Development of suitable safety performance indicators for level 4 bio-containment facilities: Phase 2

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The Health and Safety Executive’s (HSE’s) Hazardous Installations Directorate Biological Agents Unit (HID SI4) has developed a set of Safety Performance Indicators (SPIs) in collaboration with organisations working in the high hazard biological agents contained use sector. A proposed generic SPI framework has been produced through discussions between HID SI4 and a small number of organisations working with Hazard Group (HG) 4 pathogens. The project sought to understand from these organisations what aspects of the SPI frameworks developed for other major hazard industries are relevant and of value to the biological agents industry. The ultimate objective of the work was to produce a generic SPI framework that is applicable to the broad range of facilities and organisations working with HG4 human and/or animal pathogens and genetically modified organisms (GMOs). The report presents the outcome of this work in the form of a generic SPI framework that is suitable for adoption and where required modification to suit the needs of containment level (CL) 4 facility operators.

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Executive Summary

The Health and Safety Executive’s (HSE’s) Hazardous Installations Directorate Biological Agents Unit (HID SI4) has been working to develop a set of Safety Performance Indicators (SPIs) with organisations in the high hazard biological agents contained use sector. The generation of a proposed generic SPI framework has been produced through discussions between HID SI4 and a small number of organisations working with Hazard Group (HG) 4 human pathogens. The intention to date has been to understand from these organisations what aspects of the SPI frameworks developed for other major hazard industries are relevant and of value to the biological agents industry. The ultimate objective of the work was to produce a generic SPI framework that is applicable to the broad range of facilities and organisations working with HG4 human and/or animal pathogens and genetically modified organisms (GMOs), and potentially to extend that framework to certain work with HG3 agents. The report presents the outcome of this work in the form of a generic SPI framework that is suitable for adoption and where required modification to suit the needs of HG4 facility operators.
1. Introduction

1.1 Background

The Health and Safety Executive (HSE) has been working with industry for a number of years to develop appropriate key operational performance indicators as a means of monitoring the health of a company and assist in managing their major hazard risks. This work is most developed within the oil and gas industry sector as well as the rail and civil nuclear industry sector. The indicators identified provide the means to measure and manage safety performance at an operational, process, organisation, company or industry level. The indicators identified are commonly termed safety performance indicators (SPIs).

Good leadership is based on making business decisions in the full knowledge of the factors that will lead to a successful outcome and deliver the intended benefits. In the past, information on safety performance has relied on a limited number of factors such as lost time incident rates. Whilst this is a good indicator of how well personal injury accidents are being managed, it is a poor indicator of how well major hazard risks are being controlled overall. Reliance on a limited number of indicators can lead to a distorted view of the safety health of an organisation. Companies with exemplary personal injury incident rates have in the past suffered catastrophic failure in the containment of major hazards, with devastating consequences for the plant, employees, the environment and company reputation.

Building upon the work already undertaken on SPIs in other high hazard industries, the HSE’s Hazardous Installations Directorate Biological Agents Unit (HID SI4) has worked to develop a set of SPIs with organisations in the high hazard biological contained use agents sector. The ultimate aim of this initiative is for those organisations working with Hazard Group 4 (HG4) human and/or animal pathogens to be able to demonstrate that each has a mechanism for managing safety. The HSE consider SPIs as the best methodology for showing this.

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2 Micro-organisms are classified into four hazard groups (HG) by the Advisory Committee on Dangerous Pathogens (ACDP) on the basis of their pathogenicity to humans, risk to laboratory workers, transmissibility to the community, and whether effective prophylaxis is available. Each HG needs to be handled at the corresponding containment level (CL) e.g. HG1 (handled at CL1) microorganisms are considered to pose the lowest risk, and HG4 (handled at CL4) the highest:

**HG1** - an organism that is most unlikely to cause human disease.

**HG2** - an organism that may cause human disease and which may be a hazard to laboratory workers but is unlikely to spread to the community. Laboratory exposure rarely produces infection and effective prophylaxis or treatment is usually available.

**HG3** - an organism that may cause severe human disease and presents a serious hazard to laboratory workers. It may present a risk of spread to the community but there is usually effective prophylaxis or treatment available.

**HG4** - an organism that causes severe human disease and is a serious hazard to laboratory workers. It may present a high risk of spread to the community and there is usually no effective prophylaxis or treatment.
1.2 Definition of SPIs

SPIs provide an important additional tool for any organisation that handles hazardous substances, in demonstrating the adequacy of the hazard management strategies employed within that facility/organisation. The goal of any SPI development programme is to help organisations find and fix potential problems before an accident occurs. In short, effective SPIs are a set of measures that provide insights into safety that is otherwise difficult to measure directly.

A well developed set of SPIs provide a structured means of collecting and using data to give an indication of the operational health\(^3\) of an organisation. They remove the dependency and potentially mis-leading conclusions that may be drawn from the monitoring and measurement of a single or very few indicators. SPIs therefore provide a high level holistic view of the safety performance to an organisation's leadership.

SPIs are not a repetition or replacement for the data and those parameters that are monitored and measured in order to support and maintain day-to-day safe operations. This latter data should be derived from associated plant risk assessments/safety cases, together with the definition of the engineering and managerial safety functions required to deliver safe operations successfully. Examples of such data include definition of a safe operating envelope, or monitoring and preventative maintenance requirements. This does not mean however, that plant operational data cannot be used in support of measuring of SPIs, where appropriate (for example autoclave pressure and temperature used to determine the effectiveness of waste treatment processes).

SPIs are an additional tool in the support of other control systems\(^4\), in ensuring the effectiveness and adequacy of safety management strategies.

1.3 Benefits of SPIs

Companies that have developed SPIs in other industry sectors have reported an increased assurance of risk management. They have been able to demonstrate the suitability of their risk control systems, have avoided discovering weaknesses through costly incidents and have stopped collecting and reporting performance information which was no longer relevant. This has resulted in cost savings and the better utilisation of information already collected for other purposes. Setting focused ‘leading’ indicators will give early warning of when the systems relied upon for the integrity and safety of the business start to go wrong. This will then give operators time to take corrective action to avert problems. The term “systems” here is used in the broadest sense and covers both engineered systems, as well as managerial systems. Good indicators will also help track the impact of business decisions on process safety risks.

Typical benefits associated with the introduction of a well developed set of SPIs are:

- Use of a set of SPIs provides greater indication of safety performance than concentrating on one measure in isolation (or indeed a small number of random measures);
- Provides on-going assurance to internal company stakeholders that risks are being adequately controlled;
- Provides early indication of changes in operations through trending in advance of a potential accident;
- Provides confidence to the industry Regulators that risks are being adequately controlled;

\(^3\) Health in this context means the condition and ability of the organisation to safely operate facilities.

\(^4\) Such as the adequacy and maintenance of safety cases/risk assessments, and associated design substantiation and safety audits.
- Aids the preparation of facility activities, decision making, and optimisation of actions; and
- Contributes to the establishment and improvement of a risk based safety culture.

The increased assurances on risk management that can be achieved through the implementation of a successful set of SPIs within the high hazard biological agents contained use sector, will support the clearer demonstration of the hazard management. They should also aid regulatory confidence, as well as assisting in defining more targeted interaction under Regulatory interventions. This in turn will reduce the indirect costs of regulatory activity such as laboratory downtime during inspection processes, time discussing specific intervention issues and regulatory costs in the charging regime that will be implemented within the next 12 months.

1.4 Scope of the Report

The purpose of this report is to review the work undertaken to date on the development of the SPIs within the high hazard biological agents contained use sector, present the SPI framework developed through this work and the methodology used. Some examples of potential SPIs are given, as well as a checklist of questions that should be considered when identifying new SPIs. The SPI framework is presented as a generic framework for use by each organisation as the basis from which a framework specific to their organisation and facility can be developed.

1.5 Previous Work Undertaken by HSE and the Industry

Work to develop a SPI framework for use within the high hazard biological agents contained use industry sector was undertaken initially by a small number of organisations who work with HG4 human pathogens (operating as the CL4 Users SPI Working Group), following initial discussions with HID SI4. This followed an introductory event hosted by HSE (2006), and a report by the Health and Safety Laboratory (HSL). The initial HSE meeting in 2006 outlined the general concept of SPIs to key dutyholders, through presentations by speakers representing the Nuclear, Rail and Major Hazard industry sectors, within which SPIs have already been developed.

The HSL report was commissioned to report on precursor events to accidents at CL4 facilities to provide a sound knowledge base for discussions on reliable safety performance indicators. Whilst anecdotal evidence exists for facilities in other countries, there was very little incident data for CL4 laboratories within the UK. This was understood to be a result of the strict control of risk systems that is in place at CL4 facilities and the policies and procedures in place to minimise the likelihood of near misses and accidents.

The discussions between these CL4 organisations and HID SI4 determined that whilst rigorous process safety systems were in place at their facilities, there were benefits in understanding the human elements of their systems and how the interaction of people with the physical aspects of the systems may pose the most likely source of error or failure in the safety process. It was therefore agreed (by the CL4 organisations involved and HID SI4) that a set of SPIs would add value to the measurement of overall safety performance of the CL4 containment process, if it included metrics associated with these human elements.

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6 Who became the CL4 Users SPI Working Group.
Each of the organisations involved was tasked to consider their own facilities and processes and identify areas where SPIs would add value to the overall safety performance of the facility. In each case HSE asked that SPIs be considered at a Plant, People and Management level.

Following the initial work by the CL4 Users SPI Working Group, the group was extended to include representatives of all organisations working with HG4 human or animal pathogens in the UK. The generic SPI framework presented in this report has been reviewed and developed through discussions between the extended group, and HSE HID S14.

2. Review of Methodology Applied

The objective of developing a set of SPIs is to provide a structured means of collecting and using data to give an indication of the operational health (with respect to safety) of an organisation. The framework produced can help in the preparation of facility activities, decision making and the optimisation of actions, and ultimately in the establishment and improvement of a risk based safety culture. By identifying and measuring a number of SPIs, a greater indication of safety performance can be provided than concentrating on one measure (or a small number of random measures) in isolation. The framework provides on-going assurance to internal management and the Regulator that risks are being controlled adequately, and that more serious incidents may be identified and prevented before they occur.

Methodologies for the development of SPI frameworks have been published by the IAEA7, OECD8 and HSE9, with slightly different approaches being used within the nuclear, rail and chemical industries.

The methodologies as described in these documents were used as the basis of a review to ascertain the most suitable approach to be adopted in the development of SPIs for the high hazard biological agents contained use industry.

2.1 HSG 254

The methodology developed by the HSE (in guidance document HSG 254) is being used by the oil and gas, and chemical process industries. As described in more detail below it provides a bottom-up evaluation of the hazards posed by a particular industry and the systems in place to control those hazards (termed the risk control centres). The SPIs developed for the HSG 254 framework are therefore metrics which are suitable to measure or monitor the risk control centres. The approach defined within HSG 254, in looking at all the measures that control and monitor a particular identified risk centre, also includes those metrics which form the basis of the day-to-day operation of the process. As already stated in Section 1.2 above, this information is similar to that derived from the process or facility safety case. The methodology is also aimed at defining SPIs to measure the safety controls associated with continuous or batch process, with a high latent hazard potential.

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The HSE’s document HSG 254 was developed for use by major hazard chemical sites. The SPI framework described in this document (often referred to as the ‘step by step approach’) is developed by considering what can go wrong and where within a particular site, and the risk control systems (RCSs) that are in place to prevent a major accident. Leading and lagging indicator are then set for each.

The HSG 254 framework (illustrated in Figure 2.1) therefore comprises a series of RCSs and the SPIs designed to measure them. The framework produced is therefore more of a process orientated system, rather than the wider operational safety performance framework developed by the IAEA (see below).

2.2 IAEA TECDOC 1141

The methodology developed by the IAEA for the nuclear industry (IAEA-TECDOC 1141) takes a top-down approach to the identification of SPIs, by asking ‘what is required from the plant in order for it to perform safely’, and then selecting SPIs that can measure whatever is required in order to answer this question. The TECDOC 1141 approach operates outside the typical safety case reporting process, and is therefore is less process and plant specific in the metrics that the SPIs measure.

As described, the key characteristic of IAEA’s TECDOC 1141 methodology is that it considers safety performance from a top down approach by asking ‘what is required from a plant in order for
it to perform safely’. The answers to this question are termed the ‘operational safety attributes’ of the plant or facility. These consider:

- Availability of safety critical plant items;
- Maintenance needs;
- Operating limits and conditions of equipment;
- Critical plant parameters and associated monitoring and data collection;
- Associated operational controls, both engineered and managerial; and
- Contingency arrangements.

The SPI framework that is produced provides the mechanism by which the operational safety attributes identified can be measured and monitored. The SPI framework comprises four levels, as illustrated in Figure 2.2, and described below:

- Operational safety attributes – what is required from the plant in order to perform safely? For the biological agents sector this could be the control of hazards or a positive safety culture;
- Overall indicators – parameters that represent the overall level of operational safety performance. For the biological agents sector, status of plant, or biological containment are overall indicators;
- Strategic indicators – convenient parameters linking the overall indicator with the specific indicator; such as maintenance, waste treatment or human performance for the biological agents sector; and
- Specific indicators – aspects that can be measured and monitored directly so as to understand the operation of the strategic indicator (i.e. a metric). There may be more than one specific indicator for each strategic indicator.

The above methodology, building upon SPI frameworks that have been defined in the UK Nuclear industry was used as the basis for some initial work on SPIs undertaken by CL4 User SPI Working Group. The resultant framework is discussed later in this report in Section 3.
2.3 OECD Guidance on Developing SPIs

OECD’s guidance is similar to the HSG 254 framework in that it starts by identifying the key issues of concern, and the indicators that could be used to measure and monitor them. The OECD’s methodology (Figure 2.3) is similar to that described in HSG 254. Whilst some of terminology in the OECD guidance is different, the document provides some useful guidance on the development of metrics associated with the development of an SPI programme. The guidance also provides in a similar manner to HSG 254 a step by step guide to the development of SPIs, including ensuring that the development and implementation of any such SPI programme has the right level of ownership and leadership.

Figure 2.3 – OECD’s Approach to develop a SPI framework

2.4 Safety Performance Indicators

The specific indicators described in the TECDOC 1141 approach, and the leading/lagging indicators in HSG 254, are both safety performance indicators (SPIs). The measurement or monitoring of these indicators provides the data with which the strategic indicator (TECDOC 1141) or the RCS (HSG 254) can be understood. With the TECDOC 1141 framework, measurement of the SPIs across the framework provides a collective strategy to evaluate the overall safety performance of the industry, facility or plant.
In selecting SPIs for a facility the following questions need to be asked to ensure that each SPI is useful and of value:

- Is there a direct relationship between the indicator and safety? If not, why is the indicator being considered?
- Is the necessary data available, or can it be generated? How much additional effort might be required to collect the data, and is this effort appropriate to the value of the data measured?
- Can the indicator be expressed quantitatively? This will assist in identifying trending within the data collected.
- Is the indicator unambiguous?
- Is the indicator susceptible to manipulation?
- Is the significance of the indicator understood?
- Is the indicator meaningful?
- Can the indicator be integrated into normal operational activities?
- Can the indicator be validated?
- Can the indicator be linked to the cause of a malfunction?
- Can the accuracy of the data generated be subject to verification or quality control?
- Can local action(s) be taken on the basis of the indicator measured?

The SPIs selected can be direct or indirect indicators. Direct indicators measure and monitor the subject directly, with the performance of the subject therefore measurable. An example of a direct SPI is the availability of systems. Indirect indicators measure and monitor the parameters for their known effect on a subject. An example is preventative maintenance with the results on how much of this is achieved providing an indirect indication of the unavailability of a component.

An SPI framework is of greatest value to an organisation when it contains both leading and lagging SPIs. These provide an early warning of declining performance or safety (the leading indicators) as well as a reflection of actual performance (the lagging indicators). Preferably both leading and lagging indicators should be identified for each strategic indicator (or RCS), although the two indicators do not need to be linked. For some strategic indicators (or RCS) both a leading and lagging indicator may not exist.

Leading and lagging indicators can be either direct or indirect.

Collection of SPI data in the form of some suitable data is only the beginning of the process. Depending on the nature of the SPI selected, a level of tolerance or a threshold level will need to be defined in order that a response action is triggered when the threshold is reached or exceeded. Individual operators will have to define what thresholds are suitable against a particular metric, in order to evoke a particular response to data that demonstrates unacceptable trending or levels.

### 2.5 The Methodology Adopted

Following the review of existing methodologies it was agreed that the approach described in IAEA-TECDOC 1141 would be used as the basis to produce the SPI framework for the high hazard biological agents industry. This decision was based on the following reasons:

- The approach provides a clear top-down hierarchical approach to the identification and use of SPIs, which can be readily mapped to the key areas of risk management within biological agent facilities;
• The SPIs identified through this approach are consequently of a higher more generic level than data collected as part of the day to day safe operation of the facility. The SPIs are therefore more applicable to the range of facilities, processes and activities encountered in the biological agents industry at CL4. Applying a higher level more generic approach to the identification of SPIs means that the framework produced is in turn more generic and therefore more applicable to the range of facilities, processes and activities encountered in the high hazard biological agents contained use industry, than a framework based on more detailed SPIs;

• This approach removes potential confusion between SPI framework metrics and those vital parameters required to be measured to support day-to-day safe operations:

  - the day to day process indicators, such as ventilation air flow rates, filter efficiencies and glove failures are not considered to be SPIs under the TECDOC 1141 approach, although they will feed into broader elements of the SPI framework such as the correct operation of safety critical plant. Such day to day more detailed indicators may be considered as SPIs in HSG 254; and

• Builds on work done by the CL4 Users SPI Working Group since the initial discussions with HSE. Following the initial discussions in between the CL4 Users SPI Working Group and HID SI4, the users group produced a draft SPI framework based on the TECDOC 1141 approach. The framework developed considered both the process and human elements of the CL4 facilities and systems. This was identified in the early discussions as a key area where SPIs could be of benefit to the biological agents industry.

3. **Framework for SPIs**

As described, the SPI framework has been developed through discussions between the CL4 Users SPI Working Group and HSE HID SI4. Several iterations of the SPI framework have been developed in this process. Each of them has used the same top down hierarchical approach, asking ‘what is required from a facility in order for it to perform safely’?

The final version of the framework is presented in Figure 3.1.
In the development of the framework, six areas of importance were identified by the CL4 Users SPIs Working Group as contributing to the safe management of their facilities. These were:

-Transparent and effective management;
- Critical plant maintenance and competency;
- Plant and operations;
- Transport and sample receipt;
- Emergency planning; and
- Waste management.

These areas are represented in the SPI framework as detailed in Table 3.1 below.
4. Commentary on SPI Framework

The purpose of the SPI framework is to provide a structure through which the requirement described in the overall safety goal can be measured and understood as being achieved. In order to do this there needs to be a clear and logical linkage from this top level down through the framework to the SPIs.

4.1 The Overall Safety Goal

The overall safety goal (Figure 3.1) describes the key objective which the CL4 Users SPI Working Group requires from the performance of any of their facilities, namely 'safe high hazard biological containment'. This safety statement encompasses the nature of the work being undertaken, i.e. high hazard microorganisms, with the focus of the work being safe working within a contained setting\(^{10}\).

The achievement of this overarching statement of ‘safe high hazard biological containment’ is addressed through the three areas of sustained capability of operation of plant and activities; the control of hazards to the public, workers and the wider environment; and a positive safety culture with a strong positive attitude to safety supported by continual striving for improvement and effective leadership and management.

These three areas form the operational safety attributes of the framework. These are discussed further below, together with the overall indicators that support them.

\(^{10}\) The contained setting could be the laboratory or microbiological safety cabinet for example.
4.2  Sustained Capability of Operation

Sustained capability of operation covers the status and configuration of equipment, particularly safety critical plant. An important aspect in determining the health of the facility is understanding whether plant/equipment is available and also capable of operating and delivering the safety functions claimed in the risk assessments. For example, information on the effectiveness of maintenance, whether the plant has operated albeit temporarily in non-approved configurations and what plant failures have occurred, are all important indicators in this respect.

The overall indicators therefore reflect the areas where information regarding plant status will be obtained. This is through information associated with or gleaned from maintenance activities, and information regarding plant operation and configuration. The type of plant being considered is not specified in the framework, thereby keeping the framework generic for the range of equipment used at CL4.

4.3  Control of Hazards

The Control of hazards safety attribute encompasses those areas most likely to cause a hazard, and the measures in place to control them. The hazard areas of most concern, and as identified by the CL4 Users Working Group are: the handling and transport of samples; the management of waste; and unplanned events (e.g. emergencies). Overall indicators reflecting these areas have therefore been defined and presented in the framework.

The strategic indicators supporting these overall indicators are intended to reflect the areas that provide important measures of the effectiveness of the delivery of each overall indicator. For example, the hazards associated with waste management are controlled through the treatment and the disposal of the waste streams. Therefore Waste Treatment and Disposal are selected as the strategic indicators.

It should be noted the strategic indicators associated with Emergency planning are all associated with the measurement of emergency preparedness.

4.4  Positive Safety Culture

The Positive safety culture operational attribute covers the management and human elements associated with ensuring that the facility/business operates in a safe manner and is continually seeking to improve its safety performance. Whilst getting the systems and process functioning appropriately, the operational efficiency, capability and safety of these operations can be eroded readily should the staff managing and operating these systems not be trained suitably, and exhibit the correct behaviours and attitudes.

The areas therefore considered important in measuring whether a positive safety culture is being developed and sustained in an organisation, form the basis of the overall indicators for this operational safety attribute. These areas are:

- Human capability and performance; encompassing the right people being available in sufficient numbers and with appropriate competency and awareness;
- Continual improvement - demonstration that the organisation is seeking to continually improve its hazard management approach and therefore its safety performance; and
- Effective safety leadership and management - ensuring that this is being delivered both through behaviours and activities.
4.5 Strategic Indicators

The three operational safety attributes and their associated overall indicators described above, are subdivided into the strategic indicators. Leading and/or lagging SPIs (or specific indicators) can be identified for each one\(^\text{11}\), such that these strategic indicators provide the link between what can be measured at the facility (the SPI metric) and the overall goal that the facility is operating as intended, i.e. as a safe high hazard biological containment facility.

Table 4.1 provides some further information on each of the strategic indicators presented in the SPI framework (Figure 3.1). The intention of Table 4.1 is to describe what is meant by each indicator in the position assigned in Figure 3.1, and thereby providing the rationale behind the logical hierarchical structure of the SPI framework.

As stated previously the framework is generic in nature and HG4 organisations should modify it accordingly to meet the needs of their particular facility and activities. Modifications could comprise moving existing strategic indicators to other locations in the framework, deleting existing strategic indicators, or adding new ones. With any modification, the rationale behind the change should be clearly articulated, and a logical hierarchy retained through the framework. Clear presentation of the reason(s) for a change will ensure that the SPI metrics defined and the data generated by the collection of the SPI metrics is not taken out of context or misconstrued as a result of a misinterpretation of the framework hierarchy.

\(^{11}\) Some strategic indicators may not have both a leading and lagging indicator.
Table 4.1 – Commentary on the location of each indicator within the SPI framework

<table>
<thead>
<tr>
<th>SPI Framework</th>
<th>Definition and comment on location within the framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe high hazard biological containment facilities</td>
<td>The overall safety goal. Achieving this at a particular facility will depend on many aspects, including the functioning of the plant, having the appropriately trained, equipped and available staff, and the right approach from management and the wider organisation. The SPI framework is designed to capture these aspects in a logical structure. Each aspect is measured by the SPI. The framework layers of operational safety attribute, overall indicator, and strategic indicator, should form a logical link from the overall safety goal down to each specific SPI metric.</td>
</tr>
<tr>
<td>Sustained capability of operation</td>
<td>Covers ensuring that the operation of the facility is maintained such that it operates within its assessed safe operating envelop and that safety related equipment is functioning as designed and as claimed in facility risk assessments. Should therefore comprise both maintenance and operation; and is measured through the aspects of critical plant maintenance as a measure of operational capability, the status of the plant to operate, and/or events that have impacted on the plant’s ability to operate.</td>
</tr>
<tr>
<td>Critical plant maintenance</td>
<td>Covers the aspects relating to the physical maintenance of the plant, focusing on plant critical for maintaining safe high hazard biological containment, rather than all plant.</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Covers the collection of data associated with the successful delivery of maintenance programmes for critical plant. Ensuring that the correct maintenance on safety critical equipment is undertaken to schedule, and that safety functional operability has been confirmed, are key to maintaining delivery of safety.</td>
</tr>
<tr>
<td>Safety plant out of specification</td>
<td>Included in the framework to provide a different perspective on maintenance. The identification that safety plant is out of specification as a result of impending maintenance requirements, or a consequence of poor maintenance having been undertaken; or is being operated in a known degraded state, are all clear indications of a degradation of safety.</td>
</tr>
<tr>
<td>Plant condition</td>
<td>Addresses the overall condition of the plant and whether it is available for use as intended. This indicator should cover metrics that allow duty holders to understand if plant is deteriorating unexpectedly; that plant is requiring increased frequency of breakdown maintenance in addition preventative maintenance etc.</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
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</tr>
<tr>
<td>Plant operation</td>
<td>Covers the aspects relating to the physical operation of the plant. Comprises the operation of the plant, with particular reference to containment, and also how modifications to plant are dealt with. The SPIs reporting to Plant operation should not include data that is monitored to support day-to-day safe operations.</td>
</tr>
<tr>
<td>Reports</td>
<td>Covers metrics associated with incident/event/near miss reporting to understand what has impacted upon plant operation. Linked closely to continuous improvement through the undertaking of Corrective actions, and by putting in place future preventative measures or other business improvements. May also be described as Events.</td>
</tr>
<tr>
<td>Containment boundary performance</td>
<td>Provides specific consideration of the performance of the containment system, within the wider evaluation of Plant operation. Could encompass failure of containment or challenges to containment.</td>
</tr>
<tr>
<td>Plant modifications</td>
<td>Covers modifications to operating plant, for example recording the number permanent modifications have been reviewed and approved appropriately. Could also include monitoring the number of temporary modifications in place.</td>
</tr>
<tr>
<td>Containment strategies</td>
<td>Covers the operation of the containment plant in terms of whether the containment applied, and how this is operated, is appropriate to the work undertaken; and how changes or modifications to containment strategies are evaluated and documented.</td>
</tr>
<tr>
<td>Control of hazards</td>
<td>Covers the areas most likely to cause a hazard and how these are controlled, namely handling samples and the treatment of waste. Emergency planning, in terms of the effectiveness of the emergency response, and emergency preparedness, is included in this section as this also deals with the mitigation of the consequences of hazards in the event of an actual biosecurity incident, such as a spillage or failure of containment. Control of hazards is therefore sub-divided into Sample handling transport, Waste management and Emergency planning.</td>
</tr>
<tr>
<td>Sample handling transport</td>
<td>Covers the safeguards in place to control hazards associated with the handling of samples and their transport. The hazards in these areas are typically managed through procedures to log and handle samples, and physical protection of staff (through personal protective equipment (PPE)).</td>
</tr>
<tr>
<td>PPE</td>
<td>Metrics in this area could monitor the availability or appropriateness of PPE, trend failure rates of PPE, mis-use of PPE and failure to use correct PPE.</td>
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<tr>
<td>Events</td>
<td>In this location in the framework, Events covers the recording of events data associated specifically with sample handling, e.g. incorrect labelling, incorrect handling etc. In general, the evaluation of events records supports trending and the ability to identify improvements and corrective actions in place.</td>
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<tr>
<td>Category</td>
<td>Description</td>
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<tr>
<td>Waste management</td>
<td>Covers safeguards in controlling the hazards associated with waste management. Does not cover the physical operation of the waste treatment systems. These are incorporated under Plant operation.</td>
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<tr>
<td>Waste treatment</td>
<td>Covers the appropriateness of the waste treatment methodology for the particular waste stream. Indicator could also cover monitoring effectiveness of waste treatment, e.g. the need to repeat autoclave activities. Aspects such as the availability of the waste treatment equipment or chemicals should be addressed under Containment strategies, as they relate to the operation of the plant.</td>
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<tr>
<td>Disposal</td>
<td>Covers aspects relating to the treated waste being disposed of as required or as specified. This could include covering the availability of disposal routes, incorrect sentencing of waste for disposal.</td>
</tr>
<tr>
<td>Emergency planning</td>
<td>Covers aspects relating to emergency planning in the event of an actual biosecurity incident such as a spill or failure of containment. Differs from the Sample handling transport and Waste management overall indicators in that it deals with mitigation rather than safeguards.</td>
</tr>
<tr>
<td>Scenario exercise</td>
<td>Covers the scheduling of exercises to test/review emergency response or emergency plans, adherence to those plans, and the close-out of exercise/review findings.</td>
</tr>
<tr>
<td>Support functions</td>
<td>Covers the availability of advice or support functions in relation to emergency planning and delivering emergency response, e.g. medical support.</td>
</tr>
<tr>
<td>Biosecurity</td>
<td>Covers the collection of metrics resulting from emergency response performance in the instance of an actual biosecurity incident, such as a spillage or failure of containment. May also cover the status of response equipment to support delivery of maintenance of biosecurity in the event of a spill or containment failure. Does not cover maintaining the biosecurity of the laboratory. This would be located under the Sustained capability of operation operational safety attribute.</td>
</tr>
</tbody>
</table>
### Positive safety culture

The development and maintenance of a positive safety culture is key to the delivery of any hazard management strategy and associated processes and activities. A positive safety culture is reflected through the behaviours and safety performance of the staff, and demonstration that the business is:

- a learning organisation;
- one that strives for continual improvement; and
- led by a senior management in a manner conducive to the fostering of a good safety culture.

Comprises a human component covering all staff, a leadership component, and a general approach to continuous improvement. Sub-divided in this framework as Human capability, Continual improvement, and Leadership and management for safety.

### Human capability

Covers the people aspect of the operational capability of the facility.

<table>
<thead>
<tr>
<th>TIER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Human performance</strong></td>
<td>Encompasses the general capability and proficiency of staff. Could include staff operating under competency waivers, and could be determined at a company or activity specific level.</td>
</tr>
<tr>
<td><strong>Conventional H&amp;S</strong></td>
<td>Covers the attitude of staff and the organisation to health and safety. Examples could include how general hazards such as flammable materials, or manual handling are dealt with, or how general laboratory working is undertaken.</td>
</tr>
<tr>
<td><strong>Employee availability</strong></td>
<td>Addresses the availability of (suitably trained) staff to undertake the work required. This may be reflected in indicators that highlight too small a resource pool, high staff turnover or higher than average sickness rates due to high workloads.</td>
</tr>
<tr>
<td><strong>Safety issues closure</strong></td>
<td>Covers the work by staff to log and close out adverse events, and respond to legislative or regulatory requirements. Poor responses to safety issues could be symptomatic of many issues. Therefore the timely close out of safety issues is a good indicator of safety culture and attitude.</td>
</tr>
</tbody>
</table>

### Continual improvement

Covers the areas by which the facility or organisation can demonstrate forward progression in its communication and/or continual improvement management on safety related issues. Continual improvement is a means to demonstrate that complacency should not become an issue.

### Corrective actions

This is similar to safety issue close-out. The close-out of corrective actions, whether these have been identified through facility specific events or are industry led, is a good measure of safety culture. An example could be the failure or delay in implementing corrective actions identified following the investigation of an event.
| Challenges to safety systems | In this location, challenges to safety systems monitors whether a plant is operated in a manner that would/will challenge safety systems. This would indicate poor safety attitudes, and/or a poor safety culture. [Note: If challenges to safety systems is used as an indicator of how a plant was being used and how close to an actual hazardous situation operations came, or that it was operating close to / at its last line of defence, then it would fit more logically under Control of hazards.] |
| CPD/update training | Covers staff appraisals, continued development, and the continuing progression of training and/or re-training of staff in order that staff competencies are maintained as required of the safety roles being delivered. |
| Leadership and management for safety | The demonstration of effective safety leadership such that this fosters an environment for the development and maintenance of an appropriate safety culture. |
| Safety case management | The evaluation and review of the safety case for each activity or facility. Should include approval and sign-off by appropriate senior management, and the ongoing review of resource requirements. |
| Challenge function | Encompasses the peer review of activities, safety cases or independent inspection by management; and the independent challenge to design changes. Should demonstrate that where there are significant safety decisions being made in the business that there are appropriate levels of challenge to those decisions as a means of demonstrating robustness. |
| Leadership behaviour | Covers the communication of safety advice to staff, mechanisms in place for staff to make comment on safety, delivery of safety audits by senior management, as a means of demonstrating leadership by example. |

5. Example SPI Metrics

Each of the strategic indicators in the framework should be supported by one or more SPI metrics. Where possible a leading and a lagging indicator should be identified as this provides both an early warning of declining safety (the leading indicator) and a reflection of actual performance (the lagging indicator). However, both leading and lagging indicators may not exist for each strategic indicator; or a strategic indicator may have more than one leading or lagging indicator. Whilst the strategic indicators presented in the framework (Figure 3.1) were agreed as appropriate by the CL4 Users SPI Working Group, it is important that each organisation uses a framework that is fits with their own activities and structure.

Table 5.1 provides some examples of leading and lagging SPIs for the Strategic indicators listed in Figure 3.1 and Table 4.1.
<table>
<thead>
<tr>
<th>Strategic indicator</th>
<th>Example safety performance indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance</td>
<td>Percentage of safety significant equipment listed on an approved maintenance schedule (leading indicator).</td>
</tr>
<tr>
<td></td>
<td>Percentage of maintenance schedule adherence (lagging indicator).</td>
</tr>
<tr>
<td>Safety plant out of specification</td>
<td>Equipment being used outside its specification, as assumed in the facility risk assessment (lagging).</td>
</tr>
<tr>
<td>Plant condition</td>
<td>Availability of the CL4 laboratory, measured by the ratio of time when the facility is unavailable for all unplanned reasons, engineering and human, against total time that facility should be available (lagging). May also be described as programme delays due to plant failures.</td>
</tr>
<tr>
<td></td>
<td>Availability of safety critical parts for maintenance requirements (leading).</td>
</tr>
<tr>
<td></td>
<td>Number of breakdown maintenance activities (lagging).</td>
</tr>
<tr>
<td>Reports</td>
<td>Incident or near miss reports closed out within specified period (lagging).</td>
</tr>
<tr>
<td>Containment boundary performance</td>
<td>Number of times autoclave does not reach the required operating parameters (lagging).</td>
</tr>
<tr>
<td>Plant modifications</td>
<td>Number of temporary plant modifications/concessions pending implementation of approved design changes.</td>
</tr>
<tr>
<td>Containment strategies</td>
<td>Design changes documented and approved within specified period of introduction (leading).</td>
</tr>
<tr>
<td>PPE</td>
<td>Required PPE available for the activity (leading). This SPI is considered a leading indicator on the basis that the work would not be undertaken in the absence of the required PPE.</td>
</tr>
<tr>
<td>Events</td>
<td>Samples received that are incorrectly labelled or mis-labelled (lagging).</td>
</tr>
<tr>
<td>Waste treatment</td>
<td>Approved and appropriate waste treatment practices are in place for the proposed work (leading).</td>
</tr>
<tr>
<td></td>
<td>Number of waste treatment runs needing to be repeated due to the treatment regime not reaching the prescribed parameters (lagging).</td>
</tr>
<tr>
<td>Scenario exercise</td>
<td>Emergency exercise schedule has been set and implemented (leading).</td>
</tr>
<tr>
<td>Support functions</td>
<td>Availability of medical support (leading).</td>
</tr>
<tr>
<td>Biosecurity</td>
<td>Emergency response plans in place (leading).</td>
</tr>
<tr>
<td>Human performance</td>
<td>Number of temporary operating procedures in place (leading).</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Number of procedural violations identified (lagging).</td>
</tr>
<tr>
<td></td>
<td>Number of incorrect entries found on sample receipt log during audit (lagging).</td>
</tr>
<tr>
<td></td>
<td>Proportion of staff operating under competency waiver (lagging).</td>
</tr>
<tr>
<td>Conventional health and safety</td>
<td>Percentage number of staff attending the accident and emergency course (a requirement for all CL4 staff) (lagging).</td>
</tr>
<tr>
<td>Employee availability</td>
<td>Number of operations where staff requirements (numbers and competency) identified in advance for a particular piece of work (leading).</td>
</tr>
<tr>
<td></td>
<td>Staff turnover or staff sickness above specified threshold (leading).</td>
</tr>
<tr>
<td>Safety issues closure</td>
<td>Safety issues closed out within specified time (lagging).</td>
</tr>
<tr>
<td>Corrective actions (OEF)</td>
<td>Corrective actions implemented as identified following the investigation of an event (lagging).</td>
</tr>
<tr>
<td>Challenges to safety systems</td>
<td>Number of alarm utility interruptions (lagging).</td>
</tr>
<tr>
<td>CPD/update training</td>
<td>Percentage of staff having approved training schedule (leading).</td>
</tr>
<tr>
<td></td>
<td>Percentage adherence to training schedules (lagging).</td>
</tr>
<tr>
<td>Safety case management</td>
<td>Percentage of ad hoc working without specific safety case (lagging)</td>
</tr>
<tr>
<td>Challenge function</td>
<td>Director (or appropriate) safety tour programme in place (leading).</td>
</tr>
<tr>
<td></td>
<td>The number of actions (from the Director safety tour programme) outstanding for more than one month beyond the close out date (lagging).</td>
</tr>
<tr>
<td>Leadership behaviour</td>
<td>Nurturing and encouraging staff contribution to safety – e.g. number of consultative staff forums completed to programme.</td>
</tr>
</tbody>
</table>

The suitability of the SPIs proposed as valuable and useful indicators has been assessed by reviewing each one against the criteria listed in Section 2.4. These are listed again below for information:

- Is there a direct relationship between the indicator and safety? If not, why is the indicator being considered?
- Is the necessary data available, or can it be generated? How much additional effort might be required to collect the data, and is this effort appropriate to the value of the data measured?
- Can the indicator be expressed quantitatively? This will assist in identifying trending within the data collected.
- Is the indicator unambiguous?
- Is the indicator susceptible to manipulation?
- Is the significance of the indicator understood?
- Is the indicator meaningful?
Can the indicator be integrated into normal operational activities?
Can the indicator be validated?
Can the indicator be linked to the cause of a malfunction?
Can the accuracy of the data generated be subject to verification or quality control?
Can local action(s) be taken on the basis of the indicator measured?

As a worked example, these ‘suitability’ questions have been considered for leading and lagging SPIs for the Maintenance strategic indicator.

A leading and lagging indicator have been identified for the maintenance strategic indicator. The leading SPI is ‘percentage of safety significant equipment listed on an approved maintenance schedule’, and is:

- Not susceptible to manipulation – **yes** - a maintenance schedule is either in place or it is not, and safety significant equipment is either on that list or not. A tolerance threshold of 100% would be considered appropriate for this. The SPI is considered not susceptible to manipulation.
- Its significance can be understood – **yes** - it should be accepted that all equipment requires some form of maintenance in order to keep it in working order and able to deliver the functions claimed of it in the risk assessments. Therefore the significance of a maintenance requirement should be understood.
- It is meaningful – **yes** - the requirement for the maintenance schedule to be in place, be comprehensive and approved, and have some form of tolerance threshold, means that this SPI is considered meaningful.
- It can be integrated into normal operational activities – **yes** - the existence of a maintenance schedule should be part of normal facility activities.
- It can be validated – **yes** - the SPI can be validated in terms of whether it is in place or not for particular equipment.
- It can be linked to the cause of a malfunction – **no** - whilst a malfunction could be the result of an absence of maintenance of a piece of equipment, the lagging maintenance SPI is a better means to do this, than the leading one.
- Its accuracy is verifiable – **yes** - through the independent audit of the presence/absence and completeness of the maintenance schedule.
- Local actions can be taken in relation to it – **yes** – action can be taken to implement an approved maintenance schedule if it is not available.

The Maintenance **lagging** SPI is – ‘percentage of maintenance schedule adherence’, and is:

- Not susceptible to manipulation – **yes** – whilst the maintenance schedule will record whether the tasks required have been undertaken properly and in a timely manner, it is reliant on the method of recording the completion of the maintenance tasks. This can be undertaken using formal maintenance records cards, with appropriate supervision and independent checking and oversight. Whilst this process could be susceptible to manipulation, this is not in the interests of the workers and is therefore not expected. Overall it is concluded that whilst the lagging SPI is potentially susceptible to manipulation, processes can be put in place plus appropriate training to ensure such that the potential for manipulation is minimised.
- Its significance can be understood – yes – as with the leading SPI, the requirement for and completion of maintenance should be accepted and understood as a means to maintain safety.
- It is meaningful – yes – the lagging SPI is considered meaningful as the results from it will show maintenance having been undertaken. Failures to undertake maintenance to the schedule requirements can be acted upon and ultimately operations ceased until required maintenance has been completed.
- It can be integrated into normal operational activities – yes – the completion of required maintenance can be incorporated into normal facility activities. Maintenance activities are a part of expected facility activities.
- It can be validated – yes – the SPI can be validated in terms of whether it has been completed or not. Independent audit of maintenance tasks can be undertaken to check the completion, adequacy and effectiveness of maintenance tasks against the maintenance schedule.
- It can be linked to the cause of a malfunction – yes – equipment failure causing the malfunction can be traced back to the equipment not being maintained as the root cause of failure.
- Its accuracy is verifiable – yes – but only in terms of the maintenance having been completed or not. A physical verification for some equipment may only be possible through supervised maintenance.
- Local actions can be taken in relation to it – yes – action can be taken should maintenance has not been undertaken correctly, ultimately ceasing all facility operations until all required maintenance has been undertaken.

Of the leading and lagging SPIs for the Maintenance strategic indicator, the lagging SPI meets all of the assessment criteria, with a ‘yes’ against each. The leading SPI meets all but one of the eight criteria.

Whilst a pass/fail level is not proposed, a SPI that meets the majority of the eight criteria is likely to be suitable. Notice should be taken of the criteria that are not met. For example a SPI that does not meet the ‘susceptible to manipulation’ criterion may not be suitable if high susceptibility to manipulation, even if it meets all other seven criteria. The leading and lagging SPIs for the Maintenance strategic indicator are considered suitable for use in the framework.

6. Measurement and reporting

For each of the SPIs included in the framework, a tolerance threshold or trigger level needs to be identified at which action or further investigation needs to be taken. Discussions with the CL4 Users Working Group indicated that a red/amber/green (RAG) dashboard system would be the most appropriate system to flag when a tolerance threshold is met or exceeded. An example of how this could work is described below:

- A ‘green’ tagged SPI, i.e. one where the tolerance threshold is not exceeded and could be viewed as tolerable; whereas a ‘red’ tagged SPI could be defined as intolerable. The ‘amber’ tag could be used as an investigation requirement, in between tolerable and intolerable.

Exceeding a tolerance threshold does not have to mean that a hazard has occurred and that safety has been breached. On the contrary, as the SPI framework is designed to give an indication of the safety health of an activity, facility or organisation, then exceeding a tolerance threshold should mean that something (equipment, a process, or a policy) is not operating as
intended and that action or further investigation is required to prevent or avoid further deterioration towards a hazardous situation. Threshold levels should be set accordingly to recognise the issue at that level.

Tolerance thresholds should not be set so that they are never exceeded. A period of testing is likely to be required to determine the most appropriate level.

Tolerance thresholds should be set at whatever level is appropriate for the SPI. Thresholds may be quantitative or qualitative. Quantitative thresholds are likely to be presented as a percentage score, and 100% (or 0%) may be appropriate dependent upon the metric being measured.

The SPI framework is intended to be used to demonstrate to senior management, and the regulator, that there is a mechanism in place for managing safety. Depending on the complexity of the framework it may be necessary to show the results from the whole of the framework. Upward reporting mechanisms (to senior management) should be conducted so that the ability to provide mitigation or corrective actions in the event of intolerable results is undertaken at the appropriate level in the organisation.

Care should be taken that upward reporting does not dilute or obscure the safety significance of a particular intolerable metric, when collating metrics at a higher level for reporting to senior management. For example:

- a red tagged SPI should cause its strategic indicator to change to red, and so on up the framework. It is important that if only one strategic indicator, out of all those under a single operational safety attribute, changes to red, then the operational safety attribute also goes red. Red tags should not disappear as the results of the framework are summarised upwards.

### 7. Conclusions

A framework for a set of safety performance indicators for CL4 facilities has been developed by the industry in discussion with the HSE. The framework has been produced using the methodology developed by the IAEA and set out in document TECDOC-1141. This has produced a top-down hierarchical identification of SPIs applicable for the biological agents industry.

The SPI framework developed is designed to provide a comprehensive framework for use by organisations working with HG4 human or animal pathogens. Discussions with these organisations have determined that the SPI framework developed is applicable for use at their facilities. However it is important that any framework used by an organisation fits with its activities and structure. The framework described in this document may therefore need amending or modifying slightly to be directly applicable. The general structure of an overall safety goal, supported by indicators of plant, people and organisation should be applicable to all organisations.

HSE will require organisations working with HG4 human and/or animal pathogens to be able to demonstrate that each has a mechanism for managing safety. HSE consider SPIs as the best methodology for showing this, and view the SPI framework described in this document as a good structure to use covering all of the relevant areas.
8. Bibliography


Development of suitable safety performance indicators for level 4 bio-containment facilities: Phase 2

The Health and Safety Executive’s (HSE’s) Hazardous Installations Directorate Biological Agents Unit (HID SI4) has developed a set of Safety Performance Indicators (SPIs) in collaboration with organisations working in the high hazard biological agents contained use sector. A proposed generic SPI framework has been produced through discussions between HID SI4 and a small number of organisations working with Hazard Group (HG) 4 pathogens. The project sought to understand from these organisations what aspects of the SPI frameworks developed for other major hazard industries are relevant and of value to the biological agents industry. The ultimate objective of the work was to produce a generic SPI framework that is applicable to the broad range of facilities and organisations working with HG4 human and/or animal pathogens and genetically modified organisms (GMOs). The report presents the outcome of this work in the form of a generic SPI framework that is suitable for adoption and where required modification to suit the needs of containment level (CL) 4 facility operators.

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