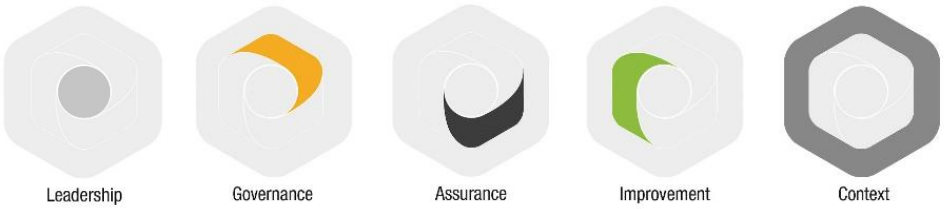
Chapter 9. Assessment & Improvement



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9.1 Assessment

9.1.1 Overview

Because of the importance of providing adequate assurance of safety, internal audit alone is not considered sufficient to assess management systems for organisations in the nuclear sector. Organisations are legally obliged and encouraged to adopt a strength-in-depth approach in providing assurance of safety. This approach extends to assessing the adequacy, implementation and effectiveness of its arrangements, and to strive for continual improvement and good practice.

This section sets out a quality management system against the requirements of ISO 9001:2015 [1] and the auditing guidance in ISO 19011:2018 [2], as well as additional information on the assessment techniques used in the nuclear sector.

9.1.2 Assessment of the Management System

The Management System for Facilities and Activities (IAEA Safety Standard GS-R-3 [3]) was widely used in the UK by most licensees to help develop their arrangements against Licence Condition (LC) 17 – Management Systems [4]. The requirements of GS-R-3 conditioned licensees' approaches to assessing their management systems. GS-R-3 did not simply include requirements for audits, as is common with most management system standards, but also required self-assessment and independent assessment. GS-R-3 was superseded by IAEA GSR Part 2 – Leadership and Management for Safety [5] in 2016. GSR Part 2 requires regular independent assessments and self-assessments to be carried out to evaluate the effectiveness of the management and to evaluate leadership for safety and safety culture. Guidance on both independent and self-assessment is currently provided in IAEA GS-G-3.1 – Application of the Management System for Facilities and Activities [6]. This guidance was issued in 2006 to support GS-R-3 and will be updated to align with GSR Part 2 in due course.

ISO 9001 requires audits to be carried out with the purpose of determining whether the quality management system conforms to the planned arrangements and the requirements of ISO 9001 and the extent to which it is effectively implemented and maintained. There is no requirement for self-assessment.

The purpose of assessing the management system in the nuclear sector is broader and audit alone is not considered sufficient. This approach is appropriate because of the potential far-reaching consequences of accidents and errors. Managers have a greater role in ensuring the adequacy and effectiveness of the arrangements and processes for which they are responsible. This role includes promoting nuclear safety culture and acting as role models. Various approaches to self-assessment and independent assessment used by UK licensees are described below.

Self-assessment

IAEA GSR Part 2 requires senior management and management at all other levels in the organisation to carry out self-assessment to evaluate the effectiveness of the management system, and leadership for safety and safety culture.

Self-assessment enables management to periodically compare its performance with management expectations, worldwide industry standards of excellence and regulatory requirements, so that deficiencies and opportunities for improvement can be identified. Self-assessment should promote continual improvement in safety performance and in the management system.

Assessments are carried out by all levels of management and include the processes and activities, for which the manager or their unit is responsible. To ensure the assessments are effective, managers may consider including supervisors and operators when carrying out assessments.

Many organisations find it is difficult to carry out self-assessment effectively and this may often be attributed to a high workload on the management team and to reactive styles of management. It is therefore important that the management system contain a simple self-assessment process which provides guidance to managers and a framework for the administration of self-assessments and the associated corrective actions.

Continual improvement and self-assessment should be seen as a normal part of routine work and therefore the frequency of self-assessment and the topics covered should be chosen carefully. Smaller and more frequent self-assessments help to make the task less onerous and part of the normal management routine. Self-assessments should also be undertaken where poor performance is identified and there is a need for a closer review. To ensure that all deficiencies and areas of weakness are identified during self-assessment, a variety of different methods and techniques are used. These may include:

- Workplace inspections or visits and informal communications with operators and other personnel;
- Analysis and review of key performance indicators (KPIs);
- Analysis and review of non-conformity reports and event reports;
- Analysis and review of process performance data;
- Benchmarking.

IAEA GSR Part 2 also requires management to evaluate the improvement of the safety culture (see Chapter 3). Identifying the methods and indicators for measuring the many intangible aspects of safety culture, such as beliefs, attitudes and behaviours, can be challenging. IAEA and others publish comprehensive guidance on this subject.

While an effective manager will be in tune with the culture within their area of responsibility, methods such as interviews, questionnaires, observations and reviews of

documentation can also be used to gauge the safety culture of the organisation. It is impossible to use a single measure to judge the safety culture, and management should use a number of methods to develop an overall picture.

Senior management plays an important role in developing a successful self-assessment culture and it is essential that senior managers support and encourage the self-assessment process. Senior managers reinforce a questioning attitude and encourage the identification and reporting of non-conformities and areas for improvement. To enable self-assessment to identify deficiencies and areas for improvement, senior management foster a blame-free reporting culture where individuals are not punished or blamed for unintentional errors.

Independent Assessment

Independent assessment is carried out on behalf of senior management to assess the effectiveness of the management system and to make sure that safety is not compromised by financial, commercial or other pressures. Independent assessment also identifies improvement opportunities and helps drive continual improvement in the management system.

Independent assessment is carried out by an independent unit within the licensee's organisation which has a reporting line directly to senior management. People do not assess their own work or work carried out by their management unit. The assessment unit needs to summarise the output from its assessment activities and present them in a logical and comprehensible format. This will allow senior management to understand the information and take strategic decisions to improve leadership, safety culture and the management system.

Below is a brief description of activities that can be included in an independent assessment programme.

Internal Audit

Internal audits in the nuclear sector are usually carried out in accordance with a process based on ISO 19011. Audits determine if the management system conforms to the planned arrangements, conforms to quality management system requirements, and is effectively implemented and maintained. Audits also identify opportunities for improving the management system and operational performance. Audits within the nuclear sector will be focused on both safety-related activities, such as site licence compliance processes, and on product realisation processes. Audits are less effective in assessing safety culture and leadership performance so other methods of assessment are more effective in the assessment of these topics.

Surveillance

Surveillance is a good technique for assessing a specific or ongoing work activity and is less formal than an audit. The timing of surveillance visits can be more flexible allowing specific

work activities to be observed. It can involve periodically visiting work areas or observing management processes over a period of time. This enables the individual making the assessment to develop a closer relationship with the personnel carrying out the task, and allows a much better assessment of the less tangible elements of safety culture, such as leadership, beliefs, attitudes and behaviours. In addition to observing the work or process being carried out, surveillance activities should include reviews of documentation and interviews with personnel. Some licensees use an internal regulator to carry out surveillance activities. The internal regulator is often based on the licensed site and has a close contact with the licensee's management team.

Inspection

The term inspection is often used by licensees, especially those with internal regulators, to describe activities that assess compliance with legal requirements, such as site licence conditions, permitting regulations or safety legislation. Inspections of legal compliance are usually carried out in addition to internal audits which have a greater focus on improving the management system.

Peer Review

Licensees can invite international organisations such as the IAEA's Operational Safety Review Team (OSART) [7], the World Association of Nuclear Operators (WANO) [8] or the Institute of Nuclear Power Operations (INPO) [9] to undertake peer reviews on their facilities. In the case of WANO and INPO, licensees need to be members of the organisations. The reviews compare the licensee's performance with international good practice, observe plant activities and material condition, review performance data and interview operators. The assessment teams identify opportunities for improvement and offer advice.

Second- and Third-party Audits

Many licensees are certificated to standards such as ISO 9001 [1], ISO 14001 [10] and ISO 45001 [11]. Certification or surveillance audits will be carried out by an accredited certification body. Similarly, some licensees are audited when their customers carry out second-party supplier audits. The output from such audits can provide a valuable input into the independent assessment process but might be focused on product realisation rather than nuclear safety processes. Licensees may carry out supply chain audits.

Regulatory Interventions

On licensed sites the regulators will have an intervention programme which describes the compliance inspections, guidance, permissioning and safety case assessment work which the regulator plans to carry out. The regulators should never be seen as part of the licensee's independent assessment programme. However, the feedback from the regulator's inspections and assessments can provide an excellent source of information on the organisation's performance and on the quality of its safety cases.

Safety Culture Assessment

IAEA GSR Part 2 requires the organisation to evaluate its safety culture. The assessment of safety culture is a specialist topic and is usually undertaken by human factors practitioners. To assess safety culture, the independent assessment programme must seek to measure the beliefs attitudes and behaviours of the workforce. Various methods have been devised to achieve this including the use of questionnaires and interviews. IAEA and HSE publish extensive guidance on assessing safety culture and there are safety culture assessment tools available.

Independent Oversight

Independent oversight plays an additional and unique part of an effective safety management system for nuclear facilities. Its purpose, as a layer in the defence-in-depth approach, is to provide directors and senior managers with assurance that nuclear risks are being effectively controlled and compliance with regulatory requirements is being achieved. Typically layers of defence are in-process oversight (not independent), functional oversight (not independent), independent oversight and external oversight.

An independent oversight function is by definition independent of any other functional or line management responsibilities. Its structure and size will be determined by the size and complexity of the operating organisation and the nature and lifecycle stage of its nuclear activities.

Independent oversight functions typically deploy a range of assessment methods appropriate to the activities and their associated risks. These can be direct methods, such as inspection, surveillance and audit, and indirect methods such as analysis of performance indicators and other information and review of documents. Independent oversight is more effective when the assessment activities are planned in a proactive manner.

The relationship between an independent oversight function and other functional groups carrying out independent assessment should be defined and their activities should be coordinated to maximise benefit. There are similarities between the assessment methods deployed by such groups, but their objectives are different. Typically, a Quality Assurance or management system function performs management system compliance-based audits to ensure the management systems complies with regulatory or company requirements. An independent oversight function focuses on nuclear safety related compliance and performance and their assessments relate to recognised nuclear industry good practice. These two functions may be combined. An independent oversight function is sometimes referred to as an internal regulator.

Interaction arrangements between the oversight function and external regulators should be agreed. These arrangements should include making the assessment programme and the results of independent oversight assessments available to external regulators. Joint

inspections, investigations and assessments should also be considered. A mutually beneficial relationship should be developed and maintained.

Guidance on the responsibilities and activities of an independent oversight function is given in [12] and [13].

9.1.3 Auditor Competence

This section identifies information that a management system auditor in the nuclear sector should be familiar with, in order to enhance their capabilities as auditors. It is assumed that they have already received formal training as a lead auditor, i.e. an accredited course in an appropriate discipline such as quality, environment or health and safety. However, under certain circumstances, auditors are required to be qualified and formally appointed.

General requirements for auditor competence are not specific to the nuclear sector, but some standards (e.g. ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications, 2017 [14]) impose specific requirements on auditor competence, auditing practices and audit reporting. An auditor should be aware of standards containing generic requirements for auditors and auditing and should be aware of applicable standards containing specific requirements and international/national auditor certification schemes.

They should understand the various types of audit that can be carried out (specified in audit criteria) and the differences between audit and inspection.

Many audits require specialist knowledge in order to effectively assess the extent of compliance. A skilled auditor is therefore adept at identifying appropriate technical experts to include on the audit team.

It should be noted that one auditor is unlikely to have the competence to audit all aspects of a management system in the nuclear sector. An auditor therefore needs to be aware of their own limitations and when to seek professional development.

Management System Standards

Audits in the nuclear sector can be carried out against the requirements of more than one management system standard. It is therefore important to understand the requirements of each management system standard, in order to assess compliance with the standard or demonstrate effective fulfilment of its requirements. This includes the aims of the various management system standards, their common features, differences and the circumstances under which they are applied.

Organisations are increasingly operating, or claiming to operate, an integrated management system. These require a joined-up approach to auditing and auditors should be equipped to undertake such audits without compromising the outcome of the audit.

Legal Framework

The nuclear sector is highly regulated and much emphasis in management systems is directed to legal compliance. The auditor should understand the international/national framework of statutory and regulatory requirements applicable to the business being audited and which influence or control the management system. This generally includes safety (both nuclear and conventional), environmental and security or safeguards.

In some instances, auditors may require detailed knowledge of specific legislation, such as the Nuclear Installations Act, Radioactive Substances Act and the nuclear site licence and regulations, consents and authorisations issued under enabling legislation (see Chapter 2).

Regulatory Regime

The auditor should understand who regulates what and how in the nuclear sector. This has a bearing on how identified nonconformities are reported and addressed. In some situations, international standards are invoked under legislation and the auditor should be aware when this applies (see Chapter 2).

Graded Application Requirements

Standards either require a graded approach or imply one, but often auditors are unable to interpret this requirement or assess an organisation's implementation. The auditor should have sufficient understanding of requirements for grading to enable them to assess, interpret and challenge the auditee's arrangements and their application (see Chapter 3).

Records

Records have an important status in the nuclear sector and are generally required to be retained for (what can be very) long periods. Auditors should be capable of assessing the auditee's retention periods and understand requirements for preservation and retrieval and issues surrounding records that are retained using electronic media (see Chapter 8).

Processes

Processes form the basis of management systems based on GSR Part 2 and ISO 9001. The auditor therefore should understand the requirements related to management and control of processes (as opposed to documents) and the interaction between processes as problems normally occur at the interfaces between processes. The auditor should understand the differences between processes and procedures and be capable of evaluating the effectiveness of processes in achieving their desired outputs.

Product Quality Requirements

The auditor should understand the sources of quality requirements relating to products. In many instances, such requirements are contained or implied in standards rather than being explicitly included in contracts or similar agreements. In many instances, the safety requirements are of equal importance to the quality requirements and evidence of

conformity and traceability is essential. This knowledge is needed in order to assess the auditee's ability to produce conforming product.

The Nuclear Baseline

This forms the basis for the core competence in the UK and influences organisational structure and human resources. The auditor should understand the roles of the intelligent customer and subject matter expert and how the auditee identifies and maintains core competence (see Chapter 3).

Control of Contractors/Agency Workers

Much work is now contracted or carried out by agency workers. The auditor should understand how the responsibilities of the organisation are retained and how work carried out through contracts or agency agreements is controlled by the organisation (see Chapters 3, 4, 5 and 6).

Owners/Parent Bodies/Site Licence Companies

The nuclear sector in the UK has undergone significant change in recent years. This affects ownership, operation and licensing. The auditor should understand the structure and interaction of the various bodies involved and understand where the authority and responsibility for the areas being audited lie.

Structure of the Organisation and Management of Change

The auditor should understand the nature and structure of the organisation and the management system that is the subject of the audit and how changes to it are managed. This may have significance in terms of understanding how responsibilities are properly allocated and how resources for certain activities such as safety are allocated (see Chapter 3).

Safety Case

The safety case underpins safety aspects of all work undertaken on or on behalf of a nuclear licensed site. The auditor should understand the basic principles of the safety case and how this influences or controls operations.

Operational Processes and Plant

The auditor should understand the basis of any operational processes, e.g. how a reactor works and factors affecting the manner in which the plant operates. This could include for example maintenance, outage and control systems. In some circumstances, this could include an understanding of the technology, reactor type or technical processes involved.

Configuration Management

This is relevant to management systems (how do parts of the organisation interact, especially when multiple organisations are involved), plant configuration and process interaction (see Chapters 3 and 5).

Traceability

The auditor should understand the importance of traceability to material specifications and material properties, and the ability to understand how to identify counterfeit items (see [6] and Chapters 4,5, 6 and 7).

9.2 Challenge

"Challenge" is not a requirement or term usually associated with management system standards but is one which is often heard on nuclear sites. It is used to describe the arrangements which satisfy the Office for Nuclear Regulation's (ONR) expectation for operators of nuclear facilities (licensees) to have an effective "challenge function", which enhances nuclear safety by presenting additional barriers to flawed decision making and inappropriate behaviours [15], [16]. The challenge function is independent of the people responsible for decision making or carrying out work, and its purpose is to identify poor decisions or performance and to resolve the issue before nuclear safety is adversely affected.

Examples of challenge functions within an operator's organisation are the nuclear safety committee, independent nuclear safety assessment and internal regulation.
In addition to detecting poor decision making and resolving poor performance, "challenge" can also provide a valuable contribution to the continual improvement of the management system, if an analysis and summary of the issues identified form one of the inputs into management review.

Appropriate challenge should be applied at all levels in the operator's organisation and be proportionate to the hazard involved. The arrangements for "challenge" should be documented in the management system.

Challenge can be applied in a number of ways at all levels in the organisation and may be a formal step in a process, a result of surveillance activity, or a challenge by an individual or group who is concerned that nuclear safety is being adversely affected by a poor decision or action. Examples of different methods of challenge which should be incorporated into the management system are shown below:

- Appropriate structure at board level which includes an appropriate number of non-executive directors who are competent to challenge decisions affecting nuclear safety and independent representation for nuclear safety, such as a safety director.
- An independent nuclear safety committee which provides advice to the operator. This is required by License Condition 13.
- Senior management meetings should include independent representation for nuclear safety (e.g. safety director or manager).

- Processes which involve taking decisions that may affect nuclear safety (e.g. producing safety cases, plant modifications, and management of changes) should include steps where decisions can be challenged by competent independent people. This may involve an independent person attending meetings or reviewing the decisions at another step in the process.
- Senior Managers should develop and, by their actions, actively promote a culture that encourages people at all levels in the organisation to have a questioning attitude and challenge decisions, actions or existing conditions which may adversely affect nuclear safety. The process for raising, reporting and resolving these concerns should be documented in the management system.
- An independent "challenge function" (e.g. internal regulation) with responsibility for the oversight of nuclear safety throughout the operators organisation is often established. This function usually carries out a number of activities to gather intelligence and information on the operator's nuclear safety performance. Activities can include on site surveillance of management decisions and actions, independent assessment and event investigation.

To promote the continual improvement of the management system, the "challenge function's" overview of nuclear safety performance and the concerns raised by its inspectors and auditors should be an important input into management review.

9.3 Learning from Experience

It is better to learn from someone else's mistakes rather than your own and the nuclear industry recognises that valuable lessons can be learned from events which occur either on the operators' own sites or which occur on nationally or internationally. One of the key attributes of a strong safety culture is that safety is learning-driven, and a questioning attitude should prevail through the organisation. The process for gathering, disseminating and using such information to improve safety performance is known in the industry as "Operating Experience" (OPEX) or "Learning from Experience" (LFE). A nuclear site's management system will usually include an LFE process which is administered by dedicated personnel.

Leaders within the organisation must support the LFE process and be role models for its implementation. Mechanisms for staff involvement in improvement, communication and knowledge sharing need to be in place. Industry suppliers often have their own arrangements for LFE in place.

Typically, an LFE process starts with the operator screening on site events and operating experience information from other sources to identify learning opportunities. Where appropriate, the events are investigated to identify the root causes. Root causes are often different to the immediate cause of the event and are frequently related to management issues rather than work related activities. Improvement actions can then be formulated to

address the root causes and prevent the event occurring or reoccurring on the operator's site. The operating experience process is monitored to ensure the process and the corrective and preventative actions taken are effective.

Nuclear sites usually participate in national and international event reporting systems, which provide participants with operational experience information from nuclear facilities around the world. IAEA and WANO both have LFE programmes. To fulfil their obligations to these programmes, operators identify the experience and learning, which is useful to the national and international community, and report this information to the coordinating body. In return, operators receive LFE feedback from the coordinating body relating to the experience of other participants.

To provide the input into the LFE process, operators may gather LFE information from a number of sources. Operators with more than one facility can make sure that all its facilities learn from events by gathering LFE from its facilities and ensuring this is disseminated and acted upon throughout its organisation. Further guidance on LFE is provided in IAEA publication SSG-50 [17].

The IAEA has a web-based incident reporting system, which is an international system jointly operated by the IAEA and the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development (OECD/NEA) [18]. Participating countries exchange experience to improve the safety of nuclear power plants by submitting event reports on unusual events considered important for safety. The Office of Nuclear Regulation is the national co-ordinator for the receipt and distribution of information to end users in the UK. The IAEA database is available to UK operators who therefore usually have access the information directly. Similar databases exist for fuel related events (IAEA/NEA Fuel Incident Notification and Analysis System) and research reactors (IAEA/NEA Incident Reporting System for Research Reactors (IRSRR)).

Members of the World Association of Nuclear Operators (WANO) can participate in its LFE programme, which relies on members reporting events and LFE is then analysed and disseminated to members.

Learning can also be gained from studying other non-nuclear national and international events, such as the Deep-Water Horizon accident in the USA or the Buncefield Fire in the UK.

New build and decommissioning sites may also obtain information from other parts of the construction sector.

Quality management system standards contain requirements for continual improvement, and management systems should include arrangements to continually improve processes and ensure the continuing suitability and effectiveness of the management system. Clearly,

to ensure that improvement activities are coordinated and prioritised appropriately, the LFE process must be aligned with and complement other improvement processes, and LFE should be an important input into management review. See also [19], [20], [21].

9.4 Non-conformity & Event Investigation

Licence Condition (LC) 7 places a duty on licensees to make and implement adequate arrangements for the notification, recording, investigation and reporting of such incidents occurring on the site. Licensees therefore have a strict legal duty to report incidents occurring on site. ONR publishes Guidance for Notifying and Reporting Incidents and Events to ONR [22]. Contractors on the nuclear site will be required to participate in the process by reporting events, cooperating in investigations and implementing improvements where appropriate.

Licence Condition 7 compliance arrangements usually use a number of levels of investigation depending on the severity or potential severity of the event. The levels of investigation may include simple trending analysis to identify precursors to declining performance, simple investigations carried out by supervisors or full root-cause analysis carried out by people who have been trained in root cause analysis techniques. The investigations identify corrective actions, which address the immediate and root causes of the event and prevent a recurrence.

On nuclear facilities, LC 17 requires quality management arrangements for all matters which may affect safety. This is in addition to any quality management arrangements which are in place to fulfil customer requirements. Consequently, non-conformities may be nuclear safety or product related. Examples of typical non-conformities found on nuclear sites are:

- All nuclear sites will have an event reporting and investigation process because site LC 7 places a strict legal duty on licensees to have “adequate arrangements for the notification, recording, investigation and reporting of such incidents occurring on the site”. Significant safety and environmental events must be reported to the Office of Nuclear Regulation or Environment Agency respectively. Operators usually have a single event reporting process, which captures all types of events and initiates corrective actions as appropriate. Events reported on site may encompass nuclear safety, industrial safety, the environment, plant defects, and any other types of abnormal events.
- Non-conformities found during internal or external audit or independent inspection activities.
- Non-conformities relating to products.

In quality management terms, all these undesirable events can be considered as non-conformances and controls, as required by quality management system standards, should be in place to prevent the inadvertent use of non-conforming products or processes and to

ensure that corrective action is taken. Events and other non-conformances are opportunities for improvement and will usually be inputs into other management system improvement processes such as 'Operating Experience / Learning from Experience' and 'Management review'.

Nuclear operators recognise that the reporting of poor performance, plant defects, unsafe behaviours is very important to nuclear safety and therefore it is common practice to develop a 'no blame' or 'just reporting' culture which actively encourages people to report all unsafe conditions or defects without fear of action being taken against them.

Operators will have systems for assessing the impact of non-conformances and determining their safety significance and impact. Due priority is given to nuclear safety when developing corrective actions and such actions should always be conservative, so safety is not compromised.

Quality standards require the causes of non-conformities to be determined and remedial actions taken to prevent their recurrence. The LFE process usually fulfils this requirement for site events, but additional systems may be needed for plant defects or product-related non-conformities.

Operators should have a process to monitor and report the status of corrective and preventative actions resulting from all types of events and non-conformances.

Where non-conformities relate to plant condition either during construction or in operation, remedial action will usually be to replace the item like for like or to repair the item to original specification. In both cases, this resolves the non-conformity by meeting the original specification and not affecting the design. If, however, a different item is fitted or a concession is raised to accept the item 'as is', the operator may have to produce an LC 20 [23] or LC 22 [24] submission which justifies the safety of the change.

Quality management standards require the causes of nonconforming products to be eliminated and this usually involves carrying out some kind of investigation into the causes of the non-conformity. On nuclear sites, the requirement to investigate events is more onerous because site LC 7 places a strict legal duty on licensees to make and implement adequate arrangements for the investigation of incidents occurring on the site. Also, because quality non-conformities are likely to have safety implications the management of health and safety at work regulations apply and their approved code of practice states that "monitoring includes... adequately investigating the immediate and underlying causes of incidents and accidents to ensure that remedial action is taken, lessons are learnt and longer-term objectives are introduced". The site's LC 7 compliance arrangements therefore usually cover the requirements for identifying and eliminating the causes of non-conformity. Additional arrangements may be needed to cover product related non-conformities.

HSE [25] and the Energy Institute [26] have produced guidance on Investigating accidents and incidents.

9.5 Management Review

Quality management system standards require organisations to undertake management review to ensure the continuing suitability and effectiveness of their management systems. Nuclear sites are no different in this respect but because LC 17 requires “adequate quality management arrangements for all matters which may affect safety”. The reviews must cover nuclear safety performance and associated processes in addition to any product quality related review.

ISO 9001 contains requirements and identify a number of inputs into management reviews. IAEA GSR Part 2 requires periodic reviews to be carried out with guidance on inputs and outputs given in IAEA GS-G-3.1 Application of the Management System for Facilities and Activities.

Inputs that are typically considered by licensees are:

- Outputs from all forms of assessment;
- Results delivered and objectives achieved;
- Non-conformances and corrective and preventive actions;
- Opportunities for improvement
- Effectiveness of risk mitigation actions;
- Lessons learned from other organizations to be included in the reviews (this is unique to the IAEA standard and is linked to the principle of operating experience).

On nuclear sites activities are closely monitored by performance indicators, and many internal and external bodies carry out independent or regulatory assessment of the management system. The potential amount of information which can form the input into management review is huge. The range of inputs can include:

- Internal audit reports and the internal regulators inspection reports;
- Status of actions from past management reviews;
- Reports from peer reviews, external audits and regulatory inspections;
- Nuclear safety performance indicators;
- Outputs from the annual review of safety presented to ONR;
- Event reports and defect reports;
- Opportunities for improvement from any source;
- Output from the LFE process identifying lessons which can be learned from other organisations;
- Feedback on the satisfaction of interested parties (e.g. customers, owners, operators, employees, suppliers, partners, trade unions, regulators);

- The performance of suppliers;
- The control of process and product non-conformances.

To enable managers to clearly understand what all this information is telling them about the organisations performance and the management system, it is essential that careful thought is given to the information provided for management review and its presentation. With a lot of information available, it is very easy to fall into the trap of discussing individual events rather than taking a wide overview of how the organisation is performing as a whole. It is often appropriate to provide a summary of the information for management review. The information provided should allow senior managers to concentrate on identifying improvement opportunities, prioritising improvement actions and deploying resources to carry them out.

An organisation may have an integrated management system, which directs and controls nuclear safety, nuclear site licence compliance, conventional safety, environmental management, commercial and financial management. If a single management review is carried out, care must be taken to give due priority to nuclear safety, so it is not overwhelmed by other review activities. If they are coordinated effectively, a series of management reviews covering each part of the system may be more effective than a single meeting.

The output from management review includes the decisions and actions relating to improving the management system and its processes. Due consideration should be given to safety and improvement actions should be prioritised accordingly. The resources needed to realise the improvements should be identified.

9.6 Benchmarking

Benchmarking allows organizations to compare their performance and approach with others and identify good practices which can help the organisation improve its safety and quality performance. Benchmarking can be a one-off or continual process which allows an organisation to improve its processes. Standard benchmarking techniques can be readily applied in the nuclear industry where an organization can find a suitable and willing benchmarking partner. However, this can be difficult as the activities carried out by UK nuclear operators are very diverse and, in some cases, there is little similarity in their processes.

Fortunately, there are many organizations and industry groups which encourage operators to challenge their own performance and learn from the experience of others (e.g. IAEA, WANO, INPO and Regulators). Consequently, there is a lot of information available which can be used to benchmark performance against good practice and to identify opportunities for improvement. Indeed, the World Association of Nuclear Operators states its mission is “to maximise the safety and reliability of nuclear power plants worldwide by working

together to assess, benchmark and improve performance through mutual support, exchange of information and emulation of best practices".

Good sources of such information are:

- IAEA Publications, including safety standards and guides [27].
- WANO website, including the WANO performance objectives and criteria. More information will be available to organizations who are WANO members.
- ONR publishes its guidance to inspectors in the form of Technical Inspection Guides [28] and Technical Assessment Guides [29] which describe relevant good practice.

UK licensees are represented at the UK nuclear industry Safety Directors' Forum (SDF) that publishes Best Practice Guides, Codes of Practice and other documents [30].

9.7 Continual Improvement – Improvement Programmes

In the nuclear industry, the principle of continual improvement is well understood and is encouraged by stakeholders and regulators throughout the industry. Quality improvement tools (e.g. Six Sigma, PDCA cycle, quality circles and TQM) can be used to improve quality and safety performance, and operators must determine how such tools are best deployed within their organisations. The nuclear industry also has a number of other mechanisms which drive continual improvement, and these are often used in preference to other improvement tools used in wider industry.

Poor safety or quality performance in the nuclear industry can result in very serious consequences, so, in addition to voluntary quality improvement programmes on nuclear sites, LC 15 places a legal duty on the licensee to "make and implement adequate arrangements for the periodic and systematic review and reassessment of safety cases" [31]. ONR's guidance to its inspectors [32] states the purpose of the periodic review of safety (PSR) is to determine, by assessment against modern standards, whether the plants, processes, management, operations and facilities covered by a safety case are safe, and that ageing and other time-related phenomena will not render them unsafe before the next PSR. Where modern standards are not met, the PSR should assess the significance of the shortfalls, and identify reasonably practicable improvements. The periodic review is usually carried out every ten years and for most facilities will initiate a significant improvement programme. Improvements may be physical improvements to the plant or improvements to the associated management arrangements including operating rules, operating instructions and the plant maintenance schedules.

Operators can invite international organisations such as the IAEA's OSART (Operational Safety Review Team), the World Association of Nuclear Operators (WANO), or the Institute of Nuclear Power Operations (INPO) to undertake peer reviews on their facilities. Such reviews are thorough and usually identify many opportunities for improvement.

Improvement programmes are often initiated in response to such reviews in order to track and manage corrective and preventative actions.

Regulators carry out compliance inspections to confirm that operators fulfil their legal duties. If a compliance inspection identifies a significant shortfall against a legal requirement, the regulator may take enforcement action and require an operator to develop and carry out an improvement programme to achieve compliance. It is always better for an operator to demonstrate robust self-regulation by identifying a shortfall and developing an improvement programme rather than allowing the regulator to find the shortfall.

9.8 References

[1] ISO 9001:2015 Quality management systems. Requirements

[2] ISO 19011:2018 Guidelines for auditing management systems

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006). Available at: https://www.iaea.org/publications/7466/the-management-system-for-facilities-and-activities

[4] ONR Technical Inspection Guide NS-INSP-GD-017 LC17 - Management Systems. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016). Available at: https://www.iaea.org/publications/11070/leadership-and-management-for-safety

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006). Available at: https://www.iaea.org/publications/7467/application-of-the-management-system-for-facilities-and-activities

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, OSART Guidelines, IAEA Services Series No. 12 (Rev. 1), IAEA, Vienna (2016). Available at: https://www.iaea.org/publications/10992/osart-guidelines

[8] World Association of Nuclear Operators (WANO). Available at: https://www.wano.info

[9] Institute of Nuclear Power Operations (INPO). Available at: https://inpo.info/

[10] ISO 14001 Environmental management systems — Requirements with guidance for use

[11] ISO 45001 Occupational health and safety management systems — Requirements with guidance for use

[12] IAEA/WANO, Guideline – Independent Oversight, GL 2018-01, January 2018. Available at: https://www.iaea.org/sites/default/files/20/09/wano-guideline-independent-oversight.pdf

[13] Nuclear Industry Safety Directors Forum, The UK Nuclear Industry Good Practice Guide To: Independent Oversight, Issue 2, December 2018. Available at:

https://www.nuclearinst.com/write/MediaUploads/SDF%20documents/IOWG/SDF_sub-group_Good_Practice_Guide_Issue_2.pdf

[14] ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications, 2017.

[15] ONR Technical Assessment Guide NS-TAST-GD-080 Nuclear Safety Advice and Independent Challenge. Available at: https://www.onr.org.uk/operational/tech_asst_guides/index.htm

[16] ONR Technical Inspection Guide NS-INSP-GD-013 LC13 - Nuclear Safety Committee. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Operating Experience Feedback for Nuclear Installations, IAEA Safety Standards Series No. SSG-50, IAEA, Vienna (2018). Available at: https://www.iaea.org/publications/12293/operating-experience-feedback-for-nuclear-installations

[18] IAEA Incident Reporting Systems for Nuclear Installations. Available at: https://www.iaea.org/resources/databases/irsni

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Nuclear Installations, IAEA Safety Standards Series No. GS-G-3.5, IAEA, Vienna (2009). Available at: https://www.iaea.org/publications/8090/the-management-system-for-nuclear-installations

[20] ONR, Internal operational instructions and guidance. Available at: https://www.onr.org.uk/operational/index.htm.

[21] ONR Technical Inspection Guide NS-INSP-GD-007 LC7 - Incidents on the Site. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[22] ONR, Notify ONR. Available at: https://www.onr.org.uk/notify-onr.htm.

[23] ONR Technical Inspection Guide NS-INSP-GD-022 LC22 - Modification or experiment on existing plant. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[24] ONR Technical Inspection Guide NS-INSP-GD-022 LC22 - Modification or experiment on existing plant Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[25] HSE, Investigating accidents and incidents, HSG245, 2004. Available at: https://www.hse.gov.uk/pubns/hsg245.pdf

[26] Energy Institute, Guidance on Investigating and Analysing Human and Organisational Factors Aspects of Incidents and Accidents, May 2008. Available at: https://publishing.energyinst.org/__data/assets/pdf_file/0016/3382/guidancemay08.pdf

[27] IAEA, Publications. Available at: https://www.iaea.org/publications

[28] ONR, Compliance inspection - Technical inspection guides. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[29] ONR, Permissioning inspection - Technical assessment guides. Available at: https://www.onr.org.uk/operational/tech_asst_guides/index.htm

[30] Nuclear Institute, Safety Directors' Forum (SDF) Publications. Available at: https://www.nuclearinst.com/SDF-publications

[31] ONR Technical Inspection Guide NS-INSP-GD-015 LC15 - Periodic review. Available at: https://www.onr.org.uk/operational/tech_insp_guides/index.htm

[32] ONR Technical Assessment Guide NS-TAST-GD-050 Periodic Safety Reviews. Available at: https://www.onr.org.uk/operational/tech_asst_guides/index.htm

Revisions

Revision date	Description	Contributors	Editors
January 2019	Hypertext links checked and updated. Minor textual changes made reflecting formation of ONR in April 2014, formerly NII / HSE. Text updated to reflect GS-R-3 superseded by IAEA GSR Part 2 and updates to ISO standards.	Richard Hibbert, Graham Watson	David Morgan
January 2023	Content and format updated by NNG.	NNG Steering Group	NNG Steering Group