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**Swiss Federal Nuclear Safety Inspectorate ENSI**



# Integrated Oversight

ENSI Report on Oversight Practice

May 2021 edition



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## **Preliminary note**

Oversight of nuclear safety at Switzerland's nuclear facilities has developed gradually. The oversight strategy that had evolved historically was thoroughly systematised in the period around the turn of the millennium, entailing the introduction of a management system and the development of an "Integrated Oversight" strategy.

The objective of this publication is to present the fundamental assumptions upon which this strategy has been developed, not only for interested members of the public and supervised parties outside of ENSI, but also for the Inspectorate's own staff.

# 1 Nuclear safety

## 1.1 Fundamentals

The objective of nuclear safety is to protect people and the environment against the harmful effects of ionising radiation<sup>1</sup>.

In order to ensure the safe operation of a nuclear facility, its licensee must implement comprehensive safety-related prevention measures. For this purpose, the influences of **Man**, **Technology** and **Organisation** must be taken into account on the basis of an integrated approach that views the nuclear facility as an **MTO** system. The safety of a nuclear facility does not depend solely on its technical design and execution, but also on the behaviour of the people who operate the facility. Moreover, the employees of a nuclear facility are integrated into an organisation whose culture has a critical influence on the employees' work and, therefore, also on the safety of the nuclear facility.

Given that the safety of a nuclear facility is dependent on Man, Technology and Organisation, all three of these areas must be taken into account for a comprehensive assessment of safety. Safety-related prevention measures and the safety they create – understood as the level of compliance with fundamental safety functions – are not parameters that can be fully measured because only certain elements of the condition of the facility, the behaviour of the staff and the organisation's culture can be observed. Furthermore, it is not possible to make direct observations about the factors in people's minds that determine their behaviour. This means that every safety evaluation is based on an incomplete picture and must be completed by subjective assessments of the reliability of the people and the safety culture of the licensee's organisation. This applies to the way the supervisory authority views the situation from outside just as much as to the licensee's view from the inside. The more elements of the picture that are accessible from different perspectives, the more realistic the overall picture that is assembled from them.

Likewise, a more realistic overall picture will make it easier to identify gaps in defence in depth, thereby improving the completeness of measures. Nevertheless, there is no such thing as absolute safety. This is true of every technical installation and every area of life, such as road traffic.

The "nuclear facility" MTO system is constantly changing, so the picture of a facility's defence in depth has to be constantly updated. Defence in depth is an ongoing task. It also includes learning through knowledge gained from other nuclear facilities and high-reliability organisations such as airlines and hospitals.

It is primarily the licensee's duty to ensure the safety of its facility<sup>2</sup>. This duty includes continuously reviewing the safety of the facility and making improvements where necessary. For this reason, the licensee must assess the safety of its facility on a systematic basis<sup>3</sup> – and in

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<sup>1</sup> "Fundamental safety objective" as per IAEA Safety Fundamentals SF-1 and Article 1, Nuclear Energy Act

<sup>2</sup> cf. Article 9 of the Convention on Nuclear Safety and Article 22, paragraph 1, Nuclear Energy Act

<sup>3</sup> Article 33, Nuclear Energy Ordinance

the case of nuclear power plants, must carry out a comprehensive Periodic Safety Review (PSR) of the facility every 10 years<sup>4</sup>. It is the supervisory authority's duty to ensure that all licensees comply with these duties<sup>5</sup> and to obtain an independent picture of the facility's safety through its own analyses, inspections and supervisory discussions. ENSI does this on the basis of Integrated Oversight.

Nuclear safety is also based on precautions to protect against unauthorised impacts and the unauthorised removal of nuclear materials. The term "security" is used to denote these precautions. They are also based on constructional, technical and organisational measures and those relating to personnel and administration.

## 1.2 The concept of fundamental safety functions

In order to take a more proactive approach towards protecting people and the environment against ionising radiation emanating from nuclear facilities and nuclear materials, these three fundamental safety functions must be met<sup>6</sup>:

S1: Controlling reactivity

S2: Cooling the fuel

S3: Confining radioactive materials

Fulfillment of these three fundamental safety functions ultimately serves the purpose of achieving the following overriding fundamental safety function<sup>7</sup>:

S4: Limiting exposure to radiation

Each fundamental safety function is based on several safety functions and sub-functions. There is no standard international definition stating how the four fundamental safety functions should be broken down into safety functions and sub-functions; to some extent, the breakdown is specific to each facility. An example of the logic for breaking the fundamental safety functions down into safety functions and sub-functions is shown in Table 1.

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<sup>4</sup> Article 34, Nuclear Energy Ordinance

<sup>5</sup> Article 72, paragraph 1, Nuclear Energy Act

<sup>6</sup> IAEA Safety Standard SSR-2/1

<sup>7</sup> The DETEC Ordinance on Hazard Assumptions and the Evaluation of Protection against Incidents in Nuclear Plants designates: 1. Controlling reactivity; 2. Cooling nuclear materials and radioactive waste; 3. Confining radioactive materials; and 4. Limitation of radiation exposure as the fundamental safety functions. In Germany, the Nuclear Safety Standards Commission (KTA) differentiated these fundamental safety functions in its KTA 2000 programme: "Controlling reactivity", "Cooling the fuel", "Confinement of radioactive substances" and "Limiting exposure to radiation". The basic regulations drafted in this connection were incorporated into the development of the structure of systematic safety evaluation by the former HSK (now ENSI).

| <b>Fundamental safety function S1: “Controlling reactivity”</b>     |   |
|---|---|
| Safety function   | Safety sub-function   |
| Control of changes in reactivity and power in the core              | Inherent self-stabilisation   |
|   | Limitation of reactivity, power and power density                         |
| Sustainable termination of the chain reaction in the core           | Reactor shutdown  |
|   | Long-term maintenance of sub-critical condition                           |
| Control of the reactivity of fuel elements outside the reactor core | Ensuring sub-critical condition for handling and storage of fuel elements |

**Table 1: Example of a possible breakdown of the “Controlling reactivity” fundamental safety function S1 into safety functions and sub-functions**

**Safety functions** and sub-functions are functions required in order to fulfil fundamental safety functions. This applies regardless of the level of defence (cf. Table 3) to which the relevant equipment or resources belong.

Safety functions may be implemented by means of structural design features, inherent characteristics or passive and active measures, and they can be implemented for all conditions of the facility, i.e. during normal operation, in case of disturbances, design-basis accidents and accidents beyond the design basis.

Appropriate measurement, limitation, alarm and triggering systems are needed in order to monitor, control and activate safety functions. ENSI does not treat the monitoring, control and activation of safety functions as separate safety functions.

The individual safety functions are not independent of one another. For example, barrier integrity depends on heat removal and the pressure limitation of components and systems.

The barrier concept for nuclear power plant reactors differentiates various barriers: fuel elements, primary circuit and containment (Table 2). The barriers serve to fulfil the fundamental safety function S3 of “Confining radioactive materials”. The barrier concept is thus not a safety concept that is independent of the fundamental safety functions, but rather a component of the defence-in-depth concept illustrated below.

| <b>Barriers when the reactor is closed</b> |  |
|--|--|
| 1st barrier                                | Fuel elements (fuel matrix and fuel rod cladding tubes)    |
| 2nd barrier                                | Primary circuit (reactor cooling system pressure boundary) |
| 3rd barrier                                | Primary containment  |

**Table 2: Barriers for nuclear power plant reactors**

Table 2 shows the barrier situation in respect of reactor safety when the reactor is closed. With the reactor open during a refuelling and maintenance outage, with fuel elements in a fuel pond, fuel elements in a transportation or storage container and radioactive waste, the barrier situation is different. But also in this case, defence in depth is based on multiple barriers.

The barrier concept can be communicated clearly and comprehensibly. However, it only represents one part of defence in depth because the integrity of the barriers can be guaranteed only if the fundamental safety functions of “Controlling reactivity” (S1) and “Cooling the fuel” (S2) are met. Accordingly, the barrier concept is not a complete safety concept.

### 1.3 The defence-in-depth concept

As shown in the presentation of the fundamental safety function concept, the safety functions are implemented in all conditions of the plant by means of structural design features, inherent characteristics of plant components as well as organisational and staffing measures. Since the International Nuclear Safety Advisory Group of the IAEA<sup>8</sup> drew up the defence-in-depth concept, it has become internationally established practice to allocate defence in depth to five levels. Each level comprises safety precautions with specific objectives geared to specific plant conditions.

The defence-in-depth concept therefore consists of several staggered levels of precautions, each one of which serves to intercept a failure of the precautions at the prior level. Levels 1 to 4 constitute **internal** defence in depth **within the facility** and level 5 represents to a substantial extent **external** defence in depth **outside the facility**.

Dividing level 4 of defence in depth into level 4a (design extension conditions without severe core damage) and level 4b (design extension conditions with severe core damage) is consistent with international recommendations.<sup>9</sup>

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<sup>8</sup> cf. Defence in Depth in Nuclear Safety, INSAG-10, as well as IAEA Safety Standard NS-R-1

<sup>9</sup> IAEA Safety Standard SSR 2/1 (Rev. 1), Safety of Nuclear Power Plants – Design, IAEA 2016 as well as WENRA Safety Reference Levels for Existing Reactors, 24 September 2014

| <b>Level of defence</b> | <b>Case of demand</b><br>Safety objective functions                                 | <b>Objective</b>  | <b>Systems, equipment and measures</b>   |
|-------------------------|---|---|--|
| <b>1</b>                | <b>Normal operation</b><br>SE1-functions  | Preventing deviations from normal operation                 | Operating systems including the necessary supply and control systems <sup>10</sup> |
| <b>2</b>                | <b>Deviations from normal operation</b><br>SE2-functions                            | Controlling deviations from normal operation                | Limiting systems including the necessary supply and control systems <sup>11</sup>  |
| <b>3</b>                | <b>Design-basis accidents</b><br>SE3-functions <sup>12</sup>                        | Controlling design basis accidents and avoiding core damage | Safety and emergency systems including the necessary supply and control systems    |
| <b>4a</b>               | <b>Design extension conditions without severe core damage</b><br>SE4a-functions     | Controlling specific design extension conditions            | Emergency systems and equipment <sup>13</sup> (preventative emergency measures)    |
| <b>4b</b>               | <b>Design extension conditions with severe core damage</b><br>SE4b-functions        | Limiting releases of radioactive material                   | Emergency equipment <sup>13</sup> (mitigating emergency measures)                  |
| <b>5</b>                | <b>Severe accidents with major release of radioactive material</b><br>SE5-functions | Mitigating the effects of radioactive releases              | Emergency protection outside the plant   |

**Table 3: Levels of defence-in-depth**

The systems listed above (operating systems, limitation and protection systems, safety systems) require a series of **supporting functions**. One of the most important supporting functions is the power supply. Other supporting functions include control air, lubricating oil, and the cooling and seal water supplies. Some supporting functions only serve individual fundamental safety functions while others are important for all the fundamental safety functions.

In addition, there is a series of other items of equipment that are also important for the fundamental safety functions: examples include leak monitoring, ventilation systems, lifting gear, seismic instrumentation, fire and lightning protection installations and communications equipment.

In accordance with their importance for nuclear safety, not only the safety functions as such but also the supporting functions must be reliably available.

<sup>10</sup> Keeping normal operational control parameters in the setpoint range with control systems is assigned to level 1.

<sup>11</sup> Returning normal operational control parameters to the setpoint range with control systems in case of minor disturbances is assigned to level 2.

<sup>12</sup> In the NEO, L3-DiD-functions are referred to as safety functions.

<sup>13</sup> Operating, safety and emergency systems can also be used at level 4a of defence in depth if they are available for the specified accident sequence.

For levels 1 to 4 of the defence-in-depth concept – precautions within the facility – the principle is that each level of defence comprises precautions for each fundamental safety function.

On level 4a of defence in depth, cooling of the fuel must be secured (fundamental safety function S2). The fundamental safety objective S1 “controlling reactivity” has also to be secured in the medium term in order to secure the fundamental safety function S2 “cooling the fuel”. If the fundamental safety functions S1 and S2 are fulfilled, also the fundamental safety function S3 “confining radioactive materials” will be fulfilled, because in this case no large release of radioactive materials will be possible.

On level 4b the fundamental safety objective S2 “cooling the fuel” is violated in any case. Emergency measures are supposed to mitigate the consequences of a severe accident. In particular, their goal is to reestablish the fundamental safety function S3 “confining radioactive materials” as far as possible.

Level 5 is the only level that exclusively serves the fundamental safety function S4 of “Limiting exposure to radiation”. For severe emergencies, it consists of measures outside the facility to minimise the radiation dose of the population and inside the facility to minimise the dose of the personnel.

## 2 Fundamentals of Integrated Oversight

As explained in section 1, the defence-in-depth concept provides the basis for meeting the fundamental safety functions and hence for ensuring nuclear safety. It is the licensee's duty to show how the defence-in-depth concept is implemented in its facility at the detailed level.

ENSI's duty is to verify whether the implemented measures conform to the latest developments in science and technology and the status of backfitting technology. For this purpose, ENSI must – independently of the licensee – obtain a picture of the facility's safety.

The effectiveness goals of official oversight are:

- **Nuclear facilities should be safe**, i.e. the facilities are technically compliant with the statutory requirements and, in particular, they correspond to the latest status of backfitting technology. Facilities are operated safely in every plant condition (e.g. normal operation, decommissioning, dismantling) by an organisation with a good safety culture.
- **The general public should feel safe**, i.e. public concerns are taken seriously by ENSI and ENSI actively informs the public about the condition of nuclear facilities and special events.

These two key effectiveness goals apply to all of ENSI's supervisory activities. They can be broken down into two main task areas or "products":

- **Assessment of facilities:** ENSI assesses construction, modification and decommissioning projects that are submitted as part of the licensing or plant modification procedure, and monitors compliance with statutory regulations and requirements imposed by the licensing authority during implementation. ENSI also assesses the Periodic Safety Reviews to be carried out by the licensees every ten years, which comprise numerous safety and accident analyses. As the basis for its assessment work, ENSI draws up guidelines that implement the underlying legal framework, and it also tracks international experience and the latest developments in science and technology as well as backfitting technology.
- **Surveillance of operations:** The operation of existing nuclear facilities is overseen and supervised by ENSI. On the basis of analyses of the licensees' reports and through inspections and checks, ENSI verifies whether a licensee is fulfilling its statutory responsibilities. ENSI orders all necessary and reasonable measures in order to maintain nuclear safety and security. It monitors releases of radioactivity into the environment and the radiation exposure of staff during operation, provides follow-through for the annual refuelling and maintenance outages, evaluates events and informs the public about the condition of nuclear facilities. In case of an accident, ENSI produces forecasts, ensures that the National Emergency Operations Centre is promptly briefed and advises the individuals and organisations involved about ordering protection measures.

For each of these products, ENSI has defined a series of oversight processes that are described in its management system. Consistent day-by-day implementation of these process-

es is the basis for official oversight. From each of these processes, ENSI obtains information on nuclear safety at every nuclear facility under its oversight. The overall body of information obtained from all these oversight processes affords insights into the nuclear safety of a facility. As already mentioned in section 1, any statement about safety becomes all the more realistic if this information provides a complete description of all the safety-related elements of the MTO system. In order to achieve maximum benefit for nuclear safety with its resources, ENSI must deploy these resources on a graded basis in accordance with the relevance to safety of the subjects of its oversight. This is known as the “graded approach”. Subjects with the greatest relevance to safety must be supervised in the most complete manner and with the greatest depth of processing, whereas oversight in other areas should be limited to random sampling. The notification and reporting obligations of the licensees are important supervisory instruments for areas overseen by random sampling. ENSI reviews the licensees’ notifications and reports, and carries out its own investigations if any aspects are unclear or in case of references to safety deficits. Safety-relevant modifications require a mandatory official permit. Here too, the intensity of verification is graded according to the safety relevance of the modification in question.

ENSI’s **Integrated Oversight** takes account of all safety-relevant elements of the nuclear facility MTO system. This enables the Inspectorate to arrive at a comprehensive assessment of a nuclear facility’s safety and to influence it through supervisory measures.

To summarise, Integrated Oversight meets three key requirements:

- **Transparency:** ENSI has a consistent, end-to-end oversight concept and regulatory framework. It follows a uniform decision-making procedure based on clear criteria. The measures which it orders are transparent and easily understood.
- **Balance:** ENSI takes comprehensive account of a facility’s safety aspects. As well as the results of deterministic and probabilistic safety analyses, this also includes knowledge gained from operation and maintenance as well as organisational procedures. The weighting of the resources deployed is graded according to the relevance to safety of the subjects of oversight. Safety requirements and the type and intensity of monitoring are regularly examined, analysed and adapted as necessary.
- **Effectiveness:** ENSI implements decisions consistently and reviews their impact. Additional measures are initiated as required.

Responsibility for nuclear safety lies with the licensee of a nuclear facility (Article 22, paragraph 1, Nuclear Energy Act). ENSI verifies whether the licensee is fulfilling this responsibility (Article 72, paragraph 1, Nuclear Energy Act). It orders all necessary and reasonable measures in order to maintain nuclear safety (Article 72, paragraph 2, Nuclear Energy Act). In accordance with the effectiveness goals mentioned above, ENSI’s oversight activities aim to ensure that nuclear facilities are safe. Oversight activities are undertaken on the basis of processes specified in the management system. In accordance with the “Plan-Do-Check-Act” principle, ENSI’s management system includes a continuous improvement process. Given that ENSI consistently gears its oversight activities to the defined effectiveness goals, the continuous improvement of its oversight processes also results in improvements to the safety of the nuclear facilities under supervision.

The following sections provide somewhat more detailed descriptions of the individual products and supervisory processes that constitute Integrated Oversight. Information from the individual supervisory instruments is collated as part of the systematic safety evaluation process, which is one of the core instruments of Integrated Oversight.

### 3 Assessment of facilities and Integrated Oversight

#### 3.1 Regulatory framework

The regulatory framework comprises the applicable laws and ordinances as well as the ENSI guidelines. This framework provides the prerequisites for ENSI’s oversight activities and gives the licensees of nuclear facilities the legal certainty that they require.

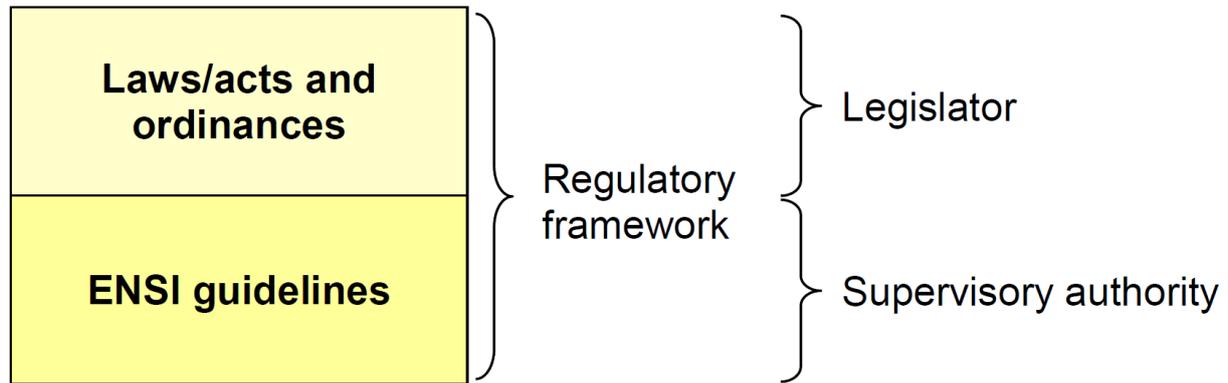


Figure 1: ENSI’s regulatory framework

In individual cases, a decision may be based on other fundamental elements in addition to the regulatory framework. Justification is required in such cases.

The basic principles of nuclear safety as outlined in section 1 must be considered when drawing up the regulatory framework. The regulatory framework must therefore be up to date and comprehensive, and it must promote safety. “Up to date” means that worldwide operating experience must be promptly incorporated into the regulatory framework. “Comprehensive” means that the regulatory framework must cover all relevant influences on nuclear safety and all elements of defence in depth. “Promote safety” means that the regulatory framework should exert a favourable influence on plant technology, the licensee’s organisation and the people involved. In particular, the regulatory framework should be designed so that it accommodates the licensee’s own responsibility for the safe operation of its facility by helping the licensee to develop an organisational culture that is geared to safety.

Federal agencies and organisations take the lead when it comes to drafting laws and ordinances. For laws and ordinances relating specifically to nuclear energy, the organisation in question is usually the Swiss Federal Office of Energy. As a general rule, the Federal Office of Justice is already represented in the working group that drafts the law or ordinance. ENSI must ensure that its own expertise and concerns are integrated into the development of new statutory bases. ENSI should be represented in the relevant working group for this reason. The ENSI representatives in the working group must be professional and experienced, and must have the required decision-making powers so that the first drafts of law and ordinances will already correctly reflect the technical aspects. It is sensible to form an internal working group within ENSI to prepare ENSI’s concerns, and to carefully review the individual sections of laws and ordinances focusing on their conformance to the principles of preventive nuclear safety.

As regards laws, attention should be paid to ensure that – primarily – only procedural requirements and basic non-quantitative safety criteria are stipulated. Laws have to be approved by parliament and they are subject to the option of a referendum in all cases. This means that amendments to laws are complex and time consuming. For the same reasons, it should be ensured that only what is absolutely necessary is stipulated in laws so that the regulatory framework can be adapted quickly enough to new knowledge gained from international operating experience and the latest developments in science and technology or in backfitting technology. Quantitative fundamental safety functions or precise specifications for calculations should therefore be avoided in laws.

Ordinances are more specific than laws and they may also include statements about technical requirements, analytical methods and quantitative criteria. But in ordinances as well, only what is necessary should be stipulated. Amendments to ordinances are easier to implement than changes to laws, but they are nevertheless time consuming. This is especially true of Federal Council ordinances. Amendments to Departmental ordinances are somewhat simpler.

ENSI issues **guidelines** on nuclear safety and security. These too should only stipulate what is necessary so that the responsibility for the safety of a nuclear facility actually remains with the licensee.

Guidelines are aids to implementation that state the legal requirements in specific terms and make it easier to standardise implementation practice. They also specify the latest status of science and technology or of backfitting technology. In individual cases, ENSI may allow deviations if the solution proposed by the licensee is at least equivalent in terms of nuclear safety and security to the solution based on the requirements stipulated in the guidelines.

As a consequence of the Nuclear Energy Act and the Nuclear Energy Ordinance which came into force in 2005, ENSI made a start on the complete revision and restructuring of its guidelines. This entailed the introduction of three series of guidelines, broken down according to the oversight-based ENSI products of **assessment of facilities** and **surveillance of operations**:

- Series **A**: guidelines concerning the **assessment of facilities**
- Series **B**: guidelines concerning the **surveillance of operations**
- Series **G**: guidelines with general requirements (with references to the assessment of facilities as well as the surveillance of operations)

The level of detail in guidelines can vary, and they may be process or goal oriented to different degrees. The more detailed and process oriented the requirements are, the more the supervisory authority will take on responsibilities that – according to Article 22, paragraph 1 of the Nuclear Energy Act – should primarily rest with the licensee.

The level of detail and process orientation of the requirements contained in a guideline is governed by the nature of the regulatory content. Depending on the levels of detail and process orientation, the supervisory authority will not only stipulate the safety objectives that the licensee should attain but also how it should set about attaining them. Detailed process requirements are indicated for calculation processes whose results should be comparable

across multiple facilities. Examples include guideline ENSI-G14, which defines the methodology and boundary conditions for calculating doses in the area surrounding a nuclear facility, and guideline ENSI-A05 with requirements for the quality and scope of probabilistic safety analyses. In the case of such detailed requirements, the supervisory authority shoulders a substantial share of the responsibility for the relevant safety aspect (for the calculated dose in the case of guideline ENSI-G14 and for the calculated risk in the case of guideline ENSI-A05).

Currently valid guidelines can be called up from the ENSI website at any time.

## **3.2 Expert opinion reports and safety-related statements**

ENSI's core tasks include drawing up expert opinion reports and safety-related statements. Expert opinion reports must be drawn up by ENSI in connection with the licensing procedure, for decommissioning plans, waste management plans and decommissioning projects, and also in connection with the "Deep Geological Repository" sectoral planning procedure. Periodic Safety Reviews (PSRs) must be produced and submitted to ENSI by the licensee of a nuclear power plant every ten years. ENSI draws up a safety-related statement on each PSR.

The scope of expert opinion reports is determined according to the applicant's request. Depending on the application in question, expert opinion reports may be comprehensive or may relate only to sub-aspects of safety.

Safety-related statements on PSRs contain a comprehensive safety assessment of a nuclear power plant that takes account of the latest developments in science and technology and/or backfitting technology.

### **3.2.1 Requirements for a PSR**

The PSR complements ENSI's ongoing oversight activities. The PSR, which must be compiled by the licensee every ten years, comprises an assessment of the power plant's specific operating experience during the last ten years and a comparison with relevant operating experience gained by other nuclear power plants. In addition, the condition of the nuclear power plant must be compared with the latest status of science and technology and with backfitting technology. The comprehensive verification of the organisation, its management system, the aging processes of components relevant to safety as well as the results of deterministic and probabilistic safety analyses on the basis of the latest hazard assumptions lead to important insights about the safety of the nuclear power plant and allow a forecast about the future safety status. For plant operation beyond 40 years, this forecast has to be completed by analyses of long-term operation. It has to be updated at least every 10 years as part of periodic safety review.

### **3.2.2 Statements by ENSI**

ENSI draws up a safety-related statement or an expert opinion report on every PSR and on applications relating to licenses. In these statements and reports, ENSI carries out an independent review and assessment of the documents submitted by the licensee of a nuclear

facility. The assessment is based on the valid regulatory framework, experience and the latest developments in science and technology or backfitting technology. ENSI verifies whether backfitting measures or other improvements are necessary or are called for on the basis of proportionality.

### 3.3 Permits

Permits are part of ENSI's core business. This activity is based, on the one hand, on Article 26 of the Nuclear Energy Ordinance in respect of structures and plant components that require permits and are specified in a construction license and, on the other hand, on Article 40 of the Nuclear Energy Ordinance, which lists changes that do not differ substantially from a license but which require permits. In particular, these include:

- Changes to structures, plant components, systems and equipment classified as relevant to safety or security.
- Changes to the reactor core.
- Changes to the content of the technical specifications, the emergency preparedness regulations, the radiation protection regulations, the power plant and operating regulations and to regulations and directives concerning security.

There is a series of special permits relating to transport and waste management:

- Approval for types of waste container
- Test of the suitability of transport and storage containers for interim storage
- Permits for the interim storage of transport and storage containers
- Permits for applications relating to the laws on dangerous goods (European Agreement concerning the International Carriage of Dangerous Goods by Road, Swiss Ordinance on the Carriage of Dangerous Goods by Road)
- Applications for transportation licenses pursuant to the Radiological Protection Act

ENSI also draws up safety-related statements for the Swiss Federal Office of Energy on specific transport applications in cases where the Swiss Federal Office of Energy is responsible for licensing:

- Transport applications under nuclear energy legislation
- Applications for the return of reprocessing waste

The key issue concerning permits is assessing safety. The safety assessment comprises the evaluation of compliance with the regulatory framework, the selected methods and the results. There must also be an assessment of how the envisaged change will affect the safety of the facility. Risk analyses are often required, especially for complex modification applications, when additional new systems are built or when type-testing new structural designs for transport and storage containers.

The scope of safety assessments can vary widely, and it depends on the complexity of the requested change.

ENSI's expenditure of time and resources on testing and review is based primarily on the permit application's importance in terms of safety (cf. the "graded approach", section 6). Requirements set for the applicant must be appropriate and reasonable.

### **3.4 Staff licensing**

A suitable organisation with qualified and reliable staff who demonstrate well-developed safety awareness are key elements of nuclear safety (Article 22, paragraph 2, letter b, Nuclear Energy Act). According to the Ordinance on the Qualifications of Personnel in Nuclear Installations, licensing is required for selected functions in nuclear power plants and research reactors. In nuclear power plants, licenses are required for reactor operators, shift supervisors and standby engineers. The license is issued after the candidate has passed a licensing examination at which ENSI is present, and it is renewed at intervals in accordance with a requalification process.

In the field of radiation protection, radiation protection experts, technicians and specialist staff must prove that they have the necessary specialist knowledge on the basis of recognised training courses with examinations (Arts. 10 to 22, Radiological Protection Ordinance). Training and examinations are supervised by ENSI.

When issuing licenses to staff who must be licensed, ENSI examines the candidates' knowledge and practical abilities.

## 4 Surveillance of operations and Integrated Oversight

### 4.1 Fundamentals

The “surveillance of operations” product comprises the safety assessment of the operation of nuclear facilities. In this way, ENSI ensures that the operation of a nuclear facility always meets the requirements in the regulatory framework and that the licensee’s organisation performs its remit in a critical and analytical manner that is primarily geared to safety.

“Surveillance of operations” can be subdivided into various processes. Important processes include:

- Inspection
- Control of periodic reporting
- Analysis of reportable events
- Plant outages
- Radiation measurements
- Remote monitoring and forecasts
- Emergency preparedness
- Safety evaluation
- Enforcement

The individual processes will be examined in more detail below. The process of safety evaluation is discussed in detail in section 5 as it constitutes a key instrument of Integrated Oversight.

### 4.2 Inspections

Inspections number among ENSI’s key monitoring instruments. An inspection verifies whether the facility is being operated in accordance with the regulatory framework and whether the licensee adheres to its own internally specified requirements. Inspection activities cover technical factors as well as “man and organisation” aspects.

Careful preparation precedes every inspection. The subjects of inspection and the bases for assessment must be defined at this stage.

The basic quantity of inspections to be conducted is defined in ENSI’s basic inspection programme, which specifies the subjects and intervals between inspections according to their importance in terms of safety and operating experience. All the inspections listed in the basic inspection programme are conducted at least once every ten years. The basic inspection programme is taken as the basis for a balanced approach to inspection activities.

An annual plan is drawn up for each year, which is refined over the course of the year as required. Reactive inspections are triggered by unforeseeable events in one’s own or a third-party plant. Inspections can be scheduled or unannounced. The announcement of an inspec-

tion has purely administrative objectives, for example the availability of specialists from the nuclear installation as contact persons or the provision of documents. If announcing an inspection could influence the result, the inspection will not be unannounced.

A site inspector is assigned to each nuclear power plant, who spends the majority of his working time in the nuclear power plant during outages and usually at least once a week during power operation. The inspections of site inspectors usually are unannounced.

Each year, ENSI also specifies current key points for inspections which will be systematically examined in more detail at each nuclear facility. Moreover, ENSI sets great store by team inspections. They make it possible to inspect the various aspects of nuclear safety from different technical perspectives. Team inspections require additional organisational preparations. Another type of inspection consists of observing emergency exercises.

### **4.3 Checks and controls**

ENSI controls reporting and notifications by the licensees (Article 72, paragraph 1, Nuclear Energy Act). If reports and notifications raise issues or if need for action is apparent, appropriate investigations and measures are triggered. Periodic reporting includes but is not limited to data which ENSI requires as the basis for determining safety indicators.

ENSI uses the safety indicators as a data source for the systematic safety evaluation. They provide indications about the development of safety-related parameters. If a safety indicator is outside of the normal empirical range, ENSI analyses the reasons and takes measures as necessary. The safety indicators used by ENSI are listed together in the Annex.

### **4.4 Analysis of reportable events**

Relevant events must be reported to ENSI by the licensee pursuant to Article 22, paragraph 2, letter f of the Nuclear Energy Act and the relevant implementation provisions. The licensee must also track operating experience and events in comparable facilities and – as necessary – derive measures on this basis. ENSI analyses and assesses reportable events independently of the licensee to determine their impact, and then orders the resultant measures to ensure nuclear safety (Article 72, Nuclear Energy Act; Article 37, Radiological Protection Act). Depending on the severity of the event, an order may be given to shut a plant down, or permission to restart it may be refused.

An analysis of events provides important information about weak points in the “nuclear facility” MTO system. These may include design shortcomings, weak points in regulations or procedures, findings regarding the condition and behaviour of the facility, or of “man and organisation”. The causes of an event must be clarified so that measures can be taken to prevent any repetition.

Measures must be taken to deal with all the weak points identified in the event analysis. If the licensee itself has not implemented effective countermeasures, ENSI requests the licensee to do so.

## 4.5 Plant outages

ENSI supervises the annual outages of the Swiss nuclear power plants intensively. The work and inspection plan of the nuclear power plant as well as planned plant modifications provide the basis for the supervisory activities during an outage.

A member of the ENSI management is assigned to each plant outage (management delegate). This assignment is decided by the management as whole. The management delegate takes part in the outage meetings and in the final inspection before the plant restart is permitted. The management delegate's aim after checking the documents required for restarting, is to obtain the certainty that the plant is in a state that allows safe operation. The delegate is responsible for the supervisory activities of the plant during the outage.

ENSI considers the inspection activities during the annual outage shutdowns of the nuclear power plants as important. The supervision of the work carried out during the outages is relevant to safety and therefore given high priority by ENSI.

The nuclear power plants require a permit to restart after a refuelling outage. The bases for this are the outage report of the plant, the results of the ENSI inspections during the outage, the reports of external experts who carried out inspections and checked technical reports on behalf of ENSI, as well as findings from the outage.

## 4.6 Radiation measurements

ENSI carries out its own radiation measurements. In the facility, these comprise contamination checks and  $\gamma$ -spectroscopic measurements of water and filter samples in ENSI's own laboratory. Regular dose rate measurements are taken in the immediate vicinity of a nuclear facility. ENSI carries out comparable measurements in connection with the national and international transportation of radioactive substances and waste from and to Swiss nuclear facilities.

These measurements give ENSI independent control of radioactive releases and they ensure that radiation protection measurements are carried out correctly in the facilities. ENSI takes part in the annual comparative measurements carried out by various laboratories.

These independent measurements constitute a key factor in developing public trust in ENSI's work.

## 4.7 Remote monitoring and forecasts

In addition, ENSI operates a measurement system for automatic dose rate monitoring in the vicinity of nuclear power plants so that the radiological situation can be monitored remotely. These measurements are used to secure evidence and for diagnosis. In the event of an accident, ENSI produces forecasts about the dispersion of radioactive substances in the surrounding area based on the latest meteorological data. These forecasts may be used as the basis for decisions on external emergency preparedness measures.

Various key plant parameters (such as pressures and temperatures) and emission data from every Swiss nuclear power plant are continuously and automatically transmitted to ENSI for

the remote monitoring of power plant data with relevance to accidents. If necessary, this material can be visualised and interpreted as part of the emergency preparedness process.

## **4.8 Emergency preparedness**

ENSI operates a standby service and an emergency organisation that is ready to deploy around the clock if an event within its scope of supervision calls for rapid measures on ENSI's part. In particular, ENSI ensures that the National Emergency Operation Centre is promptly informed about events in Swiss nuclear facilities which could result in a hazard to the surrounding area due to radioactivity. ENSI produces forecasts about the development of accidents in nuclear facilities, the potential dispersion of radioactivity in the surrounding area, and the related consequences. It assesses the expediency of the measures taken by the licensee of the nuclear facility to protect the staff and the surrounding area. ENSI advises the National Emergency Operation Centre on ordering protection measures for the public.

## **4.9 Enforcement**

Every assessment that indicates a failure to meet requirements calls for a corrective measure. When ENSI identifies a failure to meet a requirement to which the licensee has not already reacted by taking effective action, ENSI demands suitable measures.

ENSI orders all necessary and reasonable measures to maintain nuclear safety and security (Article 72, paragraph 2, Nuclear Energy Act). If there is the threat of an immediate hazard, the Inspectorate can immediately order measures that diverge from the license or order that has already been issued (Article 72, paragraph 3, Nuclear Energy Act).

## 5 Systematic safety evaluation

### 5.1 Objective

According to Article 22 of the Nuclear Energy Act, the licensee must carry out systematic safety evaluations throughout the entire period of operation. ENSI has specified the requirements in the guideline ENSI-G08. Independently of these evaluations, ENSI has set itself the task of carrying out its own annual systematic safety evaluation for every facility so as to form its own opinion about the condition and operational management of the nuclear facilities under its supervision. The basis for this safety evaluation is supplied by the oversight instruments listed in section 4.

The objective of this systematic safety evaluation is to evaluate the data and findings acquired from the nuclear facilities in the course of ENSI's oversight activities in a systematic, balanced, transparent and comprehensible manner. Periodic evaluation of the categorised and evaluated data should make it possible to identify strengths and weak points relating to individual sub-aspects of nuclear safety at an early stage, and to assemble this material to provide an integrated view of nuclear safety at the nuclear facilities.

This integral view also makes it possible to verify whether all sub-aspects of nuclear safety are covered by the oversight activities in a full and balanced manner. It therefore provides an important instrument for oversight activities in the following year, and for the planning of inspections in particular.

In addition to the ongoing systematic safety evaluation which is assessed annually, the Periodic Safety Review (PSR, cf. section 3.2.1) is another instrument for a comprehensive and overall evaluation of the safety of a nuclear power plant. This requires licensees to carry out an integral safety self-assessment once every ten years, which is then assessed and evaluated by ENSI. As opposed to the systematic safety evaluation, which is primarily geared to operational aspects, the PSR comprises additional elements for the overall evaluation of nuclear safety.

### 5.2 Procedure

Data for the systematic safety evaluation are acquired during the following oversight processes: inspections, control of periodic reporting and analysis of reportable events. These processes supply evaluations of safety-related facts assigned to various subject areas.

The process used for the systematic safety evaluation comprises three steps:

1. Safety-related facts are **rated** to determine the extent to which requirements for defence in depth and the fulfilment of fundamental safety functions are met.

ENSI's safety assessment scale, which is used for standard assessments, is essentially based on the IAEA's International Nuclear and Radiological Event Scale (INES). ENSI has refined INES in the "below-scale" range so that the same scale can be used not only to assess major shortcomings in safety precautions but also lesser deviations and the fulfilment of requirements. The assessment scale is explained in section 5.4.

Every assessment that indicates a failure to meet requirements calls for a corrective measure. When ENSI identifies a failure to meet a requirement to which the licensee has not already reacted by taking effective action at its own responsibility, ENSI demands suitable measures (cf. section 4.9).

2. Safety-related facts are **allocated to subject areas**.

The purpose of this allocation is to visualise the importance of a fact in the context of the defence in depth concept. Allocation calls for a compromise between differentiation and synthesis. If the level of differentiation is too low, differences in the functions of various safety precautions will no longer be visible in the overall assessment. If it is too high, common features disappear in a mass of detail.

The results of the systematic safety evaluation are presented in a matrix. The four key subject areas of nuclear safety are shown in the columns of the matrix:

- Design requirements
- Operating requirements
- Condition and behaviour of the plant
- Condition and behaviour of “man and organisation”

The breakdown of the safety evaluation into these four subject area takes explicit account of the safety precautions concerning the definition of the target condition (requirements for design and operation) and the actual condition of the plant, the people and the organisation as encountered.

The rows in the matrix refer to defence in depth and fundamental safety functions. On the one hand, the allocation relates to the five levels of defence-in-depth and the barriers as per the barrier concept mentioned in section 1.2. On the other hand, the allocation relates to the fundamental safety function concept. Both allocations – one from the perspective of levels of defence and barriers and the other from the perspective of fundamental safety functions – serve the purpose of assessing the completeness and balance of the safety precautions. From the perspective of fundamental safety functions, the result of defence in depth also becomes visible, i.e. fulfilment of the fundamental safety functions. Most of the facts can be allocated to levels of defence and barriers as well as fundamental safety functions. However, radiation exposure of individuals can only be shown in the fundamental safety function perspective, where it should be assessed in relation to the fundamental safety function S4 of “Limiting exposure to radiation”.

The structure of the systematic safety evaluation is shown in Figures 2 and 3.

3. The assessments of safety-related facts that are allocated to the same subject areas are **aggregated to arrive at an overall evaluation**. This step takes place at the end of the supervisory year in the course of structured internal conferences of experts at ENSI, known at ENSI as “facility conferences”. A facility conference is organised for each nuclear power plant until the final cessation of power operation. In the aggregation process, the overall assessment is dominated by the highest assessments – i.e.

those which indicate the greatest deviation from the specified requirements. As the first step, aggregation is carried out for **each cell** of the safety evaluation matrix, using ENSI's safety evaluation scale with categories G, N, V, A and above (cf. section 5.4). In the second step, ENSI performs a **qualitative overall assessment for each column** of the matrix with high, good, adequate and inadequate levels of safety. This qualitative assessment of the columns also incorporates knowledge gained from other oversight processes, in particular from expert reporting in connection with the Periodic Safety Reviews and major changes to facilities.

ENSI sets great store by providing the public with transparent information. The results of the systematic safety evaluation are published in the Oversight Report.

| Subject of assessment                          |  | Requirements        |                          | Operational experience           |   |
|--|--|---------------------|--------------------------|----------------------------------|---|
|  |  | Design requirements | Operational requirements | State and behaviour of the plant | State and behaviour of man and organisation |
| <b>Objectives</b>                              | Level 1  |                     |                          |                                  |   |
|  | Level 2  |                     |                          |                                  |   |
|  | Level 3  |                     |                          |                                  |   |
|  | Level 4  |                     |                          |                                  |   |
|  | Level 5  |                     |                          |                                  |   |
|  | <b>Barrier integrity</b>                         | Fuel integrity      |                          |                                  |   |
|  | Integrity of the primary cooling system boundary |                     |                          |                                  |   |
|  | Containment integrity                            |                     |                          |                                  |   |
| <b>Cross-level or cross-barrier importance</b> |  |                     |                          |                                  |   |

Figure 2: Structure of the systematic safety evaluation – levels of defence and barriers

| Subject of assessment |   | Requirements        |                          | Operational experience           |   |
|-----------------------|---|---------------------|--------------------------|----------------------------------|---|
|                       |   | Design requirements | Operational requirements | State and behaviour of the plant | State and behaviour of man and organisation |
| Objectives            |   |                     |                          |                                  |   |
| Safety functions      | Controlling reactivity                      |                     |                          |                                  |   |
|                       | Cooling the fuel                            |                     |                          |                                  |   |
|                       | Confining radioactive materials             |                     |                          |                                  |   |
|                       | Limiting exposure to radiation              |                     |                          |                                  |   |
|                       | Importance across multiple safety functions |                     |                          |                                  |   |

Figure 3: Structure of the systematic safety evaluation – fundamental safety functions

### 5.3 Allocation to levels versus allocation to barriers

The levels of defence-in-depth include **functions of technical equipment and measures** related to such equipment. “Equipment” refers to parts of the plant whereas “measures” are based on human resources and regulations.

By contrast, the barriers are based on the **integrity and impermeability of structures and sealed valves** whose purpose is the containment of radioactive substances, and on **measures** related to these structures. As already shown in section 1.2, however, ensuring the integrity of barriers depends in turn on functions of active and passive equipment.<sup>14</sup>

### 5.4 Assessment scale

A uniform scale is used for all assessments. This scale is based on the International Nuclear and Radiological Event Scale (INES) but is extended in the below-scale range (INES 0). This enables it not only to cover events but also undisturbed normal operation and even aspects of an exemplary nature for other facilities (cf. Figure 4). The scale comprises these categories: G (Good Practice), N (Normality), V (In Need of Improvement), A (Deviation), 1 (Anomaly), 2 (Incident) and so on as per INES. The criteria for assignment to categories G, N, V and A are shown in Figure 5.

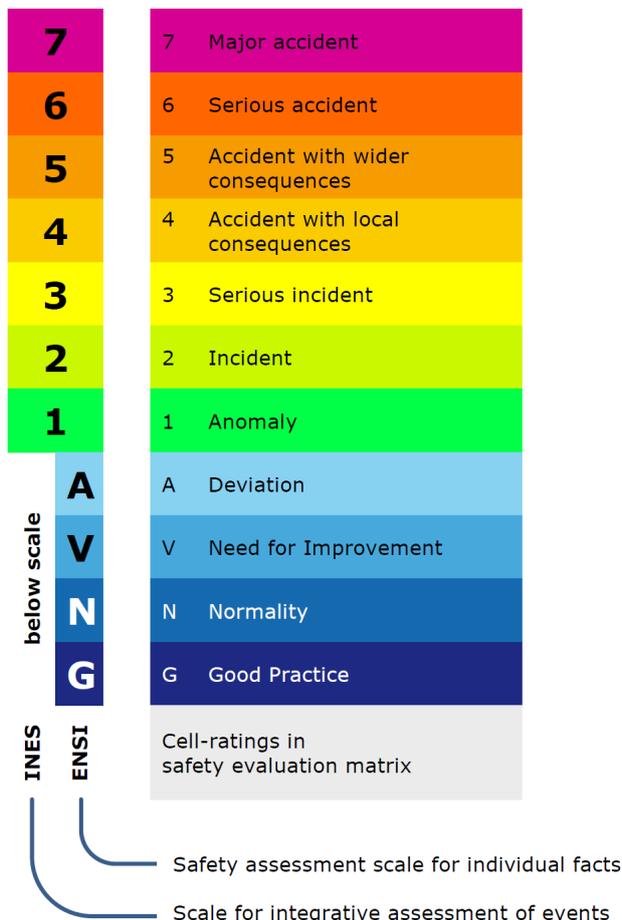
In categories G, N, V and A, all fundamental safety functions are always fulfilled to the extent required by the licensed operating conditions. The evaluations for categories 1 to 7 are based on assessments of three different criteria:

1. Radioactive releases into the environment
2. Radiation exposure of staff

<sup>14</sup> Unlike passive equipment, active equipment is reliant on supporting functions.

3. Effectiveness of defence-in-depth or – if defence-in-depth has failed – severity of core damage

The assessment is always determined by the criterion that results in the highest classification. A classification based on radioactive releases into the environment means, from category 1 onwards, that the fundamental safety function S3 of “Confining radioactive materials” has been breached, and the released activity then increases by several magnitudes until category 7 is reached. A classification due to radiation exposure of staff means, from category 1 onwards, that the fundamental safety function S4 of “Limiting exposure to radiation” has been breached, and the radiation dose increases by several magnitudes until category 4 is reached. A classification based on the effectiveness of the defence-in-depth may mean – in categories 1 to 3 – that the fundamental safety functions of “Controlling reactivity” (S1), “Cooling the fuel” (S2) or “Confining radioactive materials” (S3) are not all fulfilled to the extent required by the licensed operating conditions. However, it is also possible that these fundamental safety functions are just fulfilled but that additional faults would lead to a breach of fundamental safety functions. A classification due to the severity of core or barrier damage means that fundamental safety functions have been breached.



**Figure 4: ENSI’s safety assessment scale for individual facts and the International Nuclear and Radiological Event Scale (INES) for the integrated assessment of events**

| Categories                    | Criteria   |
|-------------------------------|--|
| <b>≥1</b>                     | in accordance with the INES criteria   |
| <b>A</b> Deviation            | <ul style="list-style-type: none"> <li>• <b>condition that constitutes a reportable event but lies within operational limits and conditions</b></li> <li>• deviation from a law, an ordinance or from an official guideline specifying statutory requirements if the deviation has an effect on nuclear safety</li> <li>• deviation from statutory requirements relating to safety at work if the deviation has an effect on nuclear safety</li> </ul> |
| <b>V</b> Need for Improvement | <ul style="list-style-type: none"> <li>• weakness</li> <li>• deviation from procedures issued by the licensee (not requiring a permit by ENSI)</li> </ul>  |
| <b>N</b> Normality            | <ul style="list-style-type: none"> <li>• compliance with all requirements</li> </ul>   |
| <b>G</b> Good Practice        | <ul style="list-style-type: none"> <li>• complies with all requirements and is significantly better than the practice in other facilities</li> </ul>   |

**Figure 5: ENSI's safety assessment scale for individual facts**

## 6 Integrated Oversight and the IAEA’s “graded approach”

### 6.1 Legal basis

The principle of **proportionality** is established at constitutional level (Article 5, paragraph 2 of the Swiss Federal Constitution). It must be heeded in all governmental activities, and in legislation as well as the application of the law. The principle of proportionality states that every governmental action must be appropriate and necessary in order to achieve the targeted objective. Moreover, the burden on private individuals resulting from a governmental measure must be in reasonable proportion to the goal to be attained (“reasonability”, no disparity of interests). For the nuclear energy sector, this means: the greater the relevance to safety, the more extensive the measures that are justified and required. The “graded approach” is an implementation of the principle of proportionality. The legislator referred to the principle of proportionality at various points in the Nuclear Energy Act. This is especially noticeable in Article 4, paragraph 3, letter b and Article 22, paragraph 2, letter g of the Nuclear Energy Act (“measures that contribute towards an additional reduction of risk insofar as they are appropriate”) and in Article 72, paragraph 2, Nuclear Energy Act (“the supervisory authority shall order all **necessary and reasonable** measures”).

Article 1 of the ENSI Act stipulates that ENSI shall be managed according to economic and business principles. According to the message to the ENSI Act, this should ensure that resources are used economically, and costs and benefits should be in reasonable proportion (which means that efficiency is addressed). However, nuclear safety must be given priority over financial aspects in performing the mandate.

It could be objected that these principles are devoid of content and therefore unsuitable to provide the basis for a safety-oriented “graded approach”. This objection is only tenable at first glance because the principle of legality is a key basic element of all actions taken under the rule of law (which include administrative activities) (see Article 5 of the Federal Constitution, and Article 3, paragraph 1 of the Government and Administration Organisation Act). The Nuclear Energy Act designates ENSI as the supervisory authority for nuclear safety and security and, in the article concerning the Inspectorate’s purpose, it also states the objective towards which ENSI must gear its activities: the protection of people and the environment against the hazards from the peaceful use of nuclear energy (Article 1, Nuclear Energy Act). The definition of the act’s purpose brings the relevance of an activity in terms of safety into play as a key yardstick for actions. Relevance to safety is therefore a major aspect that must be considered when assessing proportionality. This also applies to the specification of the principles for administrative activities: when, for instance, Article 11 of the Government and Administration Organisation Ordinance calls for priorities to be set according to “importance”, this refers primarily to “importance” viewed in terms of safety within ENSI’s area of competence.

The **IAEA** has not yet stipulated a uniform definition of the “graded approach”. The Safety Fundamentals (SF-1) touch on the “graded approach” several times (paragraphs 3.15 and 3.22), and paragraph 3.24 states:

“The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the **magnitude of the radiation risks** and their amenability to control. Regulatory control may not be needed where this is not warranted by the magnitude of the radiation risks.”

**GSR Part 1**, “Governmental, Legal and Regulatory Framework for Safety” (2010) requires the “graded approach” for a wide range of different activities by the supervisory authority, especially for reviews, inspections and decisions and also when defining the organisational structure and allocating resources.

**GS-R-3**, “The Management System for Facilities and Activities” (2006, applicable at least by analogy to supervisory authorities as well) establishes the “graded approach” as follows:

“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.”

## 6.2 The “graded approach” in practice

The law clearly requires that ENSI should observe the principles of proportionality (reasonableness) and expediency (appropriateness) in its activities. Based on the comments above, ENSI defines the “graded approach” to its activities as follows:

As regards the processing of specialised technical issues, which is actually ENSI’s core activity, the “graded approach” is based on **nuclear safety** as set out in section 1. As nuclear safety includes many aspects, the priority, depth and scope of the processing of specialised technical issues should be defined on the basis of a comprehensive assessment. A very diverse range of safety-related aspects is considered for this purpose. Examples include the safety classification of components and systems, the status of backfitting technology, risk relevance determined by means of probabilistic safety analyses, knowledge gained from events in the licensee’s own facility and third-party facilities, and findings from studies and safety reviews (such as the PSR, WANO, OSART and IRRS). By adopting this integrated approach, ENSI aims to ensure that its supervisory decisions are sound.

The line managers’ main management tasks include specifying the depth and timing of processing when issuing assignments to employees and defining the responsibilities for quality control. In this context, the outlay on a specified activity is based on the experience and expertise of the ENSI employees.

Process- and decision-related information is required so that management decisions can be made.

- **Process-related information:** Specifically, this is information about processing depth, priority, urgency and responsibility. This information explains the sequence of the process.
- **Decision-related information:** This comprises data, facts, statements, calculations, expert opinions and the like. This information explains the **technical facts** on which decisions must be made. The quality and completeness of decision-related information are also critical.

Process- and decision-related information is not static. Both types of information may change while a decision is being reached. For example: While processing a permit, it is found that the original assessment of the implications needs to be reconsidered because of the relevance to safety of the system in question. As a consequence, the processing depth or the responsible decision maker may change.

It is important to gain an awareness of the risks involved in the decision. For difficult decisions, a risk assessment regarding the consequences for ENSI must be carried out in all cases. This should always be done for projects and the results should be stated in the project plan. For transactions, this depends on the complexity or political importance of the decision.

These points should be considered when determining the implications and the complexity:

a. Implications

- relevance to safety
- potential legal consequences
- deviation from or change to existing supervisory practice
- anticipated costs and staff resources required
- number of external bodies and decision makers involved
- potential parliamentary repercussions, potential media repercussions (national, international)

b. Complexity

- number of specialist disciplines involved
- anticipated outlay on coordination
- novelty of the issue: scope of knowledge to be acquired, lack of bases for assessment

Given that every organisation also has to accomplish numerous internal tasks, this also raises the question of the “graded approach”. A distinction must be made here between tasks that indirectly impact the safety of nuclear facilities and those which are solely of interest to the internal organisation. The first group of tasks includes (for example) ENSI processes for dealing with specialist technical assignments so that quality control and uniform procedures can be defined within ENSI. Internal tasks of this sort are also important and should be accomplished efficiently with the necessary targeted approach and allocation of resources.

Another of ENSI's key tasks is **communication** within the organisation and to the outside world. This task mainly serves the purpose of credibility and it fosters transparency. Consequently, communication has high priority in all cases and it must be handled professionally. This also concerns responses to parliamentary enquiries, which must always take high priority for political reasons. Communication within the organisation should be efficient and accurately targeted.

Finally, a number of purely internal projects are necessary so that an organisation can function and continue to develop. Projects of this sort must be implemented in such a way as to enable ENSI to perform its core tasks with the required resources at all times.

In the management system, the "graded approach" is therefore reflected as appropriate in every oversight-related ENSI process. As regards internal processes, management must take and justify the right decisions and communicate them internally, taking account of the aspects outlined above.

# Annex: Safety Indicators

| Evaluation parameter [unit]  | Data source   |
|--|---|
| Definition   | Data acquisition  |
| Explanations   |   |
| <p><b>Total LCO time [h] at <u>level 1</u> of defence-in-depth (operating systems)</b></p> <p>Total of times during which operating systems failed to fulfil an applicable limiting operating condition as per the technical specification</p> <p>Note: not applicable if the technical specification for the nuclear power plant contains no limiting operating conditions for systems at level 1</p> | <p>Monthly report as per Table 3.2 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Total LCO time [h] at <u>level 2</u> of defence-in-depth (limitation and protection systems)</b></p> <p>Total of times during which limitation and protection systems failed to fulfil an applicable limiting operating condition as per the technical specification</p>   | <p>Monthly report as per Table 3.2 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Total LCO time [h] at <u>level 3</u> of defence-in-depth (safety systems)</b></p> <p>Total of times during which safety systems failed to fulfil an applicable limiting operating condition as per the technical specification</p>   | <p>Monthly report as per Table 3.2 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Total LCO time [h] at <u>level 4</u> of defence-in-depth (systems for situations beyond the design basis)</b></p> <p>Total of times during which systems for situations beyond the design basis failed to fulfil an applicable limiting operating condition as per the technical specification</p>   | <p>Monthly report as per Table 3.2 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Number of unplanned SCRAMs</b></p> <p>Number of unplanned SCRAMs from all power levels</p>   | <p>Event reports</p> <p>Indicator determined by ENSI (three-quarter-year value and annual value)</p>          |
| <p><b>Initiations of reactor protection</b></p> <p>Number of all disturbance-caused initiations of the reactor protection system taking place on one or two channels but not leading to a reactor shutdown</p>   | <p>Monthly report as per Table 3.3 a of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p> |
| <p><b>Initiations of emergency cooling systems</b></p> <p>Number of all disturbance-caused initiations of emergency cooling systems taking place on one or two channels but not leading to a reactor shutdown. The safety systems considered must be defined for each facility.</p>  | <p>Monthly report as per Table 3.3 b of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p> |
| <p><b>Initiations of other safety systems</b></p> <p>Number of all disturbance-caused initiations of safety systems without reactor protection or emergency cooling systems taking place on one or two channels but not leading to a reactor shutdown. The safety systems considered must be defined for each facility.</p>  | <p>Monthly report as per Table 3.3 c of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p> |

| <b>Evaluation parameter [unit]</b>  | <b>Data source</b>  |
|---|---|
| <b>Definition</b>   | <b>Data acquisition</b>   |
| <b>Explanations</b>   |   |
| <p><b>Initialisations of safety systems</b></p> <p>Number of unplanned initialisations of safety systems which lead to an actual start-up of the systems. Automatic and manual activations are both counted. The safety systems considered must be defined for each facility.</p>                                       | <p>Monthly report as per Table 3.3 d of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Maximum annual risk peak</b></p> <p>Maximum value for conditional core damage frequency</p>   | <p>Annual value in the report on the non-availability of systems and components as per section 14 of guideline ENSI-B02 (indicator)</p>                         |
| <p><b>Cumulative risk</b></p> <p>Incremental cumulative likelihood of core damage</p>   | <p>Annual value in the report on the non-availability of systems and components as per section 14 of guideline ENSI-B02 (indicator)</p>                         |
| <p><b>Corrective work applications for reactor protection</b></p> <p>Number of corrective work applications for reactor protection</p> <p><b>Explanation: the number of work applications arising from function tests is determined (system function tests, channel function tests, logic tests).</b></p>               | <p>Monthly report as per Table 3.4 a of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Corrective work applications for emergency cooling systems</b></p> <p>Number of corrective work applications for emergency cooling systems</p> <p><b>Explanation: the number of work applications arising from function tests is determined (system function tests, channel function tests, logic tests).</b></p> | <p>Monthly report as per Table 3.4 b of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Corrective work applications for isolation systems</b></p> <p>Number of corrective work applications for isolation system</p> <p><b>Explanation: the number of work applications arising from function tests is determined (system function tests, channel function tests, logic tests).</b></p>                  | <p>Monthly report as per Table 3.4 c of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>   |
| <p><b>Volume of unconditioned radioactive waste generated in the last 18 months [m<sup>3</sup>]</b></p>   | <p>Monthly report (changes) and annual report (all data) as per Table 2.3 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>              |
| <p><b>Ratio of volumes of unconditioned radioactive waste processed within the last 18 months to newly generated unconditioned waste</b></p>  | <p>Monthly report (changes) and annual report (all data) as per Table 2.3 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>              |
| <p><b>Inventory of combustible unconditioned radioactive waste outside of the planned waste storage locations [m<sup>3</sup>]</b></p>   | <p>Monthly report (changes) and annual report (all data) as per Table 2.3 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p>              |
| <p><b>Exhaustion of the dose guideline value as a function of source</b></p> <p>Calculated annual dose for persons most affected (adults) in the areas surrounding Swiss NPPs, divided by the dose guideline value as a function of source, which is 0.3 mSv per year</p>   | <p>Monthly reports for March, June, September and December as per Table 5.1 in Annex 5 of guideline ENSI-B02 (raw data)</p> <p>Indicator determined by ENSI</p> |
| <p><b>Collective dose [pers.-mSv]</b></p> <p>Collective dose for own and third-party staff</p>  | <p>Monthly report as per no. 8.3, letter f of guideline ENSI-B02 (indicator)</p>  |

| <b>Evaluation parameter [unit]</b><br><b>Definition</b><br><b>Explanations</b>  | <b>Data source</b><br><b>Data acquisition</b>   |
|---|---|
| <b>Lifetime doses &gt; 0.2 Sv</b>   | Monthly report as per no. 8.3, letter f of guideline ENSI-B02 (raw data)<br>Indicator determined by ENSI  |
| <b>Collective dose during outage [pers.-mSv]</b>  | Inspection report on radiation protection as per no. 9.2.4 letter a of guideline ENSI-B02 (indicator)   |
| <b>Exhaustion of tech. spec. limit for iodine-131</b><br>Iodine-131 activity in the reactor coolant water divided by the site-specific tech. spec. limit  | Monthly report as per no. 8.3, letter a of guideline ENSI-B02 (raw data)<br>Indicator determined by ENSI  |
| <b>Localised leakages [m<sup>3</sup>/h]</b><br>Average of localised leakages from the primary circuit into the drywell or into the primary containment  | Monthly report as per Table 3.5 of guideline ENSI-B02 (indicator)   |
| <b>Non-localised leakages [m<sup>3</sup>/h]</b><br>Average of non-localised leakages from the primary circuit into the drywell or into the primary containment  | Monthly report as per Table 3.5 of guideline ENSI-B02 (indicator)   |
| <b>Total leakage rate from type C tests</b><br>Total of all measured air leakage rates in system valves (as found) which penetrate the drywell and containment and are tested as per the technical specification  | Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per Table 3.6 of guideline ENSI-B02 (indicator) |
| <b>Total leakage rate from type B tests</b><br>Total of all measured air leakage rates in system valves (as found) which penetrate the drywell and containment and are tested as per the technical specification  | Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per Table 3.6 of guideline ENSI-B02 (indicator) |
| <b>Simulator training time (shift staff) [d]</b><br>Average number of training days completed on the simulator for licensed shift staff   | Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per Table 3.7 of guideline ENSI-B02 (indicator) |
| <b>Ratio of training hours to total working hours for shift staff requiring a license</b><br>Effective quota of training hours completed in relation to total working hours of shift staff requiring a license<br>Only the time stated by a trainee is counted.         | Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per Table 3.7 of guideline ENSI-B02 (indicator) |
| <b>Ratio of training hours to total working hours for shift staff not requiring a license</b><br>Effective quota of training hours completed in relation to total working hours of shift staff not requiring a license<br>Only the time stated by a trainee is counted. | Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per Table 3.7 of guideline ENSI-B02 (indicator) |
| <b>Staff turnover</b><br>Staff departures per month divided by the headcount for that month   | Monthly reports as per no. 8.4.2, letter a of guideline ENSI-B02 (raw data)<br>Indicator determined by ENSI   |

| <b>Evaluation parameter [unit]</b><br><b>Definition</b><br><b>Explanations</b>   | <b>Data source</b><br><b>Data acquisition</b>  |
|--|--|
| <p><b>Sickness rate</b></p> <p>Sum of sickness-related absences divided by the average of total working hours of all staff (mean of the values at the beginning and at the end of the year)</p>  | <p>Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December as per no. 8.1, letter m of guideline ENSI-B02 (indicator)</p> |
| <p><b>Compliance with deadlines</b></p> <p>Deadline compliance for site = <math>((N \text{ closed}) - (N \text{ externally delayed})) / (N \text{ closed})</math></p> <p>N externally delayed = number of ENSI transactions closed with external delays* during the calculation period (for the relevant NPP)</p> <p>N closed = number of ENSI transactions closed during the calculation period (for the relevant NPP)</p> <p>* externally delayed = delayed by the NPP</p> | <p>Data from ENSI business monitoring</p> <p>Taken into account by ENSI for the three-quarter-year and annual values</p>   |
| <p><b>Training time of emergency staff [d]</b></p> <p>Average number of training days for members of the emergency staff</p> <p>Training days are multiplied by the number of participants and divided by the total number of emergency staff members.</p>   | <p>Three-quarter-year value* in the monthly report for September and annual value* in the monthly report for December* as per Table 3.7 of guideline ENSI-B02 (indicator)</p>        |
| <p><b>External events assessed in depth</b></p> <p>Number of external events analysed in respect of their importance for the licensee's own facility which are documented in an internal report.</p>   | <p>Monthly reports for September and December as per no. 8.5, letter b of guideline ENSI-B02</p> <p>Taken into account by ENSI for the three-quarter-year and annual values</p>      |
| <p><b>Number of measures derived from evaluation of external events</b></p>  | <p>Monthly reports for September and December as per no. 8.5, letter b of guideline ENSI-B02</p> <p>Taken into account by ENSI for the three-quarter-year and annual values</p>      |

\* Individual indicators not available on a monthly basis are calculated for the first three quarters of the calendar year and for the completed calendar year. The three-quarter-year value is used for the provisional facility assessment by ENSI which takes place early in the following year, when the database is not complete yet. If the value for the completed calendar year results in a different assessment, this is taken into account in the definitive facility assessment that is reproduced in the Oversight Report.

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