extent.

## 7.9 Procurement and intelligent customer capability

a. When procuring products or services from external sources, it must be ensured that adequate intelligent customer capability is available on the part of the organisation's own staff. This calls for adequate knowledge and suitable methods as regards:specification of the requirements, taking account of

    1. requirements stipulated by law and by the authorities,

    2. standards, norms, codes or other regulations,

    3. the state of art of science and technology,

b. specification of products and services, taking account of interfaces and interactions with the installation and its operation,

c. external communication of requirements (tendering) and the selection of products or services offered and their providers,

d. external placement of safety-relevant tasks and agreements, especially as regards responsibilities, tasks, performance of tasks and controls,

e. the procedure in case of events,

f. proof that delivered products and services fulfil the specified requirements before they are used in the nuclear installation,

g. monitoring of the implementation of products and the provision of services.

The safety standards for the nuclear installation must be appropriately communicated to external contractors. It must be ensured that the influence of external contractors or mutual dependencies do not result in any deterioration of safety. It must always be possible to influence working procedures that involve external participation. In this context, ENSI must not be regarded as a body with a mandate to monitor procurement.

## 7.10 Information to authorities

There is a particular requirement to inform the authorities in case of safety concerns in respect of a measure required by ENSI.

# 8 List of references

IAEA Safety Standard GS-R-3: The Management System for Facilities and Activities, 2006

This Guideline was approved by ENSI on 24 June 2013.

The Director General of ENSI: signed: H. Wanner

ENSI, Industriestrasse 19, 5200 Brugg, Switzerland, Phone +41 56 460 84 00, E-Mail info@ensi.ch, www.ensi.ch