

**National Health Regulatory Authority  
Kingdom of Bahrain**



**GUIDANCE ON  
QUALITY, SAFETY AND RISK MANAGEMENT  
FOR HEALTHCARE FACILITIES  
IN THE  
KINGDOM OF BAHRAIN**

***THE PURPOSE OF THIS DOCUMENT IS TO PROVIDE GUIDANCE FOR HEALTHCARE FACILITIES IN BAHRAIN TO IDENTIFY AND MANAGE QUALITY, SAFETY AND RISKS ASSOCIATED WITH THEIR SERVICES.***

***ADDITIONAL SUPPORT AND GUIDANCE IS ALSO AVAILABLE ON A NUMBER OF KEY AREAS FOR HEALTH CARE FACILITIES LICENSED IN THE KINGDOM OF BAHRAIN***

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## **1. Introduction**

The NHRA is committed to the provision of safe, high quality health services across the Kingdom of Bahrain. Raising and maintaining the quality and safety of care requires sustained commitment to continuous improvement from everyone involved in providing health care services in the Kingdom. This should lead to achievement of best possible health and personal outcomes for patients and service users in the Kingdom.

The NHRA has developed and published licensing standards that set the criteria for all health care facilities in the Kingdom. The aim of the licensing standards is to provide a common set of requirements that will apply across all health care service providers to ensure that health services are both safe and of an acceptable quality.

This guidance document has been developed to assist health care facilities in meeting the criteria contained in the licensing standards that relate to Quality, Safety and Risk Management.

The objective of this guidance is to:

- Provide guidance for quality, safety and risk management for health care service providers, regardless of the size of facility, in the Kingdom of Bahrain;
- drive core programs of work in quality, safety and risk management, including: clinical effectiveness; service user and community involvement; risk management and patient safety; continuous professional development; and service improvement; and
- ensure that appropriate accountability and oversight arrangements are in place to monitor quality, safety and risk management and to support the provision of assurance to senior management, and to the NHRA.

It is recognized that there are many good approaches to improving quality, safety and risk management already being pursued by health care service providers in the Kingdom of Bahrain. It is not, therefore, the intention of this document to be highly prescriptive. Rather, key principles of quality, safety and risk that can be applied in a variety of different settings to varying degrees. The main areas required to achieve optimum quality, safety and risk management are set out and 'check questions' are provided for consideration by service managers and clinicians in an attempt to identify any areas for improvement.

## 2. Guidance for Integrated Quality, Safety and Risk Management

### 2.1 Introduction

Figure 1 illustrates the proposed framework which can be used for integrating quality, safety and risk management processes. The framework has been adapted from the framework developed by the Health and Safety Executive in Ireland.

Figure 1 – Framework for Integrated Quality, Safety and Risk Management.

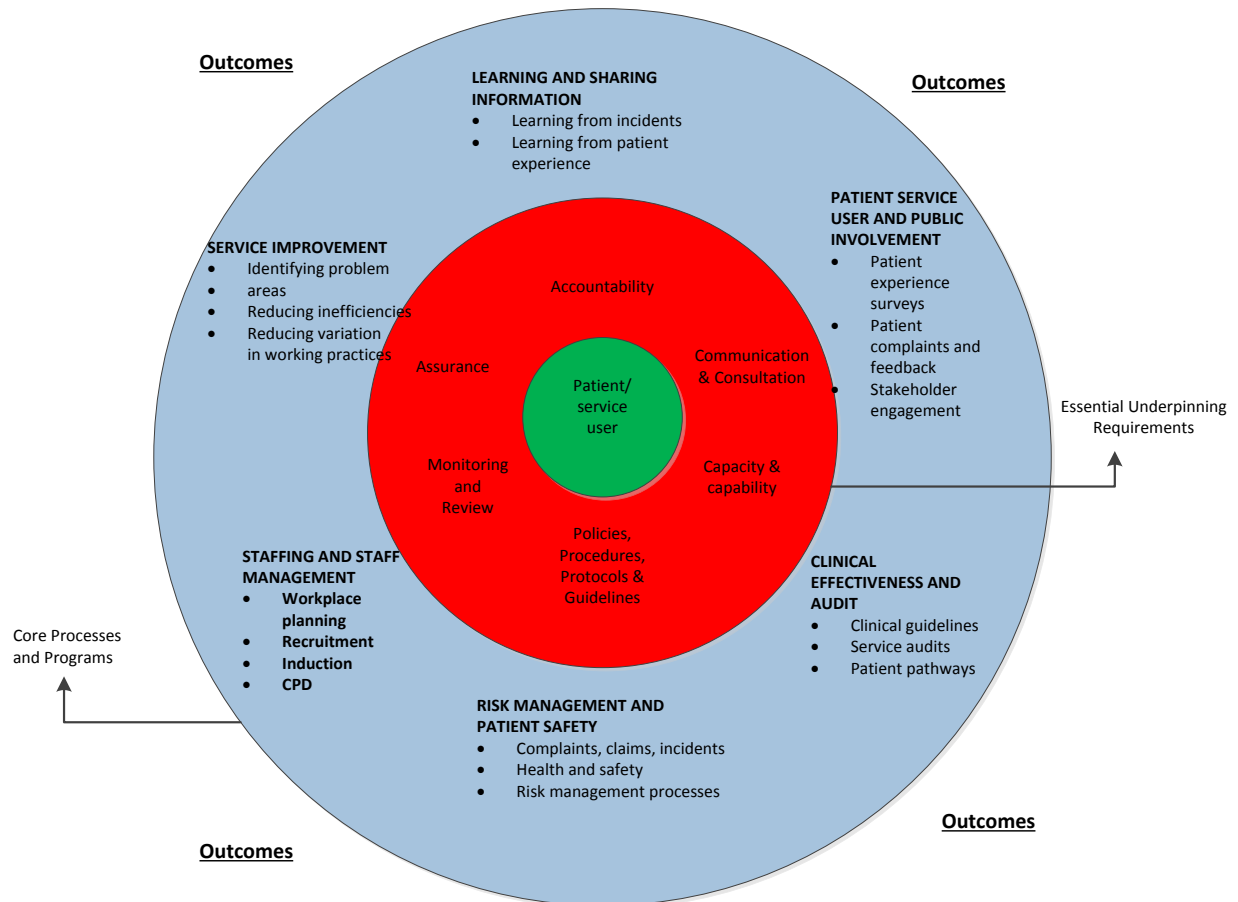


Figure 1 – Framework for integrated quality, safety and risk management. The term 'Patient/Service User' should also be interpreted as 'client.'

There are three key components to the framework:

1. Essential underpinning requirements
2. Core processes and programs that lead to good outcomes; and
3. Outcomes: (Key Performance indicators) that demonstrate improvements in quality, safety and risk management and link, where possible to good outcomes for patients.

Together, these components form the basis for a self-assessment by health care facilities of the extent to which an integrated quality, safety and risk management system is in place that conforms to the guidance and meets the requirements of the overarching NHRA licensing standards. Each component is elaborated in more detail in subsequent sections in this document and provides guidance for healthcare facilities.

A number of 'check questions' relating to key aspects of the guidance have been developed. Managers and clinicians can assess the extent to which an integrated guidance for quality, safety and risk management is in place within their healthcare facility. On completion of the self-assessment process, where improvements are required then an action plan should be developed. Regular monitoring and review of action plans will ensure that actions are being implemented, leading to better outcomes for patients and others.

## **2.2 Essential underpinning requirements**

The following are the essential underpinning requirements that health care facilities should have in place in order to drive safe and effective care. Many of these requirements will ensure that effective leadership and/or management is in place to drive forward the quality, safety and risk management agenda. The NHRA recognizes that healthcare facilities vary in size and scope of practice across the health care services available in Bahrain. However, whether a small single handed GP practice or a large hospital, these principles should still apply, although implementation may differ in complexity.

### **2.2.1 Communication and consultation with key stakeholders**

Effective communication and consultation structures and strategies should be in place with key stakeholders within and outside the facility, including staff and patients. 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. Larger facilities will in general have more stakeholders to consider than smaller single handed practices.

### **2.2.2 Clear accountability arrangements**

Appropriate accountability arrangements for quality, safety and risk management should be in place at all levels from front line staff up to the most senior accountable manager or, in the case of larger facilities, the governing board.

Individual responsibilities will typically be set out in job descriptions. Accountability arrangements should also be set down for committees and/or groups (if any) involved in quality, safety and risk management. These should include clear terms of reference and robust reporting arrangements. Committee/group structures should, where relevant, provide for coordination of all quality, safety and risk activities and information. Interdependent groups

that must work together effectively and share resources should be linked by hierarchy, information systems, common membership (where possible and appropriate), and meeting schedules, etc. Single handed practices may consider joining resources with other facilities to look at particular quality, safety and risk management practices.

It is likely that facilities will have, or will establish a committee or group (even with 2 or 3 members in smaller facilities) to oversee quality, safety and risk management performance and to report periodically to local senior management. Where relevant, consideration should be given to the need for such a committee/group to reflect the multi-professional membership required to achieve comprehensive quality, safety and risk management across all of the operations and services provided.

### **2.2.3 Adequate capacity and capability**

The facility should have the capacity and overall capability to implement and monitor effective quality, safety and risk management systems. Capacity and capability implies qualified people, adequate physical and financial resources and access to specialist expertise where necessary. Staff at all levels should fulfill their responsibility by demonstrating commitment to the management of quality, safety and risk management. Budget development and financial resources should be aligned with the quality and safety goals to ensure ongoing review and consideration of such priorities when developing service and other business plans. And, all staff should be provided with adequate quality, safety and risk management information, instruction and training appropriate to their role.

### **2.2.4 Standardised policies, procedures, protocols and guidelines including a standardised document control process.**

The facility should have a system in place to facilitate all services in the development of standardised policies, procedures, protocols and guidelines, (however named). They should be based on best available evidence and should be governed by a formal document control process that includes processes to support the ongoing review and changes. Staff should be provided with support and guidance on the sourcing, appraising, and implementation of evidence based practice and on implementing any resulting changes in practice. Where new services are being established, the development of policies, procedures, protocols and guidelines should be considered at the time of commissioning.

The NHRA has developed guidance to assist facilities in standardizing policies, procedures, protocols and guidelines.

### **2.2.5 Robust monitoring, reporting and review arrangements**

Managers should ensure adequate monitoring and review of the systems in place for quality, safety and risk management. All aspects of the guidance described in this document should be regularly monitored and reviewed in order that management can learn from any weaknesses in the systems and make improvements where necessary.

This should include subjecting key performance indicators (KPIs) relating to outcomes to regular review (e.g. monthly or quarterly) to establish trends and to pick up anomalies that require further investigation. The results of periodic independent audits should also be reviewed to ensure that action plans are developed and implemented to rectify any system weaknesses (see section 2.2.6). There is a need to develop suitable KPIs for quality, safety and risk management and to report on selected KPIs (see section 4) for additional information on suggested KPI's).

### 2.2.6 Assurance arrangements

Managers should ensure that they obtain sufficient assurance on the effectiveness of the systems in place for quality, safety and risk management to form part of their monitoring and review process. Assurances can come from a variety of sources either within or outside the Kingdom of Bahrain. The most objective assurances are derived from independent reviewers which include internal/external inspection or audit, peer review, and NHRA annual inspections.

### 2.2.7 Check questions

The table below contains 'check questions' and guidance that can be utilized by health care facilities to gain an understanding of their strengths and areas for improvement in relation to implementation of the underpinning requirements outlined above. The responses to these questions can be either 'yes', 'no', 'partial', 'not applicable' or 'don't know'. The 'partial' responses are categorised as 'low', 'moderate' or 'high'. Where a no or partial response is provided, an action plan or 'quality Improvement plan' (QIP) should be developed to implement any requirements. Where the question number box is shaded, this denotes that the response to the question may need to be made following the gathering and aggregation of appropriate information from a number of departments, service areas, etc.

<b>Essential underpinning requirements: Check questions</b>	
<b>A.</b>	<b>Communication and consultation with key stakeholders</b>
1.	<p><b>Has a 'stakeholder analysis' been carried out to identify all internal and external stakeholders relating to quality, safety and risk management?</b></p> <p><b>GUIDANCE</b>            A stakeholder analysis should be conducted to ensure firstly that all appropriate internal and external stakeholders have been identified and, secondly, that appropriate mechanisms have been defined for communicating and consulting with the various stakeholders or stakeholder groups (see questions A4 and A5). In smaller facilities, a formal stakeholder analysis may not be necessary if there is sufficient evidence that there is a clear understanding of who the key stakeholders are. Stakeholders are likely to have been identified in a range of documentation (See below). However, it is considered good practice to undertake and properly document a formal stakeholder analysis. A specimen stakeholder analysis (for illustration only) is given below.</p>

SPECIMEN STAKEHOLDER ANALYSIS (ILLUSTRATIVE)			
STAKEHOLDER	INTERNAL/ EXTERNAL	COMMUNICATION/ CONSULTATION STRATEGIES	FREQUENCY
Staff	INTERNAL	Staff handbook • Annual report • Induction Program • Newsletter • Communication boards • Staff survey	• Annually • Annually • Monthly • Quarterly • Weekly • Bi-annually
Patients/Service Users	INTERNAL	Annual report • Focus groups • Patient/Service User survey • Newspaper/magazine • Conferences • Mailshots	Annually • Ad-hoc • Annually • Quarterly • Annually • Ad hoc
NHRA	EXTERNAL	Senior management feedback Annual inspections	As required Annual

**EXAMPLES OF VERIFICATION**

- Stakeholder analysis documentation
- Strategic guidance document
- Risk management strategy
- Public engagement strategy
- HR strategy
- Training needs analysis
- Staff survey
- Patient survey

2. **Are arrangements in place to ensure that the ‘stakeholder analysis’ is maintained and up-to date?**

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In the case of a formal stakeholder analysis, there should be a documented policy outlining arrangements both for conducting the analysis and for ensuring that the analysis is maintained and up-to-date. There may be a committee or group that has responsibility for maintaining the stakeholder analysis up-to-date. Check that the analysis is indeed maintained up-to-date by reference to dated updates of the stakeholder analysis.

**EXAMPLES OF VERIFICATION**

- Relevant policy

3. **Is there effective communication and consultation with internal stakeholders in relation to the purpose, objectives and working arrangements for quality, safety and**



	<p><b>risk management?</b></p> <p><b>GUIDANCE</b>  The test of an ‘effective’ communication and consultation mechanism is ‘does it work and, as such, facilities should aim to provide clear evidence of effectiveness. Internal stakeholders will include, for example, staff, committees, groups, departments, etc. Check firstly that there is communication/consultation with all internal stakeholders, and secondly that such communication/consultation can be considered to be effective. Do all internal stakeholders have a clear understanding of the purpose, objectives and working arrangements for quality, safety and risk management?’</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Stakeholder surveys</li> <li>• Apparent impact of communication strategies on key performance indicators</li> </ul>
4.	<p><b>Are internal and, where appropriate, external stakeholders kept fully informed on progress to achieve quality, safety and risk management objectives?</b></p> <p><b>GUIDANCE</b>  Stakeholder engagement in quality, safety and risk management is extremely important. One means of keeping stakeholders engaged is to keep them informed on progress to achieve objectives. The means of keeping external stakeholders informed should be as set out in the stakeholder analysis (see question 1, above). Note that the only requirement here is to demonstrate that internal and, where appropriate, external stakeholders are kept fully informed on progress. There is no requirement to test the effectiveness of the communication processes that keep stakeholders fully informed. It is assumed that provided the information is properly communicated then stakeholders will be informed. You should check that information on progress to achieve objectives is being properly communicated to all relevant stakeholders.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Stakeholder communication logs</li> </ul>
<b>B.</b>	<b>Clear accountability arrangements</b>
1.	<p><b>Are clearly documented accountability arrangements in place to support the most senior accountable manager to discharge his/her responsibility for quality, safety and risk management?</b></p> <p><b>GUIDANCE</b>  There should be an ‘Organizational chart’ and, possibly, an ‘accountability guidance’ document that describes the accountability arrangements for quality, safety and risk management. In most instances the arrangements will be a hierarchical with structures in place that lead up to the senior accountable manager (e.g. Medical director, senior consultant, hospital manager, administration manager, etc.). In some instances, however, the accountability arrangements might reflect a more ‘matrix working’ environment with a number of ‘dotted line’ accountabilities. This</p>

	<p>guide does not presume to know the best arrangements for any particular health care facility. “What matters is what works” should be followed. The organizational chart might identify, for example, and in no particular order:</p> <ul style="list-style-type: none"> <li>• Executive management team</li> <li>• Clinical governance committee</li> <li>• Director of Quality and Risk</li> <li>• Health and Safety Office</li> <li>• Risk Manager</li> <li>• Quality Manager</li> <li>• Internal Audit Department</li> <li>• Ethics and Research Office</li> <li>• Audit Committee</li> <li>• Radiation Safety Committee</li> <li>• Quality, Risk and Safety Committee</li> <li>• Medical Safety Committee</li> <li>• Clinical Audit Committee</li> <li>• Individual directorates</li> <li>• Individual service providers</li> <li>• etc.</li> </ul> <p>For all job positions there should be clearly documented job descriptions and reporting arrangements. All committees and group should have clear terms of reference and reporting arrangements. Smaller facilities should amalgamate roles and positions to effect good practice.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Organizational structure</li> <li>• Job descriptions</li> <li>• Committee/Group terms of reference</li> <li>• Accountability guidance document</li> <li>• Quality/Safety/Risk Management strategy</li> </ul>
2.	<p><b>Do the documented accountability arrangements ensure that that the most senior accountable manager is fully informed in relation to key areas of quality, safety and risk performance?</b></p> <p><b>GUIDANCE</b></p> <p>The arrangements should cover all areas of quality, safety and risk management deemed key by the facility management. For example, if radiation protection is a consideration for the facility, then there will most likely be a radiation safety committee (however named).</p> <p>It is important to be clear about the range of performance information that will be required by the senior accountable manager to provide assurance that quality, safety and risk performance is being properly managed. Expert advice from individuals and/or</p>

	<p>functions with expert knowledge of quality, safety and risk management is essential. This can be carried out through external consultancy if required. Check that the accountability arrangements cover all key areas and are capable of keeping the senior accountable manager fully informed in relation to key areas of quality, safety and risk performance.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Organizational Structure</li> <li>• Job descriptions</li> <li>• Committee/Group terms of reference</li> <li>• Accountability guidance document</li> <li>• Quality/Safety/Risk Management strategy</li> <li>• Key performance indicators</li> </ul>
3.	<p><b>Are the roles and responsibilities played by any committees or groups described clearly within the accountability arrangements?</b></p> <p><b>GUIDANCE</b> Check all relevant documentation for clear descriptions of the roles and responsibilities for committees or groups.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Organizational chart</li> <li>• Committee/Group terms of reference</li> <li>• Accountability guidance document</li> <li>• Quality/Safety/Risk Management strategy</li> </ul>
4.	<p><b>Do committee structures and reporting arrangements provide for coordination and integration of quality, safety and risk activities and priorities?</b></p> <p><b>GUIDANCE</b> This will most likely involve a 'judgement call.' Quality, safety and risk management activities should be co-ordinated and priorities should be set across the facility, and not in 'silos'. How do the structures and reporting arrangements provide for coordination and integration? Is there evidence that an integrated approach to quality, safety and risk is being taken? Is there evidence that priorities are being set across the facility?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Organizational chart</li> <li>• Committee/Group terms of reference</li> <li>• Accountability guidance document</li> <li>• Quality/Safety/Risk Management strategy</li> </ul>
<b>C.</b>	<b>Adequate capacity and capability</b>
1.	<b>Do managers at all levels fulfill their responsibility by demonstrating commitment to the management of quality, safety and risk?</b>

	<p><b>GUIDANCE</b></p> <p>Quality, safety and risk management is everybody’s business. Managers at all levels have a particular responsibility to set the right tone for quality, safety and risk management within the facility and should lead by example. They should demonstrate their commitment to managing quality, safety and risk by ensuring these matters are considered ‘high priority’ in everything the facility does. Thus, quality, safety and risk management matters might be standing agenda items at various regular management meetings; managers might hold sub-ordinates to account for their performance in relation to quality, safety and risk management issues; and senior managers might engage in regular quality, safety and/or risk management walkarounds. In the field of patient safety, for example, it has become fashionable for senior managers to conduct executive patient safety walkarounds. Managers, who attend relevant education and training events, get involved in complaints and incidents investigations and set aside specific budgetary sums of money to address quality, safety and risk management goals (see question 3. below) may also be seen to be demonstrating commitment.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Minutes of meetings of relevant committees or groups</li> <li>• Notes associated with walkarounds, etc. showing evidence of managerial engagement</li> <li>• Manager’s job descriptions</li> <li>• Evidence of managers’ attendance at educational and training events, e.g. Root Cause Analysis</li> <li>• Evidence of managers’ involvement in complaints and incident investigations</li> <li>• Notes associated with walkarounds, etc. showing evidence of managerial engagement</li> </ul>
2.	<p><b>Do service planning and other business planning arrangements take into account the quality, safety and risk management goals and priorities of the facility when developing budgets and other financial strategies?</b></p> <p><b>GUIDANCE</b></p> <p>Look for documented evidence, in meeting minutes, etc., that service planning and other business planning arrangements take account of quality, safety and risk management goals when developing budgets and other financial strategies.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Minutes of meetings of relevant committees or groups</li> <li>• Notes associated with relevant project groups, e.g. capital development</li> </ul>
3.	<p><b>Is a defined percentage or allocation of the facility’s annual budget committed to achieving defined quality, safety and risk management goals?</b></p> <p><b>GUIDANCE</b></p> <p>Often, financial resources need to be specifically identified and protected in order for quality, safety and risk management goals to be achieved. Look to see whether senior</p>

	<p>management has set aside specific financial resources for achieving defined quality, safety and risk management goals. There may, for example, be specific quality, safety or risk management initiatives that have been allocated funding, including education and training.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Minutes of relevant meetings</li> <li>• Details of budgets, including education/training.</li> </ul>
<p>4.</p>	<p><b>Is there access to appropriate resources to implement effective quality, safety and risk management systems, e.g. qualified people, physical and financial resources, access to specialist expertise, etc.?</b></p> <p><b>GUIDANCE</b></p> <p>No facility 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 facility’s risk profile. Financial resources are partly dealt with in question 3, above, and can be a thorny issue. Facilities need to view investments in quality, safety and risk management as adding value to service provision, rather than simply being a drain on financial resources.</p> <p>There is increasing evidence in healthcare that investing in quality, safety and risk management can save money in the longer term through reduction in waste and improvements in efficiency. What is potentially more challenging to assess is the extent to which a facility has access to appropriate staffing resources for quality, safety and risk management. Larger facilities (such as general hospitals) might have an entire department or function dedicated to quality, safety and risk management with sufficient qualified and trained staff.</p> <p>As part of the self-assessment against this question, facilities might identify all staff and other resources they have available to deal with quality, safety and risk management matters. This might include qualified quality, safety and/or risk management advisors, front-line leads for quality, safety and/or risk management, etc. It might also include managers and clinicians who have undertaken any form of education and training in relation to quality, safety and/or risk management. A resource matrix can then be produced setting out all resources available at different levels. Guidance should then be sought from an experience adviser as to whether overall resources are appropriate to implement effective quality, safety and risk management systems.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Resource matrix</li> </ul>
<p>5.</p>	<p><b>Are all staff provided with adequate quality, safety and risk management information, instruction and training appropriate to their role?</b></p> <p><b>GUIDANCE</b></p> <p>All staff will need some form of quality, safety and risk management training – but only as appropriate to their role. For some staff, all of their information, instruction and</p>

	<p>training requirements will be satisfied in relation to induction and ongoing training processes. Other staff may require additional information, instruction and training. For practical purposes, ‘instruction’ relates to showing somebody how to carry out a practical activity, whereas ‘training’ is a more formal process that includes theory as well as practice.</p> <p>One way of assessing compliance with this question is for facilities to conduct an overall information, instruction and training needs analysis. Such an analysis should be informed by the facility’s risk profile.</p> <p>When thinking through provision of instruction and training, as well as considering induction and ongoing training provision, think whether you have other events going on, or have access to e.g. local quality, safety or risk management workshops; seminars; conferences; specialist in-house training. Think also about your policies, procedures and guidelines, staff booklets and other published information in relation to whether staff have adequate information.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Documented analysis of information, instruction and training needs</li> <li>• Documented assessment of whether need have been, or are being met</li> <li>• Training records for staff</li> <li>• Events log (conferences, seminars, etc.)</li> <li>• Information publications for staff</li> </ul>
<b>D.</b>	<b>Standardised policies, procedures, protocols and guidelines</b>
1.	<p><b>Does the facility operate a standardised document control process for all policies, procedures, protocols and guidelines?</b></p> <p><b>GUIDANCE</b></p> <p>Health care facilities typically have large numbers of policies, procedures, protocols and guidelines. A medium sized hospital can have several hundred policy documents. Control of these documents in terms of issuing them and maintaining them up-to-date can pose a major challenge. It is therefore necessary to ensure that the facility operates a standardised document control process.</p> <p>The document control process could be manually implemented or, ideally, will be computer-based.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Document control policy/procedure</li> </ul> <p><b>RESOURCES</b></p> <ul style="list-style-type: none"> <li>• NHRA Guidance on developing Policies, Procedures, Protocols and Guidelines</li> </ul>
2.	<p><b>Are arrangements in place for training staff in appraising and developing policies, procedures, protocols and guidelines and for identifying evidence-based best practice?</b></p>

	<p><b>GUIDANCE</b></p> <p>Specific training should be provided to relevant staff in relation to developing policies, procedures and guidelines and identifying evidence-based best practice. Such training may be provided in-house or may be externally sourced. Some facilities may have a policy on developing policies etc.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Policy on policies</li> <li>• Staff training records</li> </ul>
3.	<p><b>Are policies, procedures, protocols and guidelines standardised throughout the facility and, where appropriate, are they evidence-based?</b></p> <p><b>GUIDANCE</b></p> <p>This question is a check to ensure all policies are standardised and are evidence-based. If in doubt, randomly sample policies to confirm.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Random sampling of policies to ensure compliance.</li> </ul>
4.	<p><b>Are arrangements in place to ensure that where new services are being established, the development of policies, procedures, protocols and guidelines is considered at the time of commissioning?</b></p> <p><b>GUIDANCE</b></p> <p>This question is a check to ensure that the need for developing policies etc. when developing new services is not overlooked.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Check service development plans and actions taken to develop policies,</li> </ul>
<b>E.</b>	<b>Monitoring and review arrangements</b>
1.	<p><b>Are all aspects of the guidance described in this document regularly monitored and reviewed in order that management can learn from any weaknesses in the systems and make improvements where necessary?</b></p> <p><b>GUIDANCE</b></p> <p>Each aspect of the quality, safety and risk management system described in this guidance document should be periodically monitored and reviewed by management at least on an annual basis. This involves monitoring and reviewing, either separately or together, the following matters relating to effective quality, safety and risk management:</p> <ul style="list-style-type: none"> <li>• Communication and consultation with key stakeholders</li> <li>• Clear accountability arrangements</li> <li>• Adequate capacity and capability</li> <li>• Standardised policies, procedure and guidelines</li> <li>• Monitoring and review arrangements</li> </ul>

	<ul style="list-style-type: none"> <li>• Assurance arrangements</li> <li>• Clinical effectiveness and audit</li> <li>• Patient and public involvement</li> <li>• Risk management and patient safety</li> <li>• Staffing and staff management</li> <li>• Service improvement</li> <li>• Learning and sharing information</li> <li>• Key Performance Indicators (KPIs)</li> </ul> <p>As part of the review process, any identified weaknesses in any aspect of the guidance should be rectified.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Relevant meeting minutes that highlight reviews carried out and any actions required/taken</li> <li>• Relevant review reports</li> </ul>
2.	<p><b>Are the results of independent and other audits used to inform improvements in quality, safety and risk management systems?</b></p> <p><b>GUIDANCE</b></p> <p>For the purpose of this question, the term ‘audit’ is widely defined to encompass all types of review leading to a report on the strengths and weaknesses in the systems in place for quality, safety and risk management. To be considered independent, an audit must be carried out by an individual, function or organization that is not directly associated with the service provider. For example, independent audits might be carried out by accreditation surveyors or external inspections by the NHRA, the results of which could be used by the facility and service provider to inform improvements in quality, safety and risk management systems.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Action plans showing improvement actions linked to audits, reports, etc.</li> <li>• Minutes of relevant meetings</li> <li>• KPIs demonstrating performance improvement(s) linked to improvements in the systems for quality, safety and risk management</li> </ul>
3.	<p><b>Are key performance indicators (KPI’s) reviewed regularly to identify and correct anomalies and to drive continuous improvement in quality, safety and risk management?</b></p> <p><b>GUIDANCE</b></p> <p>KPIs can be tracked over time to determine anomalies, which can be investigated to determine whether system improvements need to be made. Consider, for example, incidents involving harm to patients, for a hospital for a whole year. The statistics show a higher number of falls during the night shift than during the day shift on a specific ward.. This anomaly is subjected to a root cause analysis and it was found to be caused by the lack of attention and provision of a night call system for elderly patients in their</p>



	<p>beds. The night nurses were not putting the night call bell within easy reach for the patient. The result was an increase in the number of reported falls incidents involving harm to patients during the night shifts. This was remedied by providing the night nurses training and education on the importance of providing the night call bell to patients before they left the ward area.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Action plans showing improvement actions</li> <li>• Minutes of relevant meetings</li> </ul>																		
<b>F.</b>	<b>Assurance arrangements</b>																		
1.1	<p><b>Does senior management receive sufficient assurance on the systems in place for quality, safety and risk management?</b></p> <p><b>GUIDANCE</b></p> <p>The determination of what constitutes sufficient assurance is a judgment call by those carrying out the self-assessment, assisted where necessary by those with specialist quality, safety and/or risk management knowledge and expertise.</p> <p>One approach to determining sufficiency is to construct a matrix of all actual sources of assurance available from within and outside the facility and determine, based on the facilities risk profile, whether it is felt that sufficient assurance exists, or whether there are gaps in assurance. The table below gives an illustrative matrix. The question that needs to be continually asked is <i>“Given the nature and extent of assurances available to me, do I feel assured that effective systems are in place for quality, safety and risk management?”</i></p> <p><b>SPECIMEN ASSURANCE MATRIX (ILLUSTRATIVE)</b></p> <table border="1" data-bbox="298 1203 1430 1677"> <thead> <tr> <th>KEY RISK (From Risk Register)</th> <th>SOURCE OF ASSURANCE</th> <th>INTERNAL/EXTERNAL</th> </tr> </thead> <tbody> <tr> <td>Infection control</td> <td>Internal Hand Hygiene audit</td> <td>Internal</td> </tr> <tr> <td>Infection control</td> <td>NHRA annual inspection report on compliance with the licensing standards</td> <td>External</td> </tr> <tr> <td>Infection control</td> <td>Random specimen sampling results</td> <td>External</td> </tr> <tr> <td>Information management</td> <td>Internal audit on records management</td> <td>Internal</td> </tr> <tr> <td>Etc.</td> <td>Etc.</td> <td>Etc.</td> </tr> </tbody> </table> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Internal audit reports</li> <li>• Clinical audit reports</li> <li>• Management reports</li> </ul>	KEY RISK (From Risk Register)	SOURCE OF ASSURANCE	INTERNAL/EXTERNAL	Infection control	Internal Hand Hygiene audit	Internal	Infection control	NHRA annual inspection report on compliance with the licensing standards	External	Infection control	Random specimen sampling results	External	Information management	Internal audit on records management	Internal	Etc.	Etc.	Etc.
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	<ul style="list-style-type: none"> <li>• Minutes of the committee(s) responsible for overseeing quality, safety and risk management</li> <li>• Reports from NHRA, and/or other accreditation review bodies</li> <li>• Reports from Professional bodies</li> <li>• Reports from external auditors</li> <li>• Reports from multi-professional audit</li> </ul>
2.1	<p><b>Do the assurances received by senior management form an integral part of their ongoing monitoring and review processes?</b></p> <p><b>GUIDANCE</b>  See also question E.2, which is related (although it deals with general management rather than, necessarily, senior management). What evidence is there that senior management utilise the assurances they are provided with on quality, safety and risk management issues as part of their own (i.e. senior management) monitoring and review of the overall facility?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Minutes of relevant meetings</li> <li>• Reports to the board</li> <li>• Reports to NHRA</li> </ul>

### **3 Core Processes and Programs**

Health care Facilities should, where appropriate, have in place the following core processes and programs. The NHRA recognizes that healthcare facilities vary in size and scope of practice across the health care services available in Bahrain. However, whether a small single handed GP practice or a large hospital, these core processes and programs can be implemented at varying degrees of complexity.

#### **3.1 Clinical effectiveness and audit**

The term 'clinical effectiveness' is used in this guidance to encompass clinical audit and evidence-based practice.

A structured program, or programs, should be in place to systematically monitor and improve the quality of clinical care provided across all services. This should include, systems to monitor clinical effectiveness activity; mechanisms to assess and implement relevant clinical guidelines; systems to disseminate relevant information; and use of supporting information systems.

The processes and outcomes of care should be regularly audited and should demonstrate that the delivery of care reflects adopted policy decisions, guidelines and protocols. Audits should be based on agreed selection criteria such as: high risk, cost, or volume; serious concerns arising from incidents, serious adverse events or complaints; new guidelines; or patient focus.

Where appropriate, and whenever possible, clinical effectiveness activities should be patient centered. That is, they should take into account the whole patient journey. This may require multi-professional working and working across boundaries between primary, secondary and tertiary care.

Clinical effectiveness activities have a significant cost implication in terms of the resources required to support projects and the opportunity cost of professionals examining and assessing their practice. These costs need to be justified but if effectively employed facilities should find that the clinical effectiveness activities that they support result in demonstrable improvements in the standards of care and represent efficient use of resources.

#### **3.2 Patient/service user and public/community involvement**

Mechanisms should be in place to involve patients/service users and the public / communities in the planning, development, delivery and evaluation of services. These mechanisms should be evaluated and the results of this involvement used to improve the manner in which services are configured or delivered. This should include a systematic process to ensure that facilities respond to, and learn from all forms of feedback.

A baseline assessment of service user and community involvement should be conducted, which provides a starting point and ensures that progress can be monitored. Service user and

community involvement should be facilitated at all levels, including individual care episodes, information development, service planning, staff and service user education and quality review and improvement.

### **3.3 Risk management and patient safety**

#### **The risk management process**

Risks of all kinds should be systematically identified, assessed and managed in order of priority. The NHRA advocates the use of a system such as the Australian/New Zealand Standard AS/NZS 4360:2004 for identifying and categorizing risk levels. (see appendix 1)

‘Risk management’. Risks of all kinds need to be managed across the facility, including risks to the safety and quality of patient care; occupational health, safety and welfare risks; environmental and fire safety risks; risks to business continuity; and so on.

The principal vehicle for managing and communicating risk at all levels is the risk register, which allows a repository of risk information to be maintained. The NHRA has included guidance on the process for managing risk to provide practical help on implementing risk management, including developing and maintaining a risk register, in accordance with AS/NZS 4360:2004. (See appendix 2)

#### **Known high priority risks**

Notwithstanding the need to systematically identify, assess and manage risks of all kinds, facilities should be able to demonstrate that they have systems in place to manage known and applicable high priority risk issues such as:

- Medication management
- Slips, trips and falls
- Violence and aggression
- Vulnerable adults and children
- Infection control
- Haemovigilance
- Utility contingency
- Medical devices
- Waste management
- Moving and Handling
- Restraint
- Suicide and deliberate self harm
- Patient absconson
- Management of patient information
- Lone working

#### **Patient safety**

Internationally, patient safety is now recognised as a major concern which requires a specific management focus. An ongoing program of patient safety improvement should therefore be in operation. All risks to patient safety should be identified, assessed and managed in line with implementing the risk management process set out above.

#### **Occupational safety, health and welfare**

All staff-related occupational safety, health and welfare risks should be identified, assessed and managed in line with implementing the risk management process set out above. Appropriate systems and processes should be in place to ensure the management of occupational safety, health and welfare.

### **Environmental and fire safety**

All environmental and fire safety risks should be identified, assessed and managed in line with implementing the risk management process set out above. Appropriate systems and processes should be in place to ensure that environmental and fire risks are minimized through meeting legislative and mandatory requirements.

### **Incidents, complaints and claims recording, analysis and learning**

Recording, analyzing and learning from all types of incidents, complaints and claims are key components of a successful reactive approach to risk management. All incidents, complaints and claims should be properly recorded; reported to management; managed in accordance with an agreed policy; rated according to impact; reviewed where appropriate to determine contributory factors, root causes and any actions required; and should be subjected to periodic aggregate reviews to identify trends and further opportunities for learning, risk reduction and quality improvement.

### **3.4 Staffing and staff management**

Systems should be in place to ensure appropriate workforce planning, recruitment, induction, and training and development for staff appropriate to their roles and responsibilities, including compliance with related:

- NHRA standards and guidance;
- Professional and other codes of practice; and
- Employment legislation.

Robust pre-employment checks should be undertaken in line with LMRA and NHRA requirements including: education qualifications of staff to ensure that they are suitably qualified through an approved education facility and are licensed by the NHRA or registered with the appropriate occupational body; health assessment must be carried out in accordance with the Kingdom of Bahrain requirements; and in all cases references should be obtained and checked.

Continuing learning and development programs aimed at meeting the development needs of staff and the service needs should be in place and should facilitate professional and regulatory requirements and inform the facilities training, education and workforce development.

### **3.5 Service improvement**

Notwithstanding the core processes and programs outlined above, healthcare facilities should ensure that there is a structured program in place to support continuous quality improvement across all services. This requires the identification of quality priorities for the healthcare facility; adopting relevant approaches to quality improvement; and utilizing appropriate quality tools to secure demonstrable benefits for stakeholders.

Facilities should participate in relevant external quality assurance programs where available. This will assist them in implementing a comprehensive quality improvement program incorporating externally recognised standards as well as internally led initiatives.

### 3.6 Learning and Sharing Information

It is essential that all healthcare facilities develop a learning culture and that effective learning and sharing processes are developed to spread good practice and generally educate/inform others. The pursuit of continual improvement in quality, safety and risk management is crucially dependent on learning from experience and on sharing information good practice for learning purposes. This requires establishment and maintenance of effective processes for learning and for sharing good practice in relation to quality, safety and risk management.

Examples of good practice can be identified by, for example, frontline staff, patients and service users, senior management, external inspectors and independent assessors. In some healthcare facilities, a library of good practice can be found on the Intranet and this can be shared with other healthcare provider's and facilities.

Internationally, some facilities establish regular learning and sharing forums where staff can bring examples of good practice for discussion.

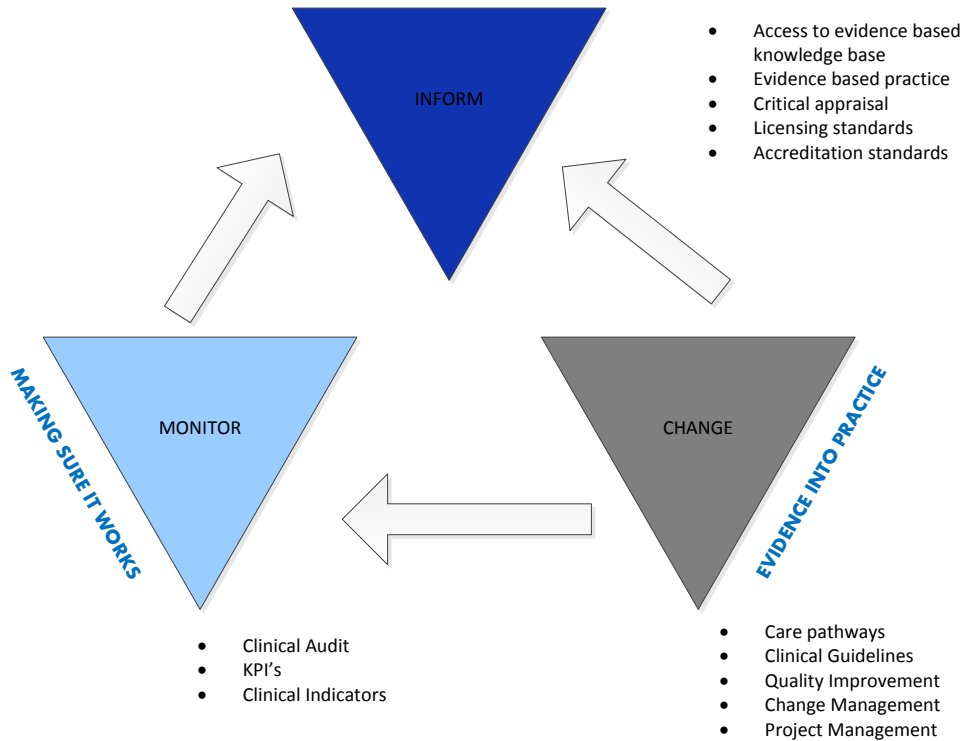
Newsletters are also a good means for disseminating information for learning and sharing.

### 3.7 Check questions

The table below contains check questions that can be utilized to gain an understanding of their strengths and areas for improvement in relation to implementation of the core processes and programs outlined above. The responses to these questions can be either 'yes', 'no', 'partial', 'not applicable' or 'don't know'. The 'partial' responses are categorised as 'low', 'moderate' or 'high'. Where a no or partial response is provided, an action plan or 'quality improvement plan' (QIP) should be developed to implement any requirements. Where the question number box is shaded, this denotes that the response to the question may need to be made following the gathering and aggregation of appropriate information from a number of departments, service areas, etc.

	<b>Core processes and programs: Check questions</b>
<b>G</b>	<b>Clinical effectiveness and audit</b>
1.	<p><b>Is a structured program, or programs, in place to systematically monitor and improve the quality of clinical care provided across all services?</b></p> <p><b>GUIDANCE</b> The NHRA has also developed guidance on Clinical Audit, available of the NHRA website. It states that "A structured program, or programs, should be in place to systematically monitor and improve the quality of clinical care provided across all services. This should include, systems to monitor clinical effectiveness activity (including clinical audit); mechanisms to assess and implement relevant clinical</p>

guidelines; systems to disseminate relevant information; and use of supporting information systems.” The ‘clinical effectiveness cycle,’ which includes clinical audit, is presented in the Figure below.



The clinical audit process is presented below. This figure is reproduced from Building a Culture of Patient Safety<sup>1</sup>



<sup>1</sup> Department of Health & Children (2008). Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance

	<p>The key requirement under this question is to check whether there is a structured program, or programs, in place to systematically monitor and improve the quality of clinical care provided across all services. The program, or programs, should be based around clinical effectiveness and clinical audit approaches as briefly outlined in the figures above.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Program documentation</li> <li>• Relevant policy/procedure</li> <li>• Minutes of relevant meetings (e.g. clinical effectiveness or clinical audit committee meetings)</li> <li>• Action/Improvement plans</li> </ul>
2.	<p><b>Are arrangements in place to monitor clinical effectiveness activity, including clinical audit?</b></p> <p><b>GUIDANCE</b></p> <p>This question provides a check on the monitoring aspect of question G.1, above. Are arrangements in place to monitor clinical effectiveness activity, including clinical audit. Are they sufficient? Do they work? Does the program, or programs, in place to improve the quality of clinical care provided across all services actually work? Are demonstrable improvements in clinical care being made as a consequence?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Relevant policy</li> <li>• Minutes of relevant meetings (e.g. clinical effectiveness or clinical audit committee meetings)</li> <li>• Clinical audit plan(s)</li> <li>• Completed clinical audit reports</li> <li>• Action/Improvement plans</li> <li>• Management reports outlining evidence of improvements in clinical care</li> </ul>
3.	<p><b>Is the implementation of evidence-based practice through use of recognised standards, guidelines and protocols promoted?</b></p> <p><b>GUIDANCE</b></p> <p>The implementation of evidence-based practice through use of recognised standards, guidelines and protocols should be promoted by the facility as a matter of policy. All relevant policy documentation should make reference to this. Evidence-based practice should not be interpreted as being limited to clinical practice. All practices, including managerial practices, should, where possible, be evidence-based. Check to ensure that every opportunity is being taken to promote the implementation of evidence-based practice through use of recognised standards, guidelines and protocols.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Relevant policies, e.g. quality, clinical effectiveness/audit, risk management, etc.</li> </ul>



	<ul style="list-style-type: none"> <li>• Minutes of relevant meetings, e.g. clinical effectiveness/audit committee</li> <li>• Ask relevant staff</li> </ul>
4.	<p><b>Are information systems being properly used to support clinical effectiveness activity?</b></p> <p><b>GUIDANCE</b>  The determination of whether information systems are being properly used is a judgment call by those carrying out an assessment.  Where information systems are in place, the key issues here are to check a) whether the information within the systems is being fully utilised to support clinical effectiveness activity and b) whether there are any deficiencies in the information systems themselves that could be improved to provide better clinical effectiveness support.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Clinical effectiveness policy/procedures</li> <li>• Ask staff engaged in clinical effectiveness activity</li> </ul>
5.	<p><b>Are clinical audits based on agreed selection criteria (e.g. high risk, cost, or volume; serious concerns arising from adverse events or complaints; new guidelines; local or national priorities; or patient focus)?</b></p> <p><b>GUIDANCE</b>  Given limited resources, it is usually necessary to prioritize clinical audit activity. The determination of priority in clinical audit selection should be based on agreed criteria. The criteria should be clearly set in the relevant policy and procedural documentation, and reflected in clinical audit work plans, etc.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Clinical audit policy/procedure</li> <li>• Documented clinical audit work plan</li> </ul>
6.	<p><b>Is there evidence that clinical effectiveness activities result in changes in clinical practice and improvements in the standards of care?</b></p> <p><b>GUIDANCE</b>  The outcome of clinical effectiveness activity is to demonstrate improvement in care through changes in clinical practice and improvement in care standards. What evidence exists to demonstrate improvement? Can clinical practice change be demonstrated? How has care standards improved as a consequence of clinical effectiveness activity?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Clinical effectiveness/audit reports</li> <li>• Minutes of relevant meetings e.g. clinical effectiveness/audit committee</li> <li>• Ask staff</li> </ul>

<b>H.</b>	<b>Service user and community involvement</b>
1.	<p><b>Is patient/service user and public feedback, including feedback on actual patient experience, regularly sought and integrated into quality, safety and risk management improvement activities?</b></p> <p><b>GUIDANCE</b> A range of approaches can be adopted to obtain feedback, including complaints and suggestions mechanisms, focus groups, surveys, meetings with patient groups, etc. Feedback should be regularly sought, analysed and the key finding from the feedback incorporated into ongoing quality, safety and risk improvement activities.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Survey report</li> <li>• Focus group reports</li> <li>• Suggestion reports</li> <li>• Minutes of relevant meetings</li> <li>• Action/improvement plans</li> </ul>
2.	<p><b>Is sufficient information and opportunity provided for patients/service users to meaningfully participate in their own care?</b></p> <p><b>GUIDANCE</b> A professional judgment, backed by meaningful patient/service user feedback, needs to be made about the sufficiency of information and opportunities for patients to participate in their own care.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Patient surveys</li> <li>• Examination of Care Plans</li> <li>• Check role of clinical nurse specialists</li> <li>• Information guides for patients/service users</li> </ul>
3.	<p><b>Are patients/service users and the public involved in the development of patient information?</b></p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Check minutes of meetings, relevant reports, etc</li> </ul>
4.	<p><b>Are arrangements in place to train and support patients/service users, staff and the public involved in the patient and public involvement process?</b></p> <p><b>GUIDANCE</b> Many healthcare facilities now use direct feedback from patients and hold user group discussion forums or meetings. This allows for training and education to occur regarding the mission and vision of the healthcare facility and helps to identify realistic expectations from a user's perspective.</p>

	<p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Evidence of completed forum meetings, user groups and training</li> </ul>
5.	<p><b>Are patients/service users and the public invited to assist in planning new services?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Check arrangements for planning new services</li> <li>• Check attendance at relevant meetings (meeting minutes)</li> </ul>
1.	<p><b>Risk management and patient safety</b></p>
1.	<p><b>Are risks of all kinds systematically identified and assessed?</b></p> <p><b>GUIDANCE</b></p> <p>Substantial guidance exists on risk management on adopting an integrated approach to quality, safety and risk management. The NHRA advocates the adoption of a system such as the AS/NZS 4360:2004 – the Australian/New Zealand guidance on risk management, as per international best practice.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Risk management policy</li> <li>• Risk register(s)</li> <li>• Evidence of risk identification workshops</li> <li>• Incident reviews</li> <li>• Complaints review</li> <li>• Business plans</li> </ul>
2.	<p><b>Are risks of all kinds managed in order of priority?</b></p> <p><b>GUIDANCE</b></p> <p>Typically, given limited resources and other considerations, risks need to be managed in some kind of priority order. This usually happens in the context of the risk register where risks are assessed and evaluated and are ranked in relation to the magnitude of the risk. Refer to appendix one for further information.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Risk register(s)</li> <li>• Risk action plan(s)</li> </ul>
3.	<p><b>Are risk registers used for the purpose of managing and communicating risk at all levels?</b></p> <p><b>GUIDANCE</b></p> <p>The key requirement of this question is to determine whether risk registers are used at all levels in the facility. Risk registers are, essentially, communication tools. They help ensure sufficient information on risks is communicated to the appropriate level in a</p>

	<p>facility to allow the risk to be properly managed.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Evidence of risk registers at all levels in the facility</li> <li>• Evidence of decision-making in relation to risk at all levels</li> </ul>
<p>4.</p>	<p><b>Are arrangements in place to manage known high priority risk issues?</b></p> <p><b>GUIDANCE</b></p> <p>Notwithstanding the need to systematically identify, assess and manage risks of all kinds, healthcare facilities should be able to demonstrate that they have systems in place to manage known high priority risk issues such as:</p> <ul style="list-style-type: none"> <li>– Medication management</li> <li>– Slips, trips and falls</li> <li>– Violence and aggression</li> <li>– Vulnerable adults and children</li> <li>– Infection control</li> <li>– Haemovigilance</li> <li>– Utility contingency</li> <li>– Medical devices</li> <li>– Waste management</li> <li>– Moving and Handling</li> <li>– Restraint</li> <li>– Suicide and deliberate self harm</li> <li>– Patient absconsion</li> <li>– Management of patient information</li> <li>– Lone working</li> </ul> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Dedicated policies covering specific high priority risk issues</li> <li>• Relevant programs to address high priority risk issues</li> <li>• Relevant action plans</li> </ul>
<p>5.</p>	<p><b>Are staff-related occupational safety, health and welfare risks identified, assessed and managed and are arrangements in place to ensure the management of occupational health, safety and welfare?</b></p> <p><b>GUIDANCE</b></p> <p>All staff-related occupational safety, health and welfare risks should be identified, assessed and managed in line with implementing the risk management process. Appropriate systems and processes should be in place to ensure the management of occupational safety, health and welfare. Be sure to seek the advice of competent occupational safety, health and welfare professionals when determining risks and actions.</p>

	<p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Inclusion of a range of occupational safety, health and welfare risks in risk register(s)</li> <li>• Action plans incorporating actions to address occupational safety, health and welfare risk issues</li> </ul>
6.	<p><b>Are environmental and fire safety risks identified, assessed and managed and are arrangements in place to ensure that environmental and fire risks are minimized through meeting legislative and mandatory requirements?</b></p> <p><b>GUIDANCE</b></p> <p>All environmental and fire safety risks should be identified, assessed and managed in line with implementing the risk management process set out above. Appropriate systems and processes should be in place to ensure that environmental and fire risks are minimized through meeting legislative and mandatory requirements. Be sure to seek the advice of competent environmental and fire safety professionals when determining risks and actions.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Environmental and fire safety audit and/or inspection records</li> <li>• Inclusion of a range of environmental and fire risks in risk register(s)</li> <li>• Action plans incorporating actions to address environmental and fire safety risk issues</li> </ul>
7.	<p><b>Is an ongoing program of patient safety improvement in operation?</b></p> <p><b>GUIDANCE</b></p> <p>Achieving significant improvements in patient safety is currently seen as a major imperative for healthcare internationally. This is evidenced by the establishment of the World Health Organization (WHO) World Alliance for Patient Safety. All risks to patient safety should be identified, assessed and managed in line with implementing a robust risk management process defined by the above questions.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Evidence of ongoing implementation of a program of patient safety.</li> </ul>
8.	<p><b>Are arrangements in place to ensure that medical devices meet the manufacturer, installation and operating requirements necessary?</b></p> <p><b>GUIDANCE</b></p> <p>A suitable policy and procedure should be in place to ensure that all alerts and safety notices are circulated to all relevant staff and, most importantly, are acted upon. Various software systems exist that enable this to be done efficiently.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Policy/procedure for dealing with medical device alerts and safety notices</li> <li>• Software system in use for identifying and circulating alerts and notices, and for</li> </ul>

	monitoring whether they have been acted upon.
9.	<p><b>Are incidents properly recorded and reported to management?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Random sample of local incident reports</li> </ul>
10.	<p><b>Are incidents managed in accordance with an agreed policy?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Local incident management policy</li> <li>• Select a sample of incidents and trace back how they were managed to establish degree of compliance with policy</li> <li>• Talk to managers, clinicians and staff</li> </ul>
11.	<p><b>Are incidents rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?</b></p> <p><b>GUIDANCE</b></p> <p>All reported incidents should be rated according to impact in order to determine what, if any, further action is required, The key to learning from incidents is root cause analysis (sometimes termed systems analysis).</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Incident reports</li> <li>• Risk register information</li> <li>• Incident investigation/RCA report</li> </ul>
12.	<p><b>Are incidents subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?</b></p> <p><b>GUIDANCE</b></p> <p>All reported incident information should be aggregated to identify trends and further opportunities for learning, etc.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Incident review reports</li> </ul>
13.	<p><b>Are complaints, comments and appeals properly recorded and reported to management?</b></p> <p><b>GUIDANCE</b></p> <p>There should be a locally agreed policy for complaints management. Further information on complaints management is available on the NHRA website.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Check a sample of complaints reports</li> </ul>

14.	<p><b>Are complaints managed in accordance with an agreed policy?</b></p> <p><b>GUIDANCE</b> This question relates to the management of the complaint subsequent to its being reported to management. There should be an agreed local policy for management of complaints .</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Local complaints management policy</li> <li>• Select a sample of complaints and ‘trace back’ how they were managed to establish degree of compliance with policy</li> <li>• Talk to managers, clinicians and staff</li> </ul>
15.	<p><b>Are complaints rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?</b></p> <p><b>GUIDANCE</b> All reported complaints should be rated according to impact in order to determine what, if any, further action is required.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Complaints reports</li> <li>• Risk register information</li> <li>• Complaints investigation/RCA report</li> </ul>
16.	<p><b>Are complaints and comments subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?</b></p> <p><b>GUIDANCE</b> All complaints information should be aggregated to identify trends and further opportunities for learning, etc.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Complaints review reports</li> <li>• Action/improvement plans</li> <li>• Risk register information</li> </ul>
<b>J</b>	<b>Staffing and staff management</b>
1.	<p><b>Are arrangements in place to ensure appropriate workforce planning?</b></p> <p><b>GUIDANCE</b> Arrangements should reflect workforce planning policies, strategies, etc.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Workforce planning policies etc.</li> <li>• Evidence of compliance with workforce planning arrangements</li> </ul>

2.	<p><b>Are arrangements in place to ensure appropriate recruitment procedures and induction training for staff appropriate to their roles and responsibilities?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Relevant policies, procedures, etc.</li> <li>• Induction programs</li> <li>• Training needs analysis reports</li> <li>• Training records</li> </ul>
3.	<p><b>Do the arrangements set out in questions 1 and 2 ensure compliance with related NHRA licensing criteria, professional and other codes of practice, and employment legislation?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Check all relevant arrangement, i.e. policies, procedures, etc.</li> </ul>
4.	<p><b>Are continuing learning and development programs in place and aimed at meeting the development needs of staff and services?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Check learning and development program details</li> <li>• Training needs analysis</li> <li>• Development needs analysis</li> </ul>
5.	<p><b>Are robust pre-employment checks carried out prior to employment offers?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Evidence of employment checks</li> </ul>
6.	<p><b>Are arrangements in place to identify and deal with poor professional performance?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Policy on identifying and dealing with poor professional performance</li> <li>• Evidence of instances where poor performance has been identified and dealt with in accordance with relevant policy</li> </ul>
<b>K. Service improvement</b>	
1.	<p><b>Are quality, safety and risk management goals clear, communicated effectively and reflected in relevant service and business planning processes?</b></p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> <li>• Communication arrangements</li> <li>• Check actual communication</li> <li>• Check relevant service and business planning processes</li> </ul>
2.	<p><b>Do quality improvement activities utilize a range of quality improvement tools to assist with assessing and diagnosing issues, identifying remedies and measuring improvement?</b></p>



	<p><b>GUIDANCE</b></p> <p>There are many quality improvement tools available in healthcare that can assist with diagnosing issues, identifying remedies and measuring improvement. Examples of quality improvement tools:</p> <ul style="list-style-type: none"> <li>• Performance measures, including clinical indicators and key performance indicators</li> <li>• Adverse event management</li> <li>• Culture and change management</li> <li>• Team Building</li> <li>• Integrated care pathways</li> <li>• Incident monitoring</li> <li>• Clinical audits</li> <li>• Flowcharts</li> <li>• Cause and effect diagrams</li> <li>• Brainstorming</li> <li>• Pareto charts</li> <li>• Histograms</li> <li>• Run charts</li> <li>• Control charts</li> <li>• Scattergrams</li> </ul> <p>Other tools include failure mode and effects analysis (FMEA), lean techniques, Plan-Do-Check-Act (PDSA), theory of constraints and six sigma. Six sigma is a particularly powerful tool for measuring and monitoring quality improvement.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Look for evidence of use of a range of quality improvement tools in service improvement projects and in day to day quality improvement activity</li> </ul>
<b>L</b>	<b>Learning and sharing information</b>
A.	<p><b>Does the facility routinely learn from patient experience?</b></p> <p><b>GUIDANCE</b></p> <p>Actively seeking patients', and other service users' views about their experience of health and social care can provide valuable insights and learning that can inform service, quality, safety and risk management improvement processes. What evidence exists that demonstrates that your facility routinely learns from patient experience?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Learning reports from patient survey information</li> <li>• Relevant policies</li> <li>• Risk register</li> <li>• Improvement action plans</li> </ul>

<p><b>B.</b></p>	<p><b>Does the facility routinely learn from incidents occurring within the facility and elsewhere?</b></p> <p><b>GUIDANCE</b>          Whilst it is unfortunate that incidents occur in healthcare, facilities should reflect upon and learn from what has happened in an effort to avoid, or reduce the likelihood of, future similar incidents. It is important that this learning happens not just within the facility, but also happens in relation to incidents occurring elsewhere – in other facilities in Bahrain, or in organizations in other countries.          In addition to learning from individual incidents, it is important to learn from incident trends. Plotting many incidents over time can reveal important issues that need to be addressed.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Incident investigation/analysis reports</li> <li>• Action plans resulting from incident review</li> <li>• Risk identification process</li> <li>• Risk register, detailing risks resulting from incident investigation/analysis/review</li> </ul>
<p><b>C.</b></p>	<p><b>Does the facility regularly communicate to patients, staff and other relevant stakeholders improvements that have been made as a consequence from learning from patient experience and incidents?</b></p> <p><b>GUIDANCE</b>          People usually appreciate knowing what improvements have been made in response to feedback on patient experience and incidents. In essence, this can be thought of as closing the loop. Such feedback can be provided in many ways such as making public specialists reports, or communicating the information in regular newsletters or general annual reports.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Patient survey reports</li> <li>• Incident reports</li> <li>• Communications policy</li> <li>• Regular newsletters</li> <li>• Annual reports</li> <li>• Internal communication noticeboards</li> </ul>
<p><b>D.</b></p>	<p><b>Are arrangements in place for learning and for sharing information on good practice in relation to quality, safety and risk management?</b></p> <p><b>GUIDANCE</b>          Assuring the safety of patients, staff and visitors is a key priority for the NHRA. This requires a collaborative approach to the analysis of quality and risk information so that</p>

	<p>the lessons learnt from analysis are shared across the Kingdom. It is essential that health care facilities develop a learning culture and that effective learning and sharing processes are developed to spread good practice and educate/inform others.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Seminars</li> <li>• Briefings</li> <li>• Workshops</li> <li>• Education programs</li> <li>• Newsletters, journals, publications etc.</li> <li>• Presentation at National/International conferences</li> <li>• Electronic self-assessment tool (Quality, safety and risk management framework)</li> </ul>
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## 4. Outcomes

### 4.1 Key Performance Indicators (KPIs)

The ultimate test of effective systems for quality, safety and risk management is the extent to which they achieve improvements in outcomes or results for patients, service users and other stakeholders. Demonstration of improvements in quality, safety and risk management requires definition of key performance indicators (KPIs). Service providers should take a systematic approach to identifying a range of KPIs relevant to them.

### 4.2 Check questions

The table below contains check questions that can be utilized by facilities to gain an understanding of their strengths and areas for improvement in relation to achieving the required outcomes from an integrated quality, safety and risk management system. The responses to these questions can be either 'yes', 'no', 'partial', 'not applicable' or 'don't know'. The 'partial' responses are categorised as 'low', 'moderate' or 'high'. Where a no or partial response is provided, an action plan or 'quality improvement plan' should be developed to implement any requirements. Where the question number box is shaded, this denotes that the response to the question may need to be made following the gathering and aggregation of appropriate information from a number of departments, service areas, etc.

	<b>Outcomes: Check questions</b>
M	<b>Key Performance Indicators (KPIs)</b>
1.	<p><b>Have local KPIs been developed for quality, safety and risk management?</b></p> <p><b>GUIDANCE</b>  A performance indicator (PI) is a clearly defined measurement of one aspect of performance. It provides an indication of how well you are performing a given activity. A key performance indicator is one that provides essential organizational level information on the performance of an activity for accountability and performance</p>

	<p>management purposes.</p> <p>Examples of local KPIs are given below</p> <ul style="list-style-type: none"> <li>• % Compliance levels with NHRA Licensing standards</li> <li>• Numbers of incidents reported and their risk grading</li> <li>• Numbers of near misses reported</li> <li>• Numbers of unreported incidents identified by other means or from other sources</li> <li>• Numbers of claims, complaints and other forms of service user feedback received and their risk grading</li> <li>• Numbers of incidents, claims and complaints investigated using Root Cause Analysis or alternative structured approach</li> <li>• Actions taken/improvements made following investigation of incidents, complaints, claims and other legal processes</li> <li>• Patient reported satisfaction</li> <li>• Staff satisfaction</li> <li>• Average Length of Stay</li> <li>• Financial position</li> <li>• Number of staff who have received complaints, incident reporting/management training.</li> <li>• Presence of fully operational, up-to-date risk registers in place</li> </ul> <p>Performance information on quality, safety and risk management is not an end in itself. It may be used to:</p> <ul style="list-style-type: none"> <li>• Measure progress towards achieving local or corporate quality, safety and risk management objectives and targets.</li> <li>• Promote the accountability of service providers to patients/service users, the public and other stakeholders.</li> <li>• Compare performance to identify opportunities for improvement.</li> <li>• Promote service improvement by publicizing performance levels.</li> </ul> <p>KPIs may take many forms. It is important that you select the key indicators that reflect your activities and management needs.</p> <p>It is likely that the NHRA will specify national KPI's set for quality, safety and risk management based, at least in part, on a review of indicators being used by local service providers.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Local performance indicator list or dashboard.</li> <li>• Indicator specification and use in specific circumstances, e.g. strategic frameworks; patient safety goals; patient satisfaction reports; medication error reports; risk management reporting; complaints management; service level reporting; etc.</li> </ul>
2.	<p><b>Are the KPIs monitored as part of ongoing quality, safety and risk management improvement activities?</b></p>

	<p><b>GUIDANCE</b> Indicators should be regularly monitored to ensure that performance is on track. Any significant variances in indicators should be investigated to determine causation. It should be noted that performance indicators do not provide answers to <i>why</i> differences exist but raise questions and suggest <i>where</i> problems may exist.</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Performance reports, clearly setting out KPI information</li> <li>• Evidence of consideration of reports by relevant committees and senior managers (e.g. see relevant minutes).</li> <li>• Evidence that, where necessary, action is taken by management in response to monitoring (e.g. see relevant minutes).</li> </ul>
3.	<p><b>Do the KPI's demonstrate that there is ongoing improvement in quality, safety and risk management?</b></p> <p><b>GUIDANCE</b> Ultimately, any system of performance measurement exists to demonstrate improvement. Do the KPIs that you use show, over time, that improvements in the quality and safety of care, together with improvements in risk management generally, are being realised?</p> <p><b>EXAMPLES OF VERIFICATION</b></p> <ul style="list-style-type: none"> <li>• Performance reports, clearly setting out improvements in KPIs over time</li> </ul>

## 5. Glossary of terms

The following glossary of terms listed in alphabetical order and, for each term, a definition is provided and the source of the definition is referenced.

### TERM DEFINITIONS AND REFERENCES

TERM	DEFINITIONS AND REFERENCES
Accountability	Accountability is the obligation to demonstrate and take responsibility for performance in light of commitments and expected outcomes (Information Management, Government of Canada, 2004)
Accountable	Being held responsible (WHO, 2007).
Accreditation	Accreditation involves self-assessment by a health care organization to evaluate their level of performance in relation to established standards. The self-assessment is validated by an external review team which consists of peers and service users (IHSAB 2005)
Actions taken	Actions taken to reduce, manage or control the harm, or probability of harm associated with an incident (WHO, 2007).
Adverse Event	Refer to Incident
Attributes	Qualities, properties or features of someone or something (WHO, 2007).
Audit	Auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. (Institute of Internal Auditors, 2007)
Clinical Audit	The systematic, critical analysis of the quality of care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient (Quality and Fairness: A Health System for You, 2001) or A quality improvement process that seeks to improve the patient care and outcomes through systematic review of care against explicit criteria and implementation of change. Aspects of the structures, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual team, or service level and further monitoring is used to confirm improvement in healthcare delivery (National Institute for Health and Clinical Excellence)
Clinical Effectiveness	The extent to which specific clinical interventions do what they are intended to do, i.e. maintaining and improve health, securing the greatest possible health gain from the available resources (NHS Scotland, 2005). or

	The extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – i.e. maintain and improve health and secure the greatest possible health gain from the available resources. (Promoting Clinical Effectiveness: A guidance for action in and through the NHS, NHS Executive, January 1996)
Clinical Guideline	Systematically developed statements to assist health care professional and patient decisions about appropriate health care for specific clinical circumstances. They identify good practice but contain little operational detail and are not rigid constraints on decisions. (Adapted from definitions by Institute of Medicine and NHS Executive, England).
Clinical Governance	A Guidance through which organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence will flourish (adapted Scally and Donaldson, 1998)
Code of Practice	Codes of Practice are general guidelines setting out good practice relating to government legislation providing guidance and direction in addressing a particular and specific area for improvement (National Disability Authority, 2001).
Complaint	A Complaint means a complaint made about any action of the Executive, or a Service Provider that, it is claimed, does not accord with fair or sound administrative practice, and adversely affects the person by whom, or on whose behalf, the complaint is made (Health Act 2004)
Confidentiality	Ensuring that information is accessible only to those authorized to have access (International Organization for Standardization, 2008a).
Continuous Quality Improvement	Continuous Quality Improvement is a management philosophy and system which involves management, staff and health professionals in the continuous improvement of work processes to achieve better outcomes of patient/client/resident care (Health Canada 1993).
Contractor	Means any individual, employer or organization whose employees undertake work for a fixed or other sum and who supplies the materials and labour (whether their own labour or that of another) to carry out such work, or supplies the labour only (Health and Safety Authority, 2006).
Contributing factor	Any factor(s) pertaining to an organization and/or person which can impact positively or negatively on the organization and/or person (adapted Information Services NHS Scotland, 2004)
Corporate governance	Corporate governance is the system by which organizations direct and control their functions and relate to their stakeholders in order to manage their business, achieve their missions and objectives and meet the necessary standards of accountability, integrity and propriety. (Guidance for corporate and financial governance of the HSE,2006).

Culture	A set of beliefs, values, attitudes, and norms of behaviour shared by individuals within an organization (Davies HTO, Nutley SM, Mannion R. 2000).
Error	Failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim (Institute of Medicine 2000).
Evaluation	Assessment/appraisal of the degree of success in meeting the goals and expected results (outcomes) of the organization, service, program, population or patients/clients (HIQA 2006).
Evidence-based practice	The conscientious, explicit and judicious use of current best evidence in making decisions about the care of patients/service users (Gardner MJ and Altman DG, 1986)
Guidance	A guidance is a set of components that provide the foundations and organizational arrangements for designing, implementing, monitoring, reviewing and continually improving (adapted International Organization for Standardization, 2008b).
Goals	Broad statements that describe the desired state for the future and provide direction for day-to-day decisions and activities (HIQA 2006).
Governance Systems	processes and behavior(s) by which organizations lead, direct and control their functions in order to achieve organizational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organizations (Department of Health, 2006)
Guideline	A Guideline is a principle or criterion that guides or directs action.(Concise Oxford Dictionary, 1995)
Harm	A detrimental impact on the organization's stated objectives, including physical, psychological, financial, environmental harm (adapted Leveson 1995)
Hazard	A source of potential harm (AS/NZS 4360:2004) Healthcare Services received by individuals or communities to promote, maintain, monitor or restore health (WHO, 2007).
Impact	The outcome of an event expressed quantitatively and / or qualitatively being a loss, injury, disadvantage or gain (adapted AS/NZS 4360:2004).
Incident	Any event that causes or has the potential to cause harm. (adapted Myatt, V.L. 2002)
Key Performance Indicators	Key Performance Indicators (KPI) are financial and non-financial metrics used to help an organization define and measure progress towards organizational goals (Parmenter D, 2007)
Likelihood	Describes the probability or frequency of an impact occurring (adapted AS/NZS 4360:2004)
Monitor	To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change from the performance level required or expected (AS/NZS 4360:2004)



Near Miss	An event that could have resulted in an incident, but did not, either by chance or through timely intervention (Quality Interagency Co- Operation Task Force, 2000)
Objectives	Concrete, measurable steps taken to achieve goals (HIQA 2006). Patient A person who is a recipient of healthcare (WHO, 2007). Patient Safety Incident Any event that causes, or has the potential to cause harm to a patient (adapted WHO, 2007).
Policy	Written statement that clearly indicates the position and values of the organization on a given subject (HIQA 2006).
Procedure	Written set of instructions that describe the approved and recommended steps for a particular act or sequence of acts (HIQA 2006).
Protocol	Operational instructions which regulate and direct activity (NHS Scotland 2005).
Quality	Doing the right thing consistently to ensure the best possible outcomes for patients, satisfaction for all customers, retention of staff and a good financial performance (Leahy and Wiley 1998).
Record	Includes any memorandum, book, report, statement, register, plan, chart, map, specification, diagram, pictorial or graphic work or other document, any photograph, film or recording (whether of sound or images or both), and any form in which data (within the meaning of the Data Protection Act 1988 and 2003) are held, and form (including machine-readable form) or thing in which information is held or stored manually, mechanically or electronically, and anything that is a part or copy, in any form, of any of the foregoing or is any combination of two or more of the foregoing (Freedom of Information Act 1997)
Residual Risk	Risk remaining after all reasonable practicable control measures are implemented (adapted AS/NZS 4360: 2004).
Risk	The chance of something happening that will have an impact on the achievement of organizational stated objectives (AS/NZS 4360:2004).
Risk Analysis	A systematic process to understand the nature of and to deduce the level of risk (AS/NZS 4360:2004)
Risk Assessment	The overall process of risk identification, risk analysis and risk evaluation (AS/NZS 4360:2004)
Risk Avoidance	A decision not to become involved in, or withdraw from a risk situation (AS/NZS 4360:2004)
Risk Control	An existing process, policy, device, practice or action that acts to minimise negative risk or enhance positive opportunities (AS/NZS 4360:2004)
Risk Criteria	Terms of reference by which the significance of risk is assessed (AS/NZ 4360:2004)
Risk Evaluation	Process of comparing the level of risk against risk criteria (AS/NZS 4360:2004)
Risk Management	The culture, processes and structures that are directed towards realizing

	potential opportunities whilst managing adverse effects (AS/NZS 4360:2004)
Risk management process	The systematic application of management policies, procedures and practices to the tasks of communicating, establishing the context, identifying analysing, evaluating, treating, monitoring and reviewing (AS/NZS 4360:2004))
Risk Management Guidance	Set of elements of an organization's management system concerned with managing risk (AS/NZS 4360 : 2004)
Risk Matrix	Is a form of presentation, a single table, which enables easy comparison of the values placed on different risks (Health Care Standards Unit and Risk Management Working Group 2004).
Risk Maturity	The extent to which a robust risk management approach has been adopted and applied, as planned, by management across the organization to identify, assess, decide on responses to and report on opportunities and threats that affect the achievement of the organization's objectives (Institute of Internal Auditors UK and Ireland, 2007).
Risk Register	A risk register is a management tool that enables an organization to understand its comprehensive risk profile. It is simply a repository for risk information (Health Care Standards Unit and Risk Management Working Group 2004).
Risk Retention	Acceptance of the burden of loss, or benefit of gain from a particular risk (AS/NZS 4360:2004)
Risk Sharing	Sharing with another party the burden of loss, or benefit of gain from a particular risk (AS/NZS 4360:2004)
Risk Treatment	Process of selection and implementation of measures to modify risk (AS/NZS 4360:2004).
Root cause analysis	A structured investigation that aims to identify the true cause(s) of a problem, and the actions necessary to eliminate it (Andersen, B. and Fagerhaug, T. 2000). (Note: this is a reactive process). Safety Freedom from Hazard (WHO, 2007).
Serious Incident	An incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public (HSE 2008).
Stakeholder	Individuals, organizations or groups that have an interest or share, legal or otherwise, in services. Stakeholders may include referral sources, service providers, employers, insurance companies or payers. (HIQA 2006)
Standards	Recognised best practice criteria by which the performance, efficiency, achievement etc. of a person or organization can be assessed (adapted Collins Dictionary 2001).
System Analysis	A structured, systematic study of a system with a view to establishing, either reactively or proactively the root cause(s) of actual or potential

	adverse effects and the actions necessary to prevent or mitigate future adverse effects (Emslie, S. 2004). (Note: this is a reactive and pro-active process).
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## 6. Frequently Asked Questions

The following are a selection of key questions relating to the guidance for Integrated Quality, Safety and Risk Management in healthcare facilities across the kingdom of Bahrain

### **Q1. What is the fundamental purpose of the Guidance?**

Fundamentally, the guidance exists to ensure:

- there is an appropriate guidance for quality, safety and risk management in place across all health care facilities in the Kingdom of Bahrain to support and drive improvements in the provision of safe, effective, high quality services;
- drive core programs of work in quality, safety and risk management, including: clinical effectiveness; service user and community involvement; risk management and patient safety; continuous professional development; and service improvement; and
- ensure that appropriate accountability and oversight arrangements are in place to monitor quality, safety and risk management performance and to support the provision of assurances to senior management, and the NHRA.

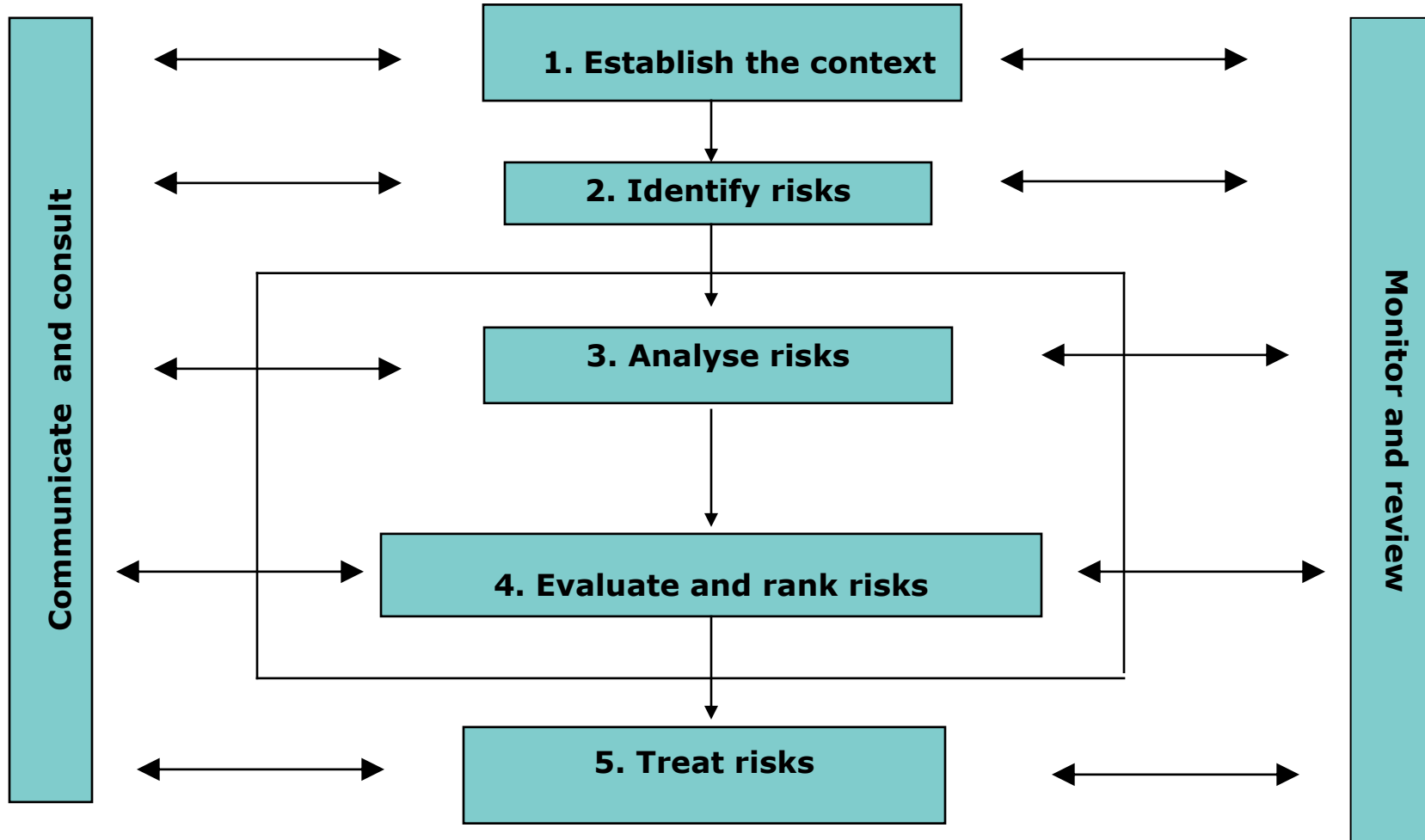
### **Q2. Why do some of the Guidance questions seem a bit woolly? Can you not make them more specific?**

The Guidance is not intended to be highly prescriptive. The NHRA recognises that healthcare facilities will want to be innovative in how they address aspects of the Guidance. Consequently, rather than pin you down with highly prescriptive requirements, we have produced a more generic quality, safety and risk management guidance that gives you as much latitude as possible to determine how best meet the requirements.

### **Q3 Why are staff not represented along with patients and service users at the heart of the Guidance diagram (the diagram containing concentric circles diagram showing patient/service user at the centre together with underpinning requirements, core processes and programs and outcomes?)**

The Guidance relates to the core purpose of the NHRA's existence, which is about providing assurances to patients and service users. The NHRA does take the issue of staff health, safety and wellbeing very seriously and this is reflected in the core processes and programs aspect of the Guidance.

Australia/New Zealand Risk Management Standard (AS/NZS 4360:2004) .



## Risk Grading System

### Instructions for use

1. *Identify the risk*
2. *Using Table 1 identify the Impact/Consequences should the risk occur and select number from scale*
3. *Using Table 2 identify the Frequency/Likelihood or immediacy of the risk occurring and select number from scale*
4. *Using table 3 and 4 Impact/Consequences Score X Frequency/Likelihood Score = Risk Grading as described in Risk Grading Matrix (Low, Moderate, High or Extreme)*

**Table 1 – Impact/Consequences Descriptors and Scores**

	1	2	3	4	5
Descriptors	Insignificant	Minor	Moderate	Major	Catastrophic
<b>Objectives/ Targets/ Budgets</b>	Insignificant cost increase/schedule slippage. No noticeable reduction in scope or quality	1% off planned activity targets. Failure to meet PfA or other target for 1 quarter. Less than 5% over budget/ schedule slippage. Minor reduction in quality/scope	2% - 4% off planned activity targets. Failure by meet PfA or other target for 2 quarters. 10% over budget/ schedule slippage. Reduction in scope or quality	5 – 10% off planned activity targets. Failure to meet PfA or other targets for > two consecutive quarters. 10-25% over budget/ schedule slippage. Secondary objectives not met.	>10% off planned activity targets. Failure by more than 25% to meet Regional and/or local targets. More than 25% over budget/ schedule slippage. Primary objectives not met.
<b>Safety (Patients, Clients, Staff &amp; Public)</b>	Minimal injury requiring no/minimal intervention or treatment. No absence from work.	Minor injury or illness requiring minor intervention. Absence from work < 3 days	Moderate injury or illness requiring extended stay in hospital or care/ professional intervention or absence from work > 3 days. RIDDOR reportable and/or other external agency. Potential health and safety prosecution.	Major injury and/or long term/ permanent incapacity/ disability (loss of limb). Mismanagement of patient client/care with long term affects > 3 months). Major outbreak. Premature retirement from work. RIDDOR or/ other external agency notification. Potential Corporate Manslaughter or other health and safety prosecution.	Death or still birth or multiple or permanent incapacity/ Disability requiring life-long care (brain damaged adult or baby). Reportable to RIDDOR and/or other external agency. Potential Corporate Manslaughter or other health and safety prosecution.
<b>Numbers Affected</b>	None	Very Few 1-2	Small numbers 3-5	18-50	50+
<b>Service User Experience</b>	Unsatisfactory experience not directly related to care or treatment	Unsatisfactory experience – readily resolvable	Mismanagement of care or treatment	Serious mismanagement of care or treatment	Totally unsatisfactory outcome of experience
<b>Service User</b>	Locally resolved	Justified complaint	Justified complaint	Multiple justified complaints.	Substantial litigation

	1	2	3	4	5
<b>Descriptors</b>	<b>Insignificant</b>	<b>Minor</b>	<b>Moderate</b>	<b>Major</b>	<b>Catastrophic</b>
<b>Experience/ Claims/ Losses</b>	complaint.  Litigation unlikely.  Damage/loss of assets/personal property < £1000	peripheral to clinical or social care. Litigation likely < £10,000.  Damage/loss of assets/personal property > £1001 < £5,000	involving lack of appropriate clinical or social care. Litigation possible > £10,000 < £50,000 Damage/loss of assets/personal property > £5,001 < £100,000	Litigation probable > £50,000 < £1M.  Damage/ loss of assets/personal property > £100,001 < £5M	involving one or more claimants probable > £1M.  Damage/loss of assets/personal property > £5M
<b>Service/ Business Interruption</b>	Loss/ interruption > 1 hour	Loss/interruption > 8 hours	Loss/ Interruption > 1 day	Loss/ interruption > 7 days	Permanent loss of service or facility
<b>Staffing and Competence</b>	Short term low staffing level temporarily reduces service quality < 1 day  Short term low staffing level (> 1 day) where there is no disruption to patient/client care.	Ongoing low staffing level reduces service quality.  Minor error due to ineffective or inadequate training/implementation of training.	Late delivery of key objective/ service due to lack of staff.  Moderate error due to ineffective or inadequate training/implementation of training.  Ongoing unsafe staffing level	Uncertain delivery of key objective/ service due to lack of staff.  Major error due to ineffective or inadequate training /implementation of training.	Non-delivery of key objective/ service due to lack of staff.  Loss of key staff.  Catastrophic error due to ineffective or inadequate training/ implementation of training
<b>Inspection/ Audit/ Statutory Compliance</b>	Small number of recommendations which focus on minor quality or safety improvement issues, Minor non-compliance – advice given.	Recommendations made which can be addressed by low level of management action.  Reduced rating if not resolved.	Repeated non-compliance with standards, policy or protocols. Challenging recommendations. Reduced rating following next assessment.	Major non-compliance with standards, policy or protocol. Enforcement action against Trust. Critical report and low rating of compliance. Very challenging recommendations.	Significant non-compliance. Prosecution. Zero Rating. Severely critical report
<b>Adverse Publicity/ Reputation</b>	Rumours	Local media - short-term interest. Little affect on staff morale	Local media – long term interest. Public confidence affected. Significant affect on staff morale	Regional media - < 3 days interest. MLA concern (Questions in Assembly). Service well below reasonable public expectation. Use of services affected.	National adverse media and/or local media > 3 days. Interest MP and/or MLA concern (Questions in House or Assembly) Total loss of public confidence. Public Enquiry.
<b>Quality and Professional Standards</b>	Minor non-compliance	Single failure to meet internal standards or to follow protocols	Repeated failure to meet internal standards or to follow protocols	Failure to meet national/professional standards	Gross failure to meet national/ professional standards

	1	2	3	4	5
Descriptors	Insignificant	Minor	Moderate	Major	Catastrophic
<b>Environment</b>	Nuisance release	On site release contained by Trust	Off site release contained by Trust	Release affecting minimal off-site area requiring external assistance, eg fire service or Radiation Protection Service	Toxic release with detrimental affect requiring external assistance
<b>Additional Guidance – For example</b>	Drug error with no apparent adverse outcome	Unnecessary radiation Grade 1 Pressure Ulcer	Increased length of stay due to HCAI < 1 week. Grade 2/3 Pressure Ulcer	Increased length of stay due to HCAI > 1 week. Grade 4 Pressure Ulcer. Retained instrument after surgery requiring further intervention.	Unexpected death/suicide/homicide committed by patient known to Trust with mental health problems. Removal of wrong body part leading to death or permanent incapacity.



## Responsibility for the management of risk

**Table 2. Frequency/Likelihood Descriptors**

The descriptors for each frequency/likelihood are as follows:

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>Descriptor</b>	<b>Rare</b>	<b>Unlikely</b>	<b>Possible</b>	<b>Likely</b>	<b>Almost Certain</b>
<b>Frequency/Likelihood</b>	Remote possibility (once every 5 years or more)	Could happen but rare (typically once a year)	Could happen occasionally (on average monthly)	Could happen often (on average once a week or more frequently)	Could happen frequently (once a day or more)

**Table 3 Risk Grading Matrix**

**Likelihood X Impact = Risk Grading**

		<b>Impact / Consequences</b>			
<b>Likelihood / Frequency</b>	<b>Insignificant</b>	<b>Minor</b>	<b>Moderate</b>	<b>Major</b>	<b>Catastrophic</b>
Almost certain	5	10	15	20	25
Likely	4	8	12	20	20
Possible	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare	1	2	3	4	5

### Risk Grading Bands

LOW	MODERATE	HIGH	EXTREME
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#### Table 4 Risk management action

An identified risk falling in the RED box is considered an EXTREME RISK to the Trust and requires immediate action to reduce the level of risk. It must be immediately notified to the relevant Director with completion of whatever immediate action is required to protect service users, staff or others. If an incident, a decision is required within two working days whether to be notified as a serious adverse incident in accordance with Trust policy. A senior clinician, Social Work practitioner or manager supported by a multi-disciplinary/directorate team including a Governance Department representative will be assigned responsibility for initiating an immediate investigation. An investigation of an incident initially graded as EXTREME can be aborted and/or downgraded as the facts become known. The report including development of a timed risk treatment action plan to eliminate/control the risk must be produced within 30 working days or earlier if the risk event is downgraded. All risks graded as EXTREME and implementation of their associated risk treatment action plans will be monitored by the Governance Management Board and Governance Committee on an ongoing basis and by the Directorate Governance Team. Where the risk is not immediately reducible the risk will be added to the Directorate and Corporate Risk Registers. The Corporate Risk Management Department must be informed of any incident or risk accorded an EXTREME rating as soon as possible.

An identified risk falling in PURPLE boxes is considered as being a HIGH RISK to the Trust and requires prompt action to reduce the risk to an acceptable level. If an incident, a decision is required within two working days as a serious adverse incident in accordance with Trust policy and will be investigated by a clinician or Social Work practitioner or manager supported by either the Directorate governance 'lead' or member of Corporate Risk Management Department to determine the root causes and complete the investigation within seven working days. A report, including a timed risk treatment action plan to eliminate/control the risk, being completed within thirty working days. An incident initially graded HIGH can be upgraded or aborted/downgraded as the facts become known. Action must be completed within three months to reduce the risk to an acceptable level. Where not immediately reducible the risk will be added to the Directorate Risk Register. These risks and implementation of their associated risk treatment action plans will be monitored by the Governance Management Board on a regular basis and by the Directorate Governance Team. Support Directorates which do not have a Directorate Governance Team Meeting will use their management team meeting to review risks and, as necessary, adjust the risk grading. The Corporate Risk Management Department must be informed of any event or risk graded as being SIGNIFICANT for inclusion in the Corporate Risk Register.

Identified risk events falling in YELLOW boxes are considered as being a MODERATE RISK to the Trust and will require action to reduce to an acceptable level. If an incident, it will not require detailed investigation but will only require a local review which should be undertaken swiftly. Action must be completed within six months to reduce the risk to an acceptable level. Risks graded as MODERATE will be added to the Directorate Risk Register. These risks and implementation of their risk treatment action plans will be monitored by the Directorate Governance Team which will review, and as necessary, adjust the risk grading.

Identified risks falling in GREEN BOXES are deemed LOW & ACCEPTABLE RISKS. Whilst unlikely that anything can be done to eliminate/control further, they will be subject to regular monitoring and any action possible should be taken to minimise the risk of their recurrence. These risks will be added to the Directorate Risk Register and will be reviewed at least annually or when their circumstances change by the Directorate Governance Team or equivalent.

### Priority Action Table

To determine when a risk requires to be actioned and reviewed

<b>KEY TO PRIORITY LEVELS</b>		
<b>RISK LEVEL</b>	<b>TIMESCALE FOR ACTION</b>	<b>TIMESCALE FOR REVIEW</b>
Red – Extreme	Action immediately	Review within 1 month
Purple – High	Action within 1 month	Review within 3 months
Yellow - Moderate	Action within 3 months	Review within 6 months
Low – Acceptable	Action within 12 months/ accept risk	Review controls within 12 months