



ONR GUIDE			
<b>LC 23: OPERATING RULES</b>			
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## 1 INTRODUCTION

- 1.1 Many of the licence conditions attached to the standard nuclear site licence require, or imply, that licensees should make arrangements to comply with regulatory obligations under the conditions. ONR inspects compliance with licence conditions, and also with the arrangements made under them, to judge the suitability of the arrangements made and the adequacy of their implementation. Most of the standard licence conditions are goal-setting, and do not prescribe in detail what the licensees' arrangements should contain; this is the responsibility of the duty-holder who remains responsible for safety. To support inspectors undertaking compliance inspection, ONR produces a suite of guides to assist inspectors to make regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of activities on the site. This inspection guide is one of the suite of documents provided by ONR for this purpose.

## 2 PURPOSE AND SCOPE

- 2.1 This guide has been prepared to facilitate a sound basis and consistent approach to Licence Condition (LC) 23 compliance inspections and to provide guidance to inspectors whilst inspecting licensees' arrangements in this area. The guide is complementary to T/AST/035, which gives guidance concerning the identification and derivation of limits and conditions from safety cases, as required by LC23. It is therefore recommended that inspectors familiarise themselves with the overview section of T/AST/035 and the terminology used before proceeding further with this guide. The two guides together describe how international good practice in regard to the identification, derivation and implementation of operational limits and conditions fits within the UK nuclear safety regulatory context.
- 2.2 As explained in T/AST/035, the licensee's approach should be targeted and proportionate, focussing its safety management controls on the most important limits and conditions. Reflecting this, the guidance presented here is intended to apply predominantly to all Operating Rules in Tiers 2 and 3 of the hierarchy described in T/AST/035 (termed High Hazard Operating Rules) together with any other Operating Rules that the licensee considers need to be subject to similar levels of control. Other (Tier 1 – Low Hazard) Operating Rules should be embedded into relevant Operating Instructions or other process-level documentation and need not be subject to the same safety management processes as used for Operating Rules in Tiers 2 and 3. However, the Tier 1 Operating Rules should still be identified within the safety case, so there is an auditable trail from the safety case to the Operating Instructions and thus this ensures that they are not potentially overlooked when changes are undertaken, either in safety case methodology or in modifications or experiments on plant under LC 22.
- 2.3 T/AST/035 emphasises that Operating Rules must be derived from the safety case. The subset of Operating Rules in Tiers 2 and 3 of the licensee's hierarchy should be sufficient to ensure that all safety functions needed for nuclear safety will be delivered appropriately, namely those necessary for:
- Control of reactivity / criticality;
  - Removal of heat;
  - Confinement or containment of radioactivity (including shielding)

- 2.4 Additionally, in line with international good practice, T/AST/035 suggests that Operating Rules should be in place to support all levels of the Defence in Depth hierarchy (see SAPs para 149ff and Table 1). In particular, inspectors should expect to see the following types of Operating Rules implemented:
- Limits and conditions for normal operation (both parametric and for plant (e.g. safety measure) availability);
  - Limits on safety system settings;
  - Surveillance requirements;
  - Safety Limits (as defined in T/AST/035).
- 2.5 In addition, there should be suitable margins between the defence in depth levels to ensure suitable independence between successive barriers.
- 2.6 The Operating Rules should define a safe operating envelope for the operator to implement, the envelope being as close to routine operations as reasonably practicable. Robust managerial controls should be in place to ensure that the facility is operated within this envelope. These managerial controls, supported by appropriate alarms and indications, provide the first line of defence for safe operation. If for whatever reason, the facility moves outside the safe envelope, a second line of defence, ideally in the form of engineered protection, should be in place to return conditions to a safe state.
- 2.7 The limits contained in the Operating Rules should cover relevant parameters such as pressures, temperatures and the settings of equipment required for nuclear safety. The settings include those on engineered protection systems, or where protection is provided by an operator acting upon alarms or indications, the alarm or indication settings.
- 2.8 The conditions contained in the Operating Rules should include the availability of equipment and staffing levels needed for nuclear safety (See Ref. 2, reference level H8.1). Such equipment could include standby pumps, batteries, essential alarms and indications, and equipment to deal with nuclear emergencies. These matters need to be controlled by Operating Rules because 'at all times' in LC 23(3) leads to the need for positive compliance.
- 2.9 This guide should not be regarded as either comprehensive or mandatory – inspectors should apply discretion, experience and judgement when deciding what aspects of the licensee's LC23 compliance arrangements are to be inspected. The guidance is divided into four main elements:
- The purpose of the Licence Condition;
  - Guidance on arrangements / procedures for LC23;
  - Guidance on inspection of arrangements / procedures;
  - Guidance on inspection of implementation of arrangements / procedures.
- 2.10 This guide, along with other TAGs and TIGs, has been written to be consistent with (Ref. 2) the Western European Nuclear Regulators Association (WENRA) Safety Reference Levels (SRL) for existing reactors, (See Ref. 2) which addresses Operational Limits and Conditions. Furthermore, there is also WENRA SRL for Waste and Spent Fuel storage (See Ref 6.). The SRL are based on the IAEA safety standards, represent good practices in the WENRA member states and provide a consensus view of the main requirements to be applied to ensure nuclear safety. The UK is committed to aligning its regulatory guidance with the WENRA SRL and in keeping with ONR's guidance on the demonstration of ALARP (Ref. 4), inspectors should consider the WENRA SRL to be Relevant Good Practice for civil nuclear reactors, etc.

### **3 LICENCE CONDITION 23: OPERATING RULES**

- 3.1 23(1) The licensee shall, in respect of any operation that may affect safety, produce an adequate safety case to demonstrate the safety of that operation and to identify the conditions and limits necessary in the interests of safety. Such conditions and limits shall hereinafter be referred to as Operating Rules.
- 3.2 23(2) The licensee, where the ONR so specifies, shall refer the Operating Rules arising from paragraph (1) of this condition to the relevant nuclear safety committee for consideration.
- 3.3 23(3) The licensee shall ensure that operations are at all times controlled and carried out in compliance with such Operating Rules. Where the person appointed by the Licensee for the purposes of condition 26 identifies any matter indicating that the safety of any operation or the safe condition of any plant may be affected that person shall bring that matter to the attention of the licensee forthwith who shall take appropriate action and ensure the matter is then notified, recorded, investigated and reported in accordance with arrangements made under condition 7.
- 3.4 23(4) The licensee shall submit to ONR for approval such of the aforesaid Operating Rules as ONR may specify.
- 3.5 23(5) The licensee shall ensure that once approved no alteration or amendment is made to any approved Operating Rule unless ONR has approved such alteration or amendment.
- 3.6 23(6) Notwithstanding the preceding provisions of this condition ONR may, if in its opinion circumstances render it necessary at any time, agree to the temporary suspension of any approved Operating Rule.

### **4 PURPOSE OF LICENCE CONDITION 23**

- 4.1 LC23(1) is intended to ensure that all operations that may affect safety are supported by an adequate safety case and that this safety case identifies the conditions and limits needed to ensure that the facility, plant or process is kept in a safe condition. It applies to all operations as identified in LC1(1) and all permitted modes of operation, i.e. not just to the principal operations or processes carried out at the facility.
- 4.2 LC23(3) requires the licensee to carry out all its operations in accordance with the Operating Rules identified under LC23(1), i.e. to operate within the safety case. It also requires the licensee to act if and when an appointed Suitably Qualified and Experienced Person (SQEP) is concerned either about the safety of the facility, or one of its operations. Inspectors should note that the wording used here is not limited to concerns in regard to whether the safety case is being complied with, but extends to any concern related to safety, including whether the safety case prepared under LC23(1) is adequate.
- 4.3 LC23(3) requires the licensee to “ensure that operations are at all times controlled and carried out in compliance with such Operating Rules”. Therefore the licensee should be able to demonstrate via suitable managerial controls that this is achieved, recognising that there may be Operating Rules which only apply in certain operational states. For the purposes of demonstrating compliance, the interpretation of “at all times” should take into account reasonable practicability and arguments made in the safety case. For example, in some instances, “at all times” may translate into checks made once per shift.
- 4.4 LC23(2) and LC23(4) provide a means for a graded approach to Operating Rules, whereby the most important limits and conditions may be referred to a relevant Nuclear

Safety Committee (NSC) and/or approved by ONR. T/AST/035 provides guidance on criteria for determining which Operating Rules should be subject to high level managerial or regulatory control measures. There should also be a clear understanding that, for the purposes of LC23, Operating Rules may be approved (frozen) or not approved by ONR, depending on the degree of regulatory control deemed necessary by ONR.

- 4.5 Where necessary, the implementation of Operating Rules is through LC24(2) which requires that written instructions are produced and then used. Inspectors should note the distinction made between limits and conditions, which are constraints on how the facility, plant or process should be operated, and instructions, as required by LC24(2), necessary to ensure that any Operating Rules are implemented. A key implication of this distinction is that the conditions and limits derived under LC23(1) need to be set in terms of verifiable operational states or conditions.
- 4.6 In addition LC27 (Safety Mechanisms, Devices and Circuits) is of indirect relevance, as it places an explicit duty on the licensee to operate (etc) its facility in accordance with limits and conditions relating to the design and number (suitability and sufficiency), availability (connectedness) and condition (working order) of the safety equipment. These limits and conditions are necessary in the interests of safety and so need to be derived in the safety case. There is thus an overlap in the duties deriving from LC27 and LC23. Inspectors should therefore seek adequate arrangements for these two licence conditions that in combination ensure that any safety mechanisms, devices and circuits identified by the safety case as being necessary in the interests of safe operations will be available whenever required. However, provided all the duties under LC23 and LC27 are delivered by the totality of the licensee's arrangements, inspectors should not be prescriptive as to where within these arrangements specific provisions should reside.
- 4.7 Although LC23 imposes specific requirements on the licensee, rather than a requirement to make and implement adequate arrangements, we would nevertheless expect that written procedures are produced to ensure and make visible compliance with the various aspects of this condition (referred to as "arrangements" in this guidance).

## **5 GUIDANCE ON INSPECTION OF ARRANGEMENTS AND THEIR IMPLEMENTATION**

- 5.1 The arrangements should address all the licence condition requirements. These should be readily available and should be reasonably up to date, signed by an appropriate senior manager and controlled under a quality management system compliant with the requirements of LC17. The arrangements should utilise a clear and consistent terminology, e.g. in regard to terms such as "Operating Rule", which may differ from the terminology used in ONR's guidance.
- 5.2 The arrangements should state that a safety case will be produced for all operations that may affect safety. "Operations" should be defined in accordance with LC1 and thus include maintenance, examination, testing and operation of the plant and the treatment, processing, keeping, storing, accumulating or carriage of any radioactive material or radioactive waste.
- 5.3 Operating Rules are used to define the control measures, both engineering and management arrangements, to be put in place to ensure that, should a fault occur, the facility will remain safe. They define the limits of normal operations together with any other limits or conditions needed for nuclear safety (e.g. to be applied in fault / accident conditions). Operating Rules are derived from the safety case and are the means through which the licensee confirms the safety case is complied with. They should be

- meaningful to the operators and should be set in measurable terms or otherwise measurable surrogates should be provided.
- 5.4 The safety case should identify all Operating Rules necessary in the interests of safety, together with how frequently and the circumstances under which, these should be monitored against. The safety case should also explain the importance of the Operating Rule within the facility's overall Defence in Depth framework. This Technical Inspection Guide has been written to focus principally on the more important (High Hazard) Operating Rules (Tier 2 and Tier 3). Inspectors should however decide on a case by case basis, the degree to which it is reasonable to expect similar standards for other (Tier 1 – Low Hazard) Operating Rules identified in the licensee's safety case.
  - 5.5 The Operating Rules should be documented within operational procedures in a manner that ensures that relevant portions of the safety case will be complied with at all times. The operational procedures should address all the actions to be taken and the limitations to be observed by operating personnel. Each Operating Rule should be clearly linked to the underlying nuclear safety concern(s) that led to its derivation and substantiated through a written statement providing the reason(s) for its adoption. The safety case should summarise key aspects, including the risks and radiological consequences that arise from failing to comply, and be written in a style and at a level that is meaningful to all its users, sufficient to allow them to be suitably informed when performing their duties. The linkage between the safety case and Operating Rules may be achieved by means of an appropriately detailed commentary. For the sake of transparency and consistency, the commentary should make reference to the relevant parts of the underlying safety case, so that the detailed aspects may be readily accessed whenever necessary. Where an Operating Rule is in place as a defence against more than one safety concern, but has been derived to cater for the most operationally-limiting fault, the commentary should nevertheless provide details of all relevant aspects for which the Operating Rule provides (or assists with) a defence.
  - 5.6 Arrangements should ensure that the Operating Rules are readily accessible to personnel with responsibility for ensuring they are complied with (See Ref. 2, reference level H3.1). Ideally, the set of Operating Rules and any accompanying commentaries should be combined into a single document, or failing this, as few documents as is reasonably practicable. This is to ensure that those with responsibility for the safety of the facility are familiar with all of the key limits and conditions within which they need to work and are aware of the risks from failing to comply. This / these document(s) would not normally list any Tier 1 (Low Hazard) Operating Rules, which should instead be documented in LC24 Operating Instructions. However, it should be remembered that all safety cases should identify all Operating Rules, including Tier 1 (Low Hazard) Operating Rules.
  - 5.7 The arrangements should ensure that Operating Rules are clearly presented, avoid ambiguity, and have technical terms explained so as to prevent any misinterpretation. In order to achieve this, the advice of human factors experts may be sought where appropriate. Each Operating Rule should be stated in such a manner that it is absolutely clear whether a breach has occurred.
  - 5.8 Following on from this, it is essential that each Operating Rule is meaningful to those charged with ensuring compliance. The circumstances in which they apply and the terms in which they are expressed should thus be defined in terms of measurable or directly observable parameters or conditions. Where measurable or directly observable parameters or conditions cannot be used, the relationship between the limiting parameter / condition and another (surrogate) measurable / observable parameter / condition should be demonstrated in the safety case.
  - 5.9 Arrangements should ensure that personnel with responsibility for the safety of the facility (e.g. control room operators) should be thoroughly familiar with the intent and

content of the Operating Rules in order to comply with the provisions contained therein and to ensure appropriate decision-making (See Ref. 2, reference level H3.2). This requires suitable training in order that they fully understand the limitations and capabilities of the plant and equipment under their control, together with relevant portions of the facility's safety case. The system should ensure that when changes are made, the operators are made promptly aware.

- 5.10 The arrangements should set out clearly how often surveillances are carried out to check compliance with the Operating Rules (See Ref. 2, reference level H9.1). The justification for these surveillance requirements should be covered in the safety case. Supporting details should be set out in the Operating Instructions to be followed by operators, which should be clear and explicit in regard to:
- What has to be checked (e.g. parameters within limits, plant configurations, equipment availability (especially of safety measures));
  - Under what circumstances the checks need to be carried out (e.g. in what permitted operating mode, or at what Level in the SAPs' Defence in Depth Framework);
  - What the acceptance criteria are;
  - How often the monitoring and surveillance needs to be undertaken;
  - What records need to be made;
  - Who is responsible for undertaking each specified activity.
- 5.11 The frequency at which compliance with Operating Rules needs to be monitored will vary considerably, depending on the type of Operating Rules and facility, and on other factors considered in the safety case. For example, operational parameters (e.g. temperatures, pressures chemical composition) might require a frequent (e.g. hourly etc), formal, recorded check in addition to any on-line continuous observations by the operators. In contrast, plant availability checks might appropriately be performed on a less frequent basis, e.g. at every shift handover. However, checks for Operating Rules set for unusual operating modes (e.g. during phases of a reactor start-up) might only take place a few times per year.
- 5.12 While the focus of the licensee's surveillance and monitoring arrangements should (naturally) be on normal operations, it is crucial to the overall Defence in Depth philosophy that there is also appropriate focus on Operating Rules that need to be met for fault and accident conditions.
- 5.13 Additionally, in line with the fact that more and more waste storage facilities are being constructed and operated and also the intent is for defueled reactors to be placed into long term care and maintenance, there is a need to ensure that the revised Operating Rules for such facilities are properly defined within the safety case and are set in suitably measurable terms (See Ref. 6, reference levels S-26 and S-27). It should be noted that in such cases, surveillance inspections will be infrequent, with long gaps, potentially years, between inspections. Thus any such Operating Rules must have robust margins of safety associated with them and this must be demonstrable within the safety case.
- 5.14 Arrangements should ensure that where a situation arises in which, for any reason, the operators do not understand the prevailing operational state or cannot demonstrate that the facility is being operated within its Operating Rules, or the plant behaves in an unpredicted way, measures should be taken without delay to bring the facility to a safer state (See Ref. 2, reference level H7.1). Further activities to re-establish Operating Rule compliance should then be taken as a matter of priority and the facility / process only returned to service once it has been shown as safe to do so (See Ref. 2, reference level H7.2). The actions necessary to achieve these tasks should be set out in detail in the Operating Instructions, so far as is reasonably practicable.

- 5.15 Arrangements should ensure that in the event of non-availability of plant or equipment important to safety, and where the Operating Rules provide for a time limit before there is a breach (e.g. to allow the equipment to be restored, or to bring alternative equipment into service, or to shutdown the process), the procedures should require immediate action so that any period of elevated risk is minimised (See Ref. 2, reference levels H7.1, H10.1).
- 5.16 The arrangements should ensure that Operating Rules and any associated Operating Instructions are supported by appropriate safety management arrangements which ensure that all limits and conditions identified in the safety case are complied with at all times. These management arrangements should ensure that:
- The Operating Rules are implemented consistent with the intent of the safety case;
  - The facility is controlled compliant with the Operating Rules;
  - Any breaches of Operating Rules are reported and acted upon; and
  - Compliance with Operating Rules is routinely reviewed.
- 5.17 Guidance on each of these aspects is provided in the following paragraphs.
- 5.18 The licensee's safety management arrangements should include a systematic and rigorous configuration management process linking the safety case to the Operating Rules and associated Operating Instructions, to ensure that each Operating Rule is implemented as intended, and that the suite of documentation remains self-consistent. The process should control the prompt update of changed Operating Rules, the deletion / suspension of unnecessary Operating Rules, and the implementation of any temporary Operating Rules. The arrangements supporting suspensions of Operating Rules or temporary Operating Rules should ensure that these are controlled with the same rigour as permanent Operating Rules. Additionally, temporary Operating Rules should be subject to pre-determined time constraints, after which consideration should be given to making them permanent (See Ref. 2, reference level H2.3).
- 5.19 Arrangements should ensure that changes to Operating Rules are treated in an analogous manner to plant changes. Safety cases justifying Operating Rule changes should be categorised and processed accordingly. Of concern in new-build construction are the conditions and limits that bound future operations in terms of Basis of Design parameters (e.g. inventory limits, pressure limits, etc.). Where safety cases may be phased, such Operating Rules identified in the first phase, e.g. civil construction, may be impacted upon by changes in design during subsequent phases, such as Building Services Installation or Process Plant and Equipment installation. Such future submissions have the capability to subvert the original Operating Rules defined in the initial submission or make greater claim on the relevant piece of equipment by placing new Operating Rules upon it that were not originally envisaged. Care must be taken by inspectors to ensure the visibility of Operating Rules during such phased construction applications especially Tier 1 (low hazard) Operating Rules as these can easily get forgotten and/or lost in the plethora of safety documentation. This could then result in ONR facing reverse ALARP arguments that were unanticipated and could be avoided.
- 5.20 The arrangements should clearly identify who is responsible for ensuring compliance with each Operating Rule. Persons given this responsibility by the licensee should be Duly Authorised in the case of Tier 2 and Tier 3 (High Hazard) Operating Rules, in accordance with LC12.
- 5.21 The licensee's arrangements should ensure that any breach of an Operating Rule is:
- Acted upon promptly and appropriately;



- Reported (notified) in a suitable and timely manner to ONR consistent with its LC7 arrangements (LC23(3));
  - Investigated, reviewed and evaluated by suitably qualified and experienced persons at an appropriate level of authority within the licensee's organisation;
  - Recorded and documented in a form that facilitates learning from experience and the promulgation of good practice;
  - Taken into account within the safety case of this and other facilities under the licensee's control.
- 5.22 As such, the Licensee's procedures should describe the detailed arrangements for ensuring each of these aspects is performed to an adequate extent (See Ref. 2, reference level H10.2).
- 5.23 The licensee's arrangements should ensure that records demonstrating compliance with Operating Rules are made and stored. These records should be evaluated and then retained in accordance with the licensee's LC6 arrangements (See Ref. 2, reference level H9.1). The evaluation process should be used to provide further assurance, in addition to that from the time of the operations, that the Operating Rules were indeed complied with. The evaluation process should be undertaken by persons independent of those who were responsible for the original records. The evaluation process should also include regular periodic reviews to ensure that the Operating Rules remain pertinent in the light of operating experience (at this facility and elsewhere), modifications to the facility and any relevant wider developments in science or technology, and then changed as necessary(See Ref. 2, reference level H2.2).
- 5.24 The arrangements should recognise that ONR may specify that Operating Rules be referred to a relevant NSC for consideration. Consideration of Operating Rules should therefore appear within the general terms of reference for the licensee's NSC through its LC13 arrangements.
- 5.25 The procedures should include provision for the temporary suspension of an approved Operating Rule (or parts of it) following the agreement of ONR in accordance with LC23(6). Any request to ONR for such suspensions should include a clear safety justification, the period for which the suspension is required, indicate what temporary procedures will be in place during this period, and have completed due process in the licensee's system.
- 5.26 The arrangements should show how the licensee will respond to a Specification issued under LC23(4) and will ensure that once approved these Operating Rules will not be altered without a further approval. In the event that a licensee proposes to modify any Operating Rule previously approved by ONR in accordance with LC23(4), the arrangements should reflect the need for an application to be made to ONR to modify it in accordance with the requirements of LC23(5).
- 5.27 In 2015, ONR undertook a review of existing approvals to Operating Rules on operational reactor sites and proposed a series of reforms to the way in which ONR regulates this area. This will result in the withdrawal of approvals to individual Operating Rules across the existing fleet of reactors in two phases in 2016.
- 5.28 As part of the proposed reforms, ONR will continue to approve over-arching conditions and limits of operation which set out the protocols for operating in compliance with and managing changes to Operating rules that define the safe operating envelope. Such limits and conditions of operation will require licensees to submit to ONR for consideration, in accordance with arrangements for controlling modification under LC22(1), only the highest classification of changes to Operating Rules. This will allow ONR greater discretion to permission or inspect modifications to Operating Rules in an elective rather than obligatory manner. Inspectors should, as part of LC23 inspections

on such sites, satisfy themselves that changes to Operating Rules have been classified appropriately.

- 5.29 The new regulatory footprint also safeguards, through the elective use of derived powers from licensees arrangements, ONR's ability to permission or register a flexible holdpoint to any proposed amendment to any classification of Operating Rule should the need arise. Typically, ONR will prioritise consideration changes of Tier 2 or 3, High Hazard, Operating Rules.
- 5.30 Further detailed guidance on specific aspects of licensee's LC23 arrangements for use during inspections are provided in the Annex.
- 5.31 Inspectors should focus their inspection of Operating Rule implementation on Tier 2 and Tier 3 (High Hazard) Operating Rules, as these are the most important from a nuclear safety perspective. However, limited inspection of Tier 1 (Low Hazard) Operating Rule implementation may also be carried out as appropriate, commensurate with overall priorities.
- 5.32 Inspectors should review the Operating Rules and select a sample for inspection. This should involve an examination of the safety case looking at consistency between the Operating Rules and the safety case and the adequacy of the justification supporting the selected Operating Rules.
- 5.33 Detailed guidance on specific aspects for review during LC23 inspections provided in the Annex, covering:
  - Safety case/user friendliness/operator awareness
  - Link to safety case and justification
  - Scope and clarity
  - Surrogate parameters
  - Safety limits and margins
  - Safety measures and set points
  - Alarms and indications
  - Change control and review
  - Accessibility
  - Operating Instructions
  - Surveillance/compliance
  - Operator actions
  - Notification of breaches

## 6 REFERENCES

- 1 Technical Assessment Guide: Limits and Conditions for Nuclear Safety (Operating Rules) T/AST/035
- 2 Report Western European Nuclear Regulators Association (WENRA) Safety Reference Levels for Existing Reactors, 24<sup>th</sup> September 2014 – <http://www.wenra.org>
- 3 "Safety Assessment Principles for Nuclear Facilities", 2014 Edition (Rev 0), November 2014.
- 4 Technical Assessment Guide, Demonstration of ALARP, T/AST/005
- 5 International Atomic Energy Authority (IAEA) Operational Limits and Conditions and Operating Procedures for Nuclear Power Plants, NS-G-2.2, November 2000
- 6 Report Waste and Spent Fuel Storage Safety Reference Levels, version 2.2, April 2014 - <http://www.wenra.org>

## 7 ANNEX

### Detailed Guidance – LC 23 Operating Rules Inspections

#### DEFINITIONS

Below Standard	Inadequate rigour in applying the requirements of the site licence and implementing the intent of the safety case.
Good Practice	Adequate with respect to compliance with the site licence and ONR inspection ratings. Achieving this level is expected at high hazard facilities.
Best Practice	More than adequate with respect to compliance with the site licence. This equates to an aspiration by licensees and ONR to work towards world class performance.
At all times	This term is used in LC23(3). However, it is recognised that the requirement for the Operating Rule to be met at all times must reflect what is reasonably practicable.
Safety Measure	See T/AST/035 terminology section.
Safety Measure Settings	See T/AST/035 terminology section.
Safety Limit	See T/AST/035 terminology section.

## **EXPECTATIONS**

The following set out ONR's expectations in regard to licensee compliance with those parts of LC23 that relate to Operating Rules. The Expectations are intended to be used as a checklist during LC23 compliance inspections, applying part or the full list depending on the scope of the inspection being undertaken. Each Expectation is followed by more detailed guidance and then by examples of Below Standard, Good and Best Practice. These examples have been provided as prompts to assist with identifying potential issues and are not intended to be exhaustive. Where compliance is found to be substandard, enforcement should be considered in accordance with the Enforcement Management Model (EMM) and Enforcement Policy Statement (EPS).

### **1 A clear and explicit understanding of all the fundamental technical safety objectives associated with the safety case should be readily available.**

1.1 An up to date and user friendly safety case should be available.

1.2 The operations that may affect nuclear safety should be explicitly identified.

1.3 The nuclear hazards associated with the various operations should be identified.

## **BELOW STANDARD**

- The safety case in its entirety is not visible, user friendly and available.
- The safety case is fragmented without adequate guidance to the operators.
- The safety case is not maintained with suitable rigour.
- There is inadequate visibility of changes to the safety case due to plant modifications.
- There is evidence that the operators do not understand the technical objectives of the safety case.

## **GOOD PRACTICE**

- The safety case is of adequate scope and regularly updated. The safety case may be fragmented but this is well managed.
- The safety case is consolidated regularly, or kept visible, accessible and user friendly by effective means.
- The safety case is readily available in hardcopy or electronic form to operators and those who are responsible for reviewing and updating Operating Rules.
- The operators have an adequate understanding of the safety case sufficient for them to discharge their responsibilities for nuclear safety.

## **BEST PRACTICE**

- The safety case is kept fully updated as a single entity.
- Safety case visibility is provided directly to operators by up to date summaries contained in operational documentation.

**2 The safety case should clearly identify what limits and conditions are required for safe operation of the facility (incorporating the effects of uncertainties) and how these have been identified. A full justification for the need for each of the Operating Rules should be readily available along with any supporting material. The technical basis for, and the radiological implications of failing to comply with, each Operating Rule should be clear to the operators.**

2.1 The licensee's safety procedures should include the requirement to derive Operating Rules as part of the safety case process.

2.2 Operating Rules should be derived by SQEP safety analysts from the safety case and be reviewed by and agreed with operating personnel to ensure they can be implemented adequately.

2.3 Each Operating Rule should be justified by a clear audit trail from the safety case. Where appropriate a commentary should be provided to allow operators to understand the rationale that underlies the Operating Rule and the potential radiological implications of a failure to comply.

2.4 The licensee's procedures should ensure that, where different safety concerns lead to differing limits on the same operational parameter, the Operating Rule will specify the most constraining limit.

2.5 Operating Rules should include the availability of plant, equipment and consumables that are necessary in the interests of nuclear safety. This includes alarms, protection and emergency equipment.

2.6 The safety case should distinguish between Operating Rules and other limits and conditions that are desirable, but not necessary in the interests of nuclear safety.

2.7 A consistent set of safety criteria should be used for determining when an Operating Rule is necessary in the interests of nuclear safety.

2.8 The safety case should ensure and justify that all Operating Rules necessary in the interests of safety have been identified.

2.9 Operators should be able to demonstrate how they ensure Operating Rule compliance.

2.10 The Operating Rules should define the minimum staffing levels during all permitted operations that will provide adequate levels for dealing with emergencies.

## **BELOW STANDARD**

- No rationale for justifying the Operating Rules.
- No clear audit trail from the safety case.
- No summary for the operators of the technical basis for each Operating Rule or the potential radiological implications of failure to comply.
- Poor wording leading to lack of clarity in the application of Operating Rules.
- Operating Rules do not identify limits and conditions necessary for safe operation.
- Operating Rules do not address requirements for the availability of plant and equipment, consumables, alarms and indications needed for nuclear safety.
- The Operating Rules do not specify staffing levels needed for nuclear safety.
- Operating Rules do not address all the requirements to enable emergency procedures to be undertaken e.g. emergency lighting and emergency communications.
- Many Operating Rules are set at low levels of public and operator dose, leading to 'masking' of those that control major hazards.

- Limits and conditions that should be covered by Operating Rules are addressed in lower level documentation that may not be subject to adequate controls, e.g. criticality clearance certificates.
- Low Hazard Operating Rules, e.g. those used to control PPE or contaminated wounds, are indistinguishable from High Hazard Operating Rules needed for nuclear safety.

### **GOOD PRACTICE**

- Clear numerical criteria are defined against which the requirement for an Operating Rule can be judged, so as to ensure consistency and coverage.
- Operating Rules specify minimum staffing levels for shift staff responsible for operations to ensure that the facility can be safely operated and emergencies dealt with effectively.
- Operating Rules encompass the availability of plant and equipment, consumables, alarms and indications needed for nuclear safety.
- There is a clear audit trail from the safety case to justify the need for and sufficiency of the Operating Rules.
- Operating Rules are meaningful to operators and bound the routine operation of the facility. They cover all normal operations and ensure that, should a fault occur, the facility will remain within safety limits.
- Operating Rules are readily available to operators in a suitable form.
- Operators are aware of their responsibilities to comply with Operating Rules.
- Operating Rules address all the requirements to enable emergency procedures to be undertaken e.g. controls are in place to ensure the availability of emergency lighting and emergency communications.
- Operating Rules include limits and conditions to prevent unintended criticality.
- Operators responsible for Operating Rule compliance are highly knowledgeable about the Operating Rules and their technical basis.

### **BEST PRACTICE**

- The Operating Rules adopt a graded approach to reaching limits and conditions during normal operation (such as in Technical Specifications).
- The Operating Rules are derived within the safety case, rather than interpreted from the safety case.

### **3 Operating Rules should ensure nuclear safety in all permitted operational states and conditions.**

3.1 All operational states and conditions relevant to the facility should be identified and defined.

3.2 Permitted operational states and conditions include routine operation, start-up, shut-down, maintenance; waste treatment and processing; accumulating, storing, packing and unpacking of radioactive material; and transport of any radioactive material both within and outside the facility.

3.3 Operating Rules should be relevant to and clearly identify the operating state for which they are applicable.

#### **BELOW STANDARD**

- Operating Rules do not identify all the permitted normal operating states.
- Operating Rules are not treated with consistent rigour across all normal operating states (e.g. shutdown conditions versus routine operations).
- Operating Rules do not adequately address all possible sources of nuclear risk (e.g. from radioactive waste or handling nuclear material).

#### **GOOD PRACTICE**

- The Operating Rules provide clear definitions of all permitted operational states and the limits and conditions that apply.
- The Operating Rules cover routine operations and any limits or conditions needed for and during fault conditions.
- There is a clear linkage between the Operating Rules and the actions that need to be undertaken to comply with them including those for fault conditions within Emergency Instructions covered by LC 24.
- The Operating Rules provide a clear demarcation between normal operations and fault conditions.

#### **BEST PRACTICE**

- None identified.



**4 Operating Rules should be technically achievable and meaningful to operators of the facility. The Operating Rules should be written in such a way that it is clear whether or not a breach has occurred.**

4.1 The information available to the operator to ensure Operating Rule compliance should be directly determined from measurements or observations, where practicable without further interpretation or calculation.

4.2 Parameters relevant to Operating Rules should be directly controllable by the operator.

4.3 Operating Rules should be defined such that it is clear when a breach has occurred.

**BELOW STANDARD**

- Operating Rules set at such a high level that they have little relevance to normal operations.
- Information is not available to the operator to ensure Operating Rule compliance.

**GOOD PRACTICE**

- Operating Rules are written in terms of specific operational limits and conditions necessary for safety that are meaningful to the operators.
- Operating Rules are defined at a level that is relevant to operator actions taken to operate the facility.
- Operating Rules are unambiguous so that it is clear whether or not operations are being undertaken in compliance with them.
- Operators have been involved in the safety case process to define the Operating Rules.
- Where plant and equipment is required to be available by the Operating Rules; formal processes are in place to verify that the plant and equipment will deliver their required safety functions.

**BEST PRACTICE**

- Compliance with Operating Rules is determined by operators directly from measurements and observations.
- The parameters relevant to the Operating Rules can be fully controlled by the operator.

**5 In the absence of a directly measurable or observable parameter, an alternative surrogate parameter should be identified. The relationship of this surrogate to the critical safety parameter should be clearly understood and unambiguous. The value of the surrogate should be chosen in such a way as to demonstrate definitively whether a breach of Operating Rules has occurred.**

5.1 The relationship between any surrogate parameter used in an Operating Rule and the relevant critical safety parameter should be clearly defined, justified and be demonstrably unambiguous.

5.2 Any interpretation, translation or manipulation of data by the operator supported by formal systems should be fit for purpose (e.g. tables, diagrams or computing techniques) and suitable training should be provided.

5.3 If an Operating Rule has been defined in terms of a surrogate value, adequate warning of a breach should be provided and it should be immediately clear to the operators when a breach has occurred.

### **BELOW STANDARD**

- Safety is assured by only calling for compliance with lower level documentation (e.g. in Criticality Clearance Certificates and Operating Instructions) rather than Operating Rules.
- Guidance on the derivation of Operating Rules does not address the need for directly measurable surrogate parameters, where the critical safety parameter cannot be measured or observed.
- There is an unnecessary delay in ascertaining Operating Rule compliance due to the need to perform time consuming calculations.

### **GOOD PRACTICE**

- Where a surrogate parameter is used in an Operating Rule, the relationship to any relevant safety critical parameter is justified in the safety case.
- Interpretation, translation or manipulation of data by operators or support staff is minimised and controlled by formal systems.
- There is analysis to demonstrate that compliance calculations can always be completed within adequate timescales.
- Conditions and limits derived from criticality analyses are translated into operational parameters that are meaningful to the operator and included in the Operating Rules.

### **BEST PRACTICE**

- No use is made of surrogate parameters.

**6 Safety Limits should be chosen conservatively so that no significant consequence can arise without at least one safety limit being exceeded. The degree of conservatism should minimise as far as reasonably practicable, the effects of any uncertainties.**

6.1 The Licensee should define safety limits in accordance with the guidance provided in T/AST/035.

6.2 A clear audit trail linking each Operating Rule to relevant Safety Limits should be provided.

**BELOW STANDARD**

- There is no clear audit trail for the Safety Limits underpinning each Operating Rule.
- Safety Limits are not formally defined.
- Safety Limits are used in place of Operating Rules to control normal operations.

**GOOD PRACTICE**

- Safety Limits underpinning Operating Rules are established in the safety case and are demonstrably conservative.
- Margins between Operating Rules and Safety Limits are as large as is reasonably practicable.

**BEST PRACTICE**

- None identified.

**7 Safety measure set/ initiation points should be chosen making due allowance for any potential errors in initiation, from whatever cause, and stated in the Operating Rules.**

7.1 The Licensee should define safety measure settings in accordance with T/AST/035.

7.2 The safety measure settings should be derived in the safety case and derivation should be demonstrated through a clear audit trail.

7.3 The safety case should demonstrate that safety measure set points will prevent safety limits from being exceeded for all design basis events.

7.4 Human performance should be considered in the specification of safety measure settings and a suitable allowance made.

7.5 The safety measure settings, with due allowance for drifts and uncertainties, should be defined in the Operating Rules.

**BELOW STANDARD**

- Operating Rules do not include safety measure settings.
- Human performance is not adequately assessed.

**GOOD PRACTICE**

- The settings of the engineered systems and the settings of any alarms needed for safety measures are given in the Operating Rules.
- The settings take potential equipment drift into account.
- The settings take into account the time for the equipment or operator to respond so that there is a high degree of confidence that the safety measure will deliver its required safety functions with adequate margins.

**BEST PRACTICE**

- All safety measures are engineered systems and not reliant upon operator action.

**8 Operating Rules for normal operation should be set below safety measure settings, with an adequate margin, in order to provide a clear demarcation between normal operational states and fault / accident conditions.**

8.1 A suitable rationale should be applied for the margins between Operating Rules for normal operation and the safety measure settings.

8.2 The operator should be in a position to control normal operations to avoid spurious activation/ initiation of safety measures. Suitable alarms and indications should be provided.

**BELOW STANDARD**

- Operating Rules for normal operation are not set below safety measure settings.

**GOOD PRACTICE**

- Operating Rules are set at an adequate margin below the settings of the safety measures to prevent spurious activation of the safety measure.

**BEST PRACTICE**

- There is a large margin between the normal operating point and the Operating Rules.

**9 The availability of alarms and indications needed to ensure nuclear safety should be covered within the Operating Rules. The Operating Rules should ensure that adequate alarms will be provided so that operating personnel have enough time to initiate corrective actions before safety measures are initiated.**

9.1 An adequate margin should be allowed for in the alarm settings to enable operators to identify problems and take corrective action, for example before safety measures are activated/initiated.

9.2 Alarms should be managed such that standing alarms do not impair the operator response to genuine alarm signals.

9.3 Defects from standing alarms should be remedied as soon as reasonably practicable.

### **BELOW STANDARD**

- Operating Rules do not address the availability of suitable and sufficient alarms and indications.

### **GOOD PRACTICE**

- The availability of those alarms and or indications that form part of a safety measure is covered in the Operating Rules.

### **BEST PRACTICE**

- There are Operating Rules covering the maximum number of standing alarms.

**10 A rigorous process should be in place to control changes to Operating Rules. Such changes should be notified to ONR along with supporting justification and amendments to the safety case for regulatory assessment and Approval (where ONR has specified under LC23(4)). Any temporary changes to, or suspensions of, Operating Rules should be justified and controlled with the same rigour and according to the same rules as permanent changes. A suitable time limitation should be specified for temporary changes.**

10.1 Operating Rules may need to be submitted to ONR for approval (see T/AST/035). The potential requirement for this should be reflected in the Licensee's arrangements for controlling modifications under LC22.

10.2 The Licensee's procedures should ensure that the effects of changes to Operating Rules are analysed and controlled under the modifications procedure.

10.3 The Licensee's procedures should ensure that suitably qualified and experienced persons are responsible for amending the Operating Rules.

10.4 The Licensee's procedures should ensure that where changes have been made to the safety case, the relevant changes are also made promptly to the Operating Rules.

10.5 The Licensee's procedures should require a suitably rigorous review of changes to Operating Rules within the organisation (e.g. that they are to be reviewed by the Nuclear Safety Committee).

10.6 The Licensee's procedures for temporary changes to, or suspension of, Operating Rules should provide the same level of control as those for permanent changes.

10.7 Temporary changes to Operating Rules should be time-limited and subject to review procedures.

#### **BELOW STANDARD**

- Temporary changes to Operating Rules become semi-permanent.

#### **GOOD PRACTICE**

- Temporary changes to Operating Rules are controlled in the same manner as permanent changes.

#### **BEST PRACTICE**

- No best practice has been identified.

**11 Arrangements should be in place to review Operating Rules on a regular basis to ensure that any changes in the facility or operational feedback information are incorporated. These reviews should be undertaken regardless of whether the facility has been modified physically in any way.**

11.1 Operating Rules should be reviewed periodically (at a minimum as part of the PSR) to ensure they remain appropriate in the light of operational experience and technological developments.

11.2 An audit of the documentation implementing the Operating Rules should be included in the quality management system.

### **BELOW STANDARD**

- There has not been an adequate review of Operating Rules.

### **GOOD PRACTICE**

- Operating Rules are included explicitly in periodic safety reviews.
- Audit of documentation implementing Operating Rules is included in the quality management system.
- The safety case is reviewed regularly to establish that all necessary Operating Rules are in place.

### **BEST PRACTICE**

- No best practice has been identified.



**12 Operating Rules should be readily accessible at all times to relevant staff in a suitable form.**

12.1 Operating Rules should be collected together in one document or one set of documents.

12.2 Operating Rules should be readily available to operators in a suitable form, at the operational point of work (e.g. control room or work station).

**BELOW STANDARD**

- Operating Rules are not available to the operator.

**GOOD PRACTICE**

- Controlled copies of Operating Rules are available in control rooms and held for use by other relevant staff.

**BEST PRACTICE**

- No best practice has been identified.

**13 A clear set of Operating Instructions, governing all permitted modes of normal operation, should be available that ensures the facility is operated within the Operating Rules. In addition, operational processes should be in place to ensure that risks are at all times ALARP.**

13.1 Operating Instructions should cover all permitted operational states and conditions.

13.2 Operating Instructions should be authorised, up to date and available to all relevant operations staff.

13.3 Operating Rules, Operating Instructions and other supporting documentation should be maintained as a consistent set of documents.

13.4 Operating Instructions should ensure that the facility is operated so as to maximise the margin between normal operations and Safety Limits.

13.5 Compliance with Operating Rules alone may not be sufficient to demonstrate that the overall risk from the facility is ALARP. Therefore operations and configuration should be kept under surveillance (e.g. through the use of risk monitors).

#### **BELOW STANDARD**

- Operating Instructions necessary to support Operating Rule requirements are not provided to a consistent standard.
- Effective means to demonstrate that operational risks are reduced to ALARP are not in place.
- Operating Instructions for alarms are not available at the work station or within the control room.

#### **GOOD PRACTICE**

- Formal management meetings provide confirmation that overall risks are reduced to ALARP and drive towards the fully-planted state.
- Any Operating Instruction that implements an Operating Rule is clearly identified as such.

#### **BEST PRACTICE**

- Quantitative measures of risk are available and used to drive down operational risks to ALARP (e.g. through the use of risk monitors).

**14 The licensee should be able to demonstrate that effective management controls are in place to ensure compliance with Operating Rules. These should cover all permitted operational states and conditions. A human factors assessment should cover the means by which Operating Rules are implemented and monitored.**

14.1 Compliance with Operating Rules should have defined surveillance requirements and should be demonstrated by suitable records (logs) that form part of the facility's quality management system.

14.2 Suitably qualified and experienced persons should be responsible for compliance with the Operating Rules.

14.3 Surveillance programmes should be established consistent with the safety case to ensure Operating Rule compliance at all times.

14.4 Surveillance procedures should require compliance with Operating Rules is recorded, as well as non-compliance.

14.5 Procedures should ensure that operators are always aware of trends in relevant plant parameters and the availability/status of the safety measures.

14.6 Procedures for controlling, indicating, communicating and assessing the availability of safety measures, other plant, equipment and essential consumables required by Operating Rules should be in place.

14.7 Such procedures should cover the extension of allowable periods of unavailability.

**BELOW STANDARD**

- Wording of Operating Rules makes demonstrating compliance difficult.
- No arrangements are in place for demonstrating compliance with Operating Rules.
- There is no Duly Authorised Person (DAP) sign-off of compliance with Operating Rules.

**GOOD PRACTICE**

- Effective management controls are in place to ensure compliance with Operating Rules at all times, in all permitted operational states and conditions.
- Operating Rules are worded such that compliance can be readily demonstrated.
- The management controls ensure that positive compliance is demonstrated and that the controls are regularly audited for compliance.
- Arrangements for ensuring compliance with Operating Rules are underpinned by physical inspection to confirm the operational state and availability.
- There is human factors assessment of the means by which Operating Rules are implemented and monitored.

**BEST PRACTICE**

- No best practice has been identified.

**15 Operating Instructions should be in place setting out the surveillance programmes needed to demonstrate compliance with the Operating Rules. These Operating Instructions should provide explicit acceptance criteria for the safety measures required to ensure Operating Rule compliance.**

15.1 Surveillance programmes should provide explicit acceptance criteria which may be compared directly with information available to the operator.

15.2 The Licensee should have formal procedures for assessing the availability of safety measures required by Operating Rules.

### **BELOW STANDARD**

- Operating Rules do not provide a basis for surveillance.
- Operating Instructions necessary to support Operating Rule surveillance requirements are not provided or are not written to a consistent standard.
- Compliance with criticality clearance certificates is not covered by the surveillance programme.

### **GOOD PRACTICE**

- Detailed instructions are available to support the surveillance programme.
- Surveillance schedules provide details of the expected range, or condition of equipment or parameters and the frequency at which they should be monitored.

### **BEST PRACTICE**

- Surveillance schedule requirements are explicitly derived from the safety case.

**16 Operating Rules should be set at a level which ensures prompt action by operating staff will bring the facility to a recognised safe state if unexpected behaviour occurs. The recognised safe states should be defined in the operational documentation (e.g. Emergency Operating Instructions).**

16.1 Operating Rules should require staff to monitor limits and conditions, take appropriate controlling actions and report any deviations or non-compliance.

16.2 Operating Rules and supporting procedures should provide for clear operator action in the event of unexpected behaviour.

16.3 The Licensee should have a safety culture which encourages conservative decision-making following any unexpected behaviour.

**BELOW STANDARD**

- Operating Rules are not set at a level aimed at preventing excursions from normal operation, e.g. their focus is instead on serious fault states in which one or more safety measures have failed.

**GOOD PRACTICE**

- Operating Instructions describe how to bring conditions back within normal operations following a deviation from the normal operating state.
- Operating Instructions instruct the operator on how to deal with all faults identified in the safety case, including how to bring conditions back into a safe state.

**BEST PRACTICE**

- No best practice has been identified.

**17 Arrangements should be in place to investigate any breach of an Operating Rule and to only allow the resumption of normal operations when it is safe to do so. The arrangements should make provision for the notification, recording, and reporting of such events to the Regulator.**

17.1 The Licensee should have suitable procedures in place to investigate the cause of any abnormal event (e.g. plant trip) and ascertain if it is safe to resume normal operations.

17.2 The Licensee should have adequate procedures to ensure that breaches of Operating Rules are investigated, recorded and reported under LC 7 arrangements.

17.3 A responsible person should be designated within the procedures for reporting breaches of Operating Rules to the Regulator.

**BELOW STANDARD**

- Information concerning breaches of Operating Rules is not available.

**GOOD PRACTICE**

- Suitable procedures are in place to investigate the cause of any Operating Rule breach and ascertain if it is safe to resume operations.
- Investigations are carried out in accordance with the licensee's arrangements.
- Breaches of Operating Rules are investigated, recorded and reported under LC 7 arrangements.
- The licensee has effective learning from experience arrangements which ensure that the safety case and its Operating Rules are updated appropriately following incidents and events.

**BEST PRACTICE**

- No best practice has been identified.