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1.0 Introduction

This document describes the standard to be used as part of the implementation of an integrated quality and risk management framework across the HSE. Quality and risk management are complementary and, together, are key components of healthcare governance. Effective risk management underpins healthcare quality management activity and can result in:

- Better patient care
- Improved public perception and confidence
- Reduction in errors
- Reduction in staff turnover
- Fewer complaints
- Improved reputation
- A more open culture
- A more proactive approach to managing risk
- Systematic identification of organisational weaknesses
- Improved communication with stakeholders
- Improved performance and effectiveness
- Reduced likelihood of unexpected events
- Better decision making at all levels
- Improved project management
- Better outcomes
- Better resource planning and utilisation
- Compliance with legislation
- Greater rationality and transparency in decision making
- Protection of public funds
- Assurance to Risk and Audit Committees and thereby assurance to the HSE Board and all stakeholders and the public

This document outlines the components of this standard comprising a ‘statement of standard’ together with supporting ‘criteria’ and brief ‘guidance’ (Appendix 1). Each criterion reflects the elements of a higher level management model (see Figure 1 on next page) describing a ‘system of internal control’ for a healthcare organisation, the risk management aspects of which conform to the requirements of the Australian/New Zealand risk management standard AS/NZS 4360:2004, which has been formally adopted as the process for managing risk in the HSE.

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1 Best practice in ‘corporate governance’ requires organisations to establish an effective system of internal control and risk management. The model presented here does that.
The model (see Figure 1) sits within an overarching Governance approach and influences, and is influenced by, the Organisational Culture. The model specifies a generic approach to providing assurances to stakeholders that a healthcare organisation is meeting its various objectives and providing the right ‘outcomes’. In this case the objective is to ensure implementation of an integrated quality and risk management framework. Various criteria, including outcomes criteria, have been devised in line with the elements of the model as follows:

- The principal **Objective** is to ensure that “Healthcare quality and risk are effectively managed through implementation of an integrated quality and risk management system that ensures continuous quality improvement.” This is known as the ‘Statement of Standard.’

- **Stakeholders** should be identified and there should be proper Communication and Consultation with all relevant stakeholders within and outside the organisation.

- An appropriate **Accountability** framework to meet the objective should be developed by each Directorate, encompassing suitable management structures and practices (leadership, committees, reporting arrangements, policies and strategies, etc.) at all levels in the Directorate.
• The **Core Processes and Programmes** required to produce the desired outcomes should be in place – these include a range of quality and risk management processes.

• The organisation (or department, etc.) should have the necessary **Capability** (leadership, knowledgeable and skilled staff, adequate financial and physical resources, etc.) to ensure the entire system works effectively.

• Management should receive sufficient objective **Independent Assurance** as to the robustness of the system defined by the model.

• Management should continuously **Monitor, Review, Learn and Improve** all aspects of the system defined by the model. Such monitoring etc. will necessarily include taking cognisance off any independent assurances received. Overall, this process will ensure that the quality and risk management system is properly configured and working effectively to achieve the desired outcomes and overall objective(s).

2.0 **Standard**

2.1 **Statement of Standard**

The full text of the standard reads as follows:

‘**Healthcare quality and risk are effectively managed through implementation of an integrated quality and risk management system that ensures continuous quality improvement.**’

2.2 **Assessment of compliance with the Standard**

There are three levels at which compliance with this standard will be assessed

**Level 1.** The service has *approved* documentation which describes the process for managing quality and risk as outlined for each criterion in the standard. This documentation should outline responsibilities, policy procedures and guidelines (PPG’s) and implementation plans including the learning and development needs of relevant staff.

**Level 2.** The service can demonstrate implementation of the *approved* documentation which describes the process for managing quality and risk as set out in this standard.

**Level 3.** The service can demonstrate that there are processes in place to monitor the overall effectiveness of the *approved* documentation which describes the process for managing quality and risk as set out in this standard.
There are 22 criteria incorporated within this standard divided in line with the internal control model as described on page 4 of this document.

In order to comply with the standard, it is necessary to comply with each of the criteria.

3.0 Criteria

3.1 Communication and consultation

1. Appropriate and effective mechanisms are in place for communication and consultation on quality and risk matters with key stakeholders within and outside the organisation.

   **Guidance:**
   
   A stakeholder analysis should be conducted to ensure firstly that all appropriate stakeholders have been identified and, secondly, that appropriate mechanisms have been defined for communicating and consulting with the various stakeholders or stakeholder groups. The test of an ‘effective’ communication and consultation mechanism is ‘does it work and, as such, services should aim to provide clear evidence of effectiveness?’

3.2 Accountability

2. Individual responsibility for quality and risk management is clearly defined and there are clear lines of accountability for quality and risk management leading up to the most senior manager or director.

   **Guidance:**
   
   Implementation of quality and risk management programmes at all levels, especially at the corporate level, is a challenge for all managers. Its success will depend largely on the support of senior managers at all levels in the HSE. Critical to this process is the involvement of all relevant professionals, including clinical and social care professionals – nursing, medical, social services and health and social care professionals - estates, finance, ICT, administration, human resources, support personnel, etc.

   Quality and risk management is everybody’s business. Consequently, individuals should be clear about their responsibilities for managing quality and risk. Responsibilities should be stated in individual job descriptions, or in relevant policy and procedural documents. There should be an overall accountability framework for risk management within the organisation or department that leads to the most senior manager or director. At National level, the accountability framework for quality and risk management will extend to individual national directors, the CEO and the Board of the Health Service Executive (HSE).
### 3.3 Core Processes and Programmes

<table>
<thead>
<tr>
<th>3</th>
<th>Standardised policies, procedures and guidelines are in use that are based on best available evidence and are governed by a formal document control process.</th>
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<tbody>
<tr>
<td><strong>Guidance:</strong></td>
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<tr>
<td>There is a system in place to facilitate all services in the development of Quality and Risk Management Systems, Policies, Procedures and Guidelines (PPGs) with supporting Document Management and Document Control in the HSE. These PPGs should be based on evidence based practice.</td>
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<tr>
<td>The organisation and all services have a responsibility to identify and develop PPGs to support all elements of service provision so that there is guidance and advice on all key decisions made by that service, implement evidence based practice, implement practice to change and educate staff on the correct processes.</td>
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<tr>
<td>Staff are provided with support and guidance on the sourcing, appraising, and implementation of evidence based practice and on the implementation and management of change to practice. Services have processes in place to facilitate the education of staff and to up skills staff on any new or improved processes.</td>
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<tr>
<td>There is a system in place to ensure effective document management and document control of Quality Systems including processes to support the ongoing review and change of PPGs and identifying evidence based best practice</td>
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<tr>
<th>4</th>
<th>A comprehensive programme of clinical and healthcare audit is in place that involves staff in multi-disciplinary audits.</th>
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<tr>
<td><strong>Guidance:</strong></td>
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<tr>
<td>Clinical and Healthcare Audit involves comparing current practice to evidence based best practice in the form of standards, identifying areas for quality improvement and implementing changes to practice to meet the standards.</td>
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<tr>
<td>It is the duty of all healthcare professionals to ensure they deliver the highest possible standard of care to their patients/clients so by definition all staff should be auditing their work. Clinical and Healthcare Audit ideally should be multidisciplinary but unidisciplinary audits may also be conducted.</td>
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<td>5</td>
<td>Healthcare services participate in relevant standards-based quality assurance processes.</td>
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<td><strong>Guidance:</strong></td>
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<td>In pursuit of excellence, the HSE is committed to meeting the requirements of relevant quality assurance programmes e.g. accreditation process. Through this process, management and staff identify the strengths of their organisation as well as areas for improvement. Using this standardised approach, healthcare providers can prioritise areas for improvement and based on evidence based best practice, implement standards in these areas. This process looks at the services from a cross functional perspective rather than individual department. Each healthcare organisation will be required to provide evidence of independent assurance of performance against these standards. This process is a key part of the HSE’s commitment to a programme of Continuous Quality Improvement.</td>
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<td>6</td>
<td>Continuing learning and development programmes aimed at meeting the development needs of health service staff and the service needs of the organisation are in place.</td>
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|   | **Guidance:**  
*Continuous learning and development has been increasingly recognized by all staff groups in recent years. The demand for quality, accountability and efficacy of practice has highlighted the need for staff to demonstrate that they are keeping abreast of new knowledge, techniques and developments related to their professions. The importance of continual professional development is also being recognised by professional bodies and much work has been carried out to ensure that it is a feature of the requirements of continued registration.*  
The HSE had recognised the importance of staff development and has sought through the Human Resources Function to put in place mechanisms to assist managers and staff in meeting their requirements for continuing learning and development.  
Learning and development should not be seen as an isolated process and requires discussion, negotiation and agreement between individuals and managers to identify and support training and development needs. Whilst each partner may have their own responsibilities, learning and development should be seen as a collaborative process which benefits the patient, the service and the individual. Services should be able to demonstrate that they have conducted an analysis of the learning and development requirements of staff in order to support delivery of a high quality service and have plans to support staff in achieving necessary learning and development. |
| 7 | Patients and the public are involved in quality improvement and assurance processes. |
|   | **Guidance:**  
*Patient and public involvement is now recognised as integral to reduce risk and improve the quality, safety and accountability of health and social care services. The perspective of the patient and public brings an added dimension to what constitutes high quality and safe care. It is only by working in partnership with patients and the public and listening and learning from their feedback, that it is possible for health services to truly appreciate what constitutes high quality, safe healthcare.*  
Services should be able to demonstrate that they have in place mechanisms which involve patients and the public, at an appropriate level, in a meaningful way and that these mechanisms are evaluated and that the results of this involvement are used to improve the manner in which services are configured or delivered. |
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<th>Text</th>
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| 8    | Quality improvement activities utilise a range of quality improvement tools to assist with assessing and diagnosing issues, identifying remedies and measuring improvement.  

**Guidance:**  
*Improvement comes from the application of knowledge; generally the more complete and appropriate the knowledge, the better the improvements will be when the knowledge is applied to making changes. Any approach to improvement, therefore, must be based on building and applying knowledge. The ability to develop, test and implement changes is essential for continuous improvement.*  

*A fundamental starting point is the use of recognised quality tools to accurately diagnose issues, identify remedial actions, implement these and then to assess and measure the change that has occurred.* |
| 9    | Risks of all kinds are systematically identified, assessed and managed in order of priority in accordance with Australian/New Zealand Standard AS/NZS 4360:2004 ‘Risk management.’  

**Guidance:**  
The Australian/New Zealand risk management Standard sets out a generic process for managing risks of all kinds. The Standard is used by many healthcare organisations and systems around the world, including in Australian healthcare, the UK National Health Service and the Irish Health Service Executive. A central concept in the Standard is the ‘risk register’, which is a simple tool for creating and maintaining a repository of risk information. The Standard is supported by HB436:2004, the Risk Management Guidelines Companion to AS/NZS 4360:2004 and the HSE’s Risk Management Framework which provides further detailed guidance on implementing the Standard.  

The risk register takes account of risk identified from a number of quality and risk sources e.g. clinical audit, inspections, accreditation, risk assessment (health and safety and clinical/care) incident management, etc.  

The aggregation of this data will allow for the systematic monitoring, communication and targeting of risks for quality improvement at all levels in the organisation.  

The accuracy and effectiveness of the risk register is also dependant on the service developing it having identified risks from the widest range of information.  

The risk register is a dynamic document and should be the subject of regular review and updating. |
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<tr>
<th>10</th>
<th>An ongoing programme of patient/service user safety improvement is in operation.</th>
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**Guidance:**

> Based on the premise that patient/service user safety is an integral part of the delivery of quality care, health care settings should establish comprehensive patient safety programmes.

> The key elements of such a programme include (1) a shared belief that although health care is a high-risk undertaking, delivery processes can be designed to prevent failures and harm to participants; (2) a structured approach to the proactive identification and actioning of those aspects of a service that have a potential to cause harm. This should include evidence from sources within the healthcare setting locally, nationally and internationally. (3) an organisational commitment to detecting and analysing patient/service user incidents and near misses; and (4) the development of a just and fair culture which supports patients/service users and staff and has an emphasis on learning to improve.

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<tr>
<th>11</th>
<th>Appropriate systems are in place to ensure the management of occupational health, safety and welfare.</th>
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**Guidance:**

> The safety and welfare of persons who work in and access our service is critically important. The occupational health safety and welfare programme seeks to ensure, as far as is reasonably practicable, that the workplace, work equipment and systems of work are safe. Occupational health should aim at: the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations; the prevention amongst workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; the placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological capabilities; and, to summarize, the adaptation of work to the person and each person in his job. (WHO 1995)

> Services should be able to demonstrate that there are in place systems and processes to address the requirements of occupational health, safety and welfare, and that these systems are operating as part of the overall risk management system.

> The programme should be in line with the HSE’s Corporate Safety Statement
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<tr>
<th>12</th>
<th>Appropriate systems and processes are in place to ensure that environmental and fire risks are minimized through meeting legislative and mandatory requirements.</th>
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<tbody>
<tr>
<td><strong>Guidance:</strong></td>
<td>There should be a clearly defined fire safety policy to protect all those using the premises – such as patients, staff and visitors – which should include arrangements for planning, organisation, control, monitoring and review of fire safety measures.</td>
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<td>Poor management of the work environment can result in injuries to staff and those that access services. This includes how we design, equip and maintain our facilities and the systems that are in place to minimise harm.</td>
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<td></td>
<td>Services should be able to demonstrate that there are in place systems and processes to address the requirements of environmental and fire safety and that these systems are operating as part of the overall operational management system.</td>
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<tr>
<th>13</th>
<th>All incidents are properly recorded; reported; managed; rated according to impact; reviewed where appropriate to determine contributory factors, root causes and any actions required; and are subjected to periodic aggregate reviews to identify trends and further opportunities for learning, risk reduction and quality improvement.</th>
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<tr>
<td><strong>Guidance:</strong></td>
<td>Many studies internationally have shown that the root causes of adverse events in healthcare tend to lie in inadequate systems rather than bad or poorly performing people. Consequently, the organisation must establish the true causes of adverse events and make systems improvement to help ensure that similar adverse events do not recur. A ‘just’ or ‘fair’ culture is an essential prerequisite to improving the safety and quality of care. Services should have in place a process for incident management which is in line with HSE policy and the requirements of relevant external agencies.</td>
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<th>14</th>
<th>All complaints, comments and appeals are properly recorded and, where appropriate, managed; rated according to impact; reviewed to determine contributory factors, root causes and any actions required; and are subjected to periodic aggregate reviews to identify trends and further opportunities for learning, risk reduction and quality improvement.</th>
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<tbody>
<tr>
<td><strong>Guidance:</strong></td>
<td>Complaints, comments and appeals are sometimes inextricably linked and are complementary sources of information for improving the safety and quality of the healthcare service. All</td>
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</table>
complaints, comments, appeals and incidents should be managed in line with the HSE’s Complaints Policy.

Services should demonstrate that consumer feedback is actively encouraged and promoted. Local processes should support best practice in complaint handling where both the rights of consumers and staff are upheld throughout the complaint management process.

Evidence should also demonstrate that complaints information is integrated into organisational improvement activities.

| 15 | All claims are recorded and analysed to identify opportunities for learning, risk reduction and quality improvement. |

**Guidance:**
Claims typically follow on from incidents and complaints and are a complementary source of potential information for improving the safety and quality of care. All claims should be managed in line with HSE arrangements with its indemnifiers.

Evidence should also demonstrate that claims information is integrated into organisational improvement activities.

| 16 | Effective processes are in place for learning and for sharing information on good practice in quality and risk management. |

**Guidance:**
Assuring the safety of patients, staff and visitors is a key priority within the HSE. This requires a collaborative approach to the analysis of quality and risk information so that the lessons learnt from this analysis are shared across the service area and across the HSE.

It is essential that all areas in the HSE develop a learning culture and that effective learning and sharing processes are developed to spread good practice and educate/inform others.
### 3.4 Capability

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<tr>
<td><strong>17</strong></td>
<td>Managers at all levels of the organisation fulfil their responsibility by demonstrating commitment to the management of quality and risk</td>
</tr>
<tr>
<td>Guidance:</td>
<td>Managers at all levels have a responsibility for the strategic direction of the organisation and for creating the environment, the structures and related processes for quality and risk management to operate effectively. Quality and risk management is actively supported by managers at all levels. Quality and risk are effectively managed in the organisation in a timely way</td>
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<tr>
<td><strong>18</strong></td>
<td>Resources are provided to implement and support quality and risk management.</td>
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<tr>
<td>Guidance:</td>
<td>No organisation has infinite resources to deal with quality and risk management, or any other matter. The resources that are provided need to be realistic, i.e. in line with issues such as the organisation’s risk profile.</td>
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<tr>
<td><strong>19</strong></td>
<td>All staff are provided with adequate quality and risk management information, instruction and training appropriate to their role.</td>
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<tr>
<td>Guidance:</td>
<td>Note that this criterion refers to all staff. Some staff will require more quality and risk management information, instruction and training than others. A 'training needs analysis' should, where possible, be conducted in relation to the organisation’s (or department’s) risk profile.</td>
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3.5 Outcomes

| 20 | There is demonstrable improvement in key performance indicators related to quality and risk management. |

**Guidance:**

*Demonstration of improvements in managing quality and risk requires definition of key performance indicators (KPIs). Consequently a fundamental outcome of the quality and risk management process is that KPIs have been defined. Directorates and healthcare facilities should take a systematic approach to identifying a range of relevant KPIs.*

*In addition to locally developed KPI’s all areas in the HSE will report against the following KPI on an annual basis.*

*"There is demonstrable improvement in compliance with this quality and risk management standard."*

*(A self-assessment must be carried out on an annual basis to check compliance against each of the criteria contained in this standard. A simple spreadsheet tool has been developed to aid this process.)*

*It is expected that with the management of quality and risk there should come demonstrable improvements in these KPIs.*
3.6 Monitoring and Review

All aspects of the system in place for quality and risk management are monitored and reviewed by management for the purposes of learning and improvement.

Guidance:
Each aspect of the quality and risk management system described by this standard should be periodically monitored and reviewed by local management and submitted to the Head of Quality and Risk on an annual basis. This involves monitoring and reviewing, either separately or together, the following matters relating to effective quality and risk management:

- The objectives for managing quality and risk
- Communication and consultation processes
- Accountability arrangements
- Core processes
- Capability issues, e.g. human, financial and physical resources, knowledge, skills, expertise, etc.
- Outcomes
- Monitoring, review, learning and improvement processes
- Independent assurance processes

3.7 Independent Assurance

Senior management receives independent assurance(s) that an integrated quality and risk management system is in place that meets the requirements of this standard.

Guidance:
To be considered ‘independent’ the assurance (or assurances) should come from a source(s) independent of the department, Directorate or organisation receiving the assurances. This does not necessarily mean that assurance providers need to be wholly independent of the organisation. For example, Internal Audit and the Quality and Risk Office may well have the requisite independence necessary to provide adequate assurances to senior management depending on the area requiring assurance.

A self assessment tool is also being developed. This will enable staff to assess their level of compliance with the criteria and establish a plan for improvement.
4.0 References

1. Department of Health (UK) *Risk Management Standard Controls Assurance Unit 2001*


4. Section on Quality in Health Care Medical Development Division *Risk management framework Standard Ministry of Health Malaysia 2006*

5. Standards Australia/Standards New Zealand, *Australian/New Zealand Standard: Risk Management (AU/NZS 4360) 2004*


Appendix 1: Examples of verification for each criterion.

Please note: these examples are purely illustrative in nature and should not be considered as a check list for compliance or as an exhaustive list of examples. Each service should consider verification criteria that best reflect the individual service and the business processes involved in service delivery.

Criterion 1  Communication and Consultation

Open disclosure policy,
Executive walk arounds,
Risk reduction quality improvement suggestion schemes,
Staff surveys,
Patient experience surveys,
Patient focus or consumer focus groups. (This is not an exhaustive list and further guidance may be obtained from ‘The Patient Participation Framework document’).
Safety Statement
Involvement of safety representatives

Criterion 2  Accountability

Risk management strategic/operational plan in line with the HSE approach to risk management has been developed and approved by the senior manager.
Responsibility and accountability for management of risk is reflected in the job descriptions of all staff
Check job descriptions – do they include responsibilities and/or accountabilities
Risk management organisational chart which outlines the accountabilities for risk management
Terms of reference of the management committee(s) responsible for overseeing risk management
Minutes of the management committee(s) responsible for overseeing risk management
Copy correspondence or minutes of meetings of the executive directors with responsibility for risk management
As risk is defined as anything which threatens the achievement of an organisation’s objectives – checks/audits of compliance with objectives – i.e. risk management, financial, organisational and clinical and social care are a measure of accountability

Criterion 3  Standardised Policies, Procedures, Guidelines

Use of a structured approach to the identification areas where PPG development is required
That the process for PPG development includes all relevant stakeholders
That PPGs take account of best available evidence
That PPGs are constructed using standardised formatting
That the distribution, implementation and review of PPGs is done in a structured manner
That PPGs are aligned with the area of development and with areas for which there is overlap
That the development of PPGs involves a process of consultation which is documented.
That PPGs are formally ratified at senior level and that this process is documented.

Criterion 4  Participation in Standards Based Quality Assurance Programmes

Organisational commitment at all levels
Minutes of meetings
Inspection reports such as HACC
Accreditation/Award achievement incl. Hygiene Award(s), Decontamination audit
Radiation standards
EU Blood Directive compliance against standard
Criterion 5  **Clinical and Healthcare Audit**

- Explicit organisational commitment
- Audit Plan
- Multi Professional Audit Teams
- Completed audit reports
- Results of Audit used in planning/improvement
- Linkages with other Quality and Risk Programmes
- Link with relevant Risk Registers

Criterion 6  **Continuing Professional Development**

- Training needs analysis
- Personal Development Planning
- Access to and availability of appropriate training programmes
- Linkage between organisational plan and training plan
- Team based Performance Management

Criterion 7  **Patient and Public Participation**

- Evidence of public and patient participation on relevant committees
- Patient engagement mechanisms
- Surveys
- Comments/Suggestions

Criterion 8  **Use of Quality Improvement Tools**

- Use of tools such as Statistical Process Control, Process Mapping Plan Do Study Act cycle etc
- Quality improvement planning based on evidence from analysis
- Monitoring of Quality Improvement plans using quality improvement tools

Criterion 9  **Proactive Risk Management Process**

- Risk management/governance strategy.
- Risk identification tools.
- Hazard reporting policy and forms.
- Completed risk assessments.
- Risk treatment options.
- Evidence of risk treatment.
- Business plans.
- Annual report.
- Risk registers.
- Minutes of committees.
- Job descriptions.
- Training programmes.
- Action plans.
- Evidence of communication with stakeholders.
- Evidence of communication with staff.
- Monitoring and review procedure.
- Performance indicators.
- Evidence of monitoring and review.
- Management minutes.
- Patient surveys.
- Incident, complaints and claims analysis.
- Evidence of prominent placement of risk management on management team agendas
- Board Risk Committee
Criterion 10  Patient/Service User Safety Programme

Patient Safety Improvement initiatives based on the risks identified from local, national and international information sources.
Training for staff in relation to patient safety.
Evidence of alignment of business planning and financial resources with patient/service user goals.
Evidence of active engagement of management and staff involved in the clinical care of the patient in the patient/service user safety improvement process.
Evidence of prominent placement of patient/service user safety on management team agendas
Evidence of patient/service user involvement in development the patient/service user safety improvement programme.

Criterion 11  Occupational Health, Safety and Welfare Programme

Evidence of compliance with Health and Safety Authority Safety and Health Audit Tool for the Healthcare Sector

Evidence of compliance with policies with relevant policies e.g.

- Prevention of Blood Borne Diseases in a Healthcare Setting
- Management of Tuberculosis in Healthcare Staff
- Vaccination Policies – Hepatitis B, MMR, Varicella
- MRSA Policy for the Healthcare Worker
- Management of Health and Wellbeing at Work
- Manual Handling
- Skin Surveillance
- Alcohol and Drugs in the Workplace
- Rehabilitation of ill/injured Workers
- Pregnant Worker Policy
- Night Worker Policy
- Lone Worker Policy
- Management of Workplace Violence and Aggression
- Display Screen Equipment and Eyesight Testing

Evidence of relevant OHSW audits e.g.
- Sickness and absence trends and costs
- Ill health retirement trends and costs
- Management referrals trends and costs
- Occupationally acquired illness/disease

Criterion 12  Environmental and Fire Safety Programme

Evidence of compliance with Fire Safety legislation
In Healthcare premises, evidence that the capability and dependency of occupants was considered when determining suitable procedures, actions and fire safety measures to meet their personal evacuation needs.
Evidence that there is both an emergency fire action plan in place and arrangements to implement the plan.
That a written emergency fire action plan is kept on the premises and that there is evidence that it is available to and known by staff and form the basis of the training and instruction which is provided. This plan should be available for inspection by the enforcing authority.
Evidence of compliance with relevant Environmental legislation e.g. Management and Disposal of Waste (healthcare and other) Food Safety to include the Food Safety Authority of Ireland Act 1998 and relevant regulations and standards
Evidence that there is an appropriate environmental safety management system to include
Roles and Responsibilities for Environmental Safety are described
Education programmes for relevant staff in respect of environmental safety
Availability and maintenance of relevant equipment
Environmental risk assessments and improvement plans

**Criterion 13  Incident Management**
- Incident reporting policy/procedure.
- Incident report form and guidelines for completion.
- Incident investigation reports.
- Trend analysis reports.
- Minutes of the committees responsible for overseeing risk management.
- Evidence of reporting to the indemnifiers and to other relevant external bodies and stakeholders.
- Induction training programmes.
- Completed incident report forms
- Relevant correspondence
- Action plans and follow up reports;
- Major incident policy.

**Criterion 14  Complaints Management**
- Complaints policy/procedure.
- Claims handling policy/procedure.
- Evidence of dissemination within the organisation and use of the National HSE complaints policy and associated documentation.
- Job descriptions.
- Management reports.
- Reports of the committee responsible for overseeing risk management.
- Complaints committee reports.
- Training needs analysis.
- Training programmes.
- Training evaluation forms.
- Induction programme.
- Complaints leaflets and posters.
- Complaints files.
- Independent review reports.
- Evidence of claims management training.
- Evidence of claim settlement negotiations.

**Criterion 15  Claims Management**
- Claims handling policy/procedure.
- Evidence of dissemination within the organisation and use of the National HSE complaints policy and associated documentation.
- Job descriptions.
- Management reports.
- Reports of the committee responsible for overseeing risk management.
- Claims committee reports.
- Claims files.
- Review of and learning from case settlement reports
- Evidence of claims management training.
- Evidence of claim settlement negotiations.

**Criterion 16  Learning and Sharing Good Practice**
- Seminars.
- Briefings.
- Workshops.
- Education programmes.
- Coaching and Mentoring Courses.
- Newsletters, journals, publications etc.
Presentation at National/International Initiatives or Conferences.

**Criterion 17  Leadership for Quality and Risk Management**

- Quality and Risk Management strategy/policy
- Quality/risk/safety/governance committees and/or evidence that quality and risk is an item on committee/team meeting agenda’s at all levels of the organisation.
- Documented quality and risk management processes e.g. incident reporting and review process.
- Evidence of review of quality and risk information and follow up action
- Evidence of on-going monitoring and review of actions
- Evidence of support staff employed in the organisation with a quality and/or risk management support role E.g. risk advisor, Health and Safety advisor, quality facilitator
- Evidence of Patient Safety Leadership WalkAroused

**Criterion 18  Resources for Quality and Risk Management**

- Identified budgetary provision for issues relating to Quality and Risk
- That risk register is used as a decision making tool for targeting resources to areas of highest priority

**Criterion 19 Staff Information, Instruction and Training**

- Key risks identified within the organisation are reflected in the business plan.
- Training needs assessment.
- Training prospectus.
- Local training needs assessment.
- Training records (risk management training in the wider sense such as training on fire safety, health & safety, first aid/CPR, management of needle stick injuries, management of aggression, records management, etc.).
- Reports on attendance levels.
- Induction programme.
- Local induction procedures.
- Training objectives.
- Evidence of review of training objectives.
- Training course evaluations.
- Team based performance management

**Criterion 20  Outcomes**

- Evidence of development of locally agreed KPI’s in relation to Q&R
- Evidence of monitoring of agreed KPI’s
- Improvement plans to address performance

**Criterion 21  Monitoring and Review**

- Risk management/governance strategy/policy.
- Risk identification tools.
- Hazard reporting/management policy and forms.
- Risk assessment tools and forms.
- Completed risk assessments.
- Risk treatment options.
- Evidence of risk treatment.
- Business plans.
- Annual report.
- Risk registers.
- Minutes of committees.
- Job descriptions.
- Training programmes.

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1Patient Safety Leadership Walkarounds is a tool for improving patient safety developed by the Institute for Healthcare improvement. 
2http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/tools/PatientSafetyLeadershipWalkarounds
Action plans.
Evidence of communication with stakeholders.
Evidence of communication with staff.
Monitoring and review procedure.
Performance indicators.
Evidence of monitoring and review.
Management minutes.
Patient surveys.
Consultation with staff
Incident, complaints and claims analysis.
Audit of the Quality and risk management system
Board Risk Committee

Criterion 22  **Independent Assurance**

- Internal audit report(s).
- Reports from Quality and Risk
- Minutes of the committee(s) responsible for overseeing quality and risk management.
- Reports from HIQA. Mental Health Commission and other review bodies.
- Reports from Professional Bodies
- Reports from external audit.
- Reports from multi-professional audit.