



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

**Towards Excellence in Clinical Governance –
A Framework for Integrated Quality, Safety and
Risk Management across HSE Service Providers**

COMPANION GUIDE

This guide provides supplementary information in support of self-assessment against the Framework Document. The content of this document will be subject to continuous review and improvement in light of experience of implementing the Framework.

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February 2009

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1. Introduction

1.1 Background

This *Companion Guide* provides managers and clinicians in hospital and primary, community and continuing care service providers with concise, non-exhaustive additional information upon which to base their judgements of their organisational unit's compliance with the various 'check questions' contained in the *Framework Document*. There is information contained in the Guide for each check question, including, where appropriate, brief additional guidance, examples of verification and pointers to web-based and other resources. The HSE's Quality and Risk Management Standard should also be consulted for additional guidance. **Service providers are strongly encouraged to submit their own examples of guidance, verification and resources for sharing with other providers through updated versions of this Companion Guide.**

The Guide is based, in part, on practical insights gained, and feedback obtained whilst undertaking 'pilots' of the draft *Framework* document, together with feedback from information workshops and self-assessment training events held following the pilots. The pilots were carried out during summer 2008 and involved three hospitals and three local health offices (LHOs). Information workshops and subsequent self-assessment training events involving several hundred people from across HSE providers were conducted between November 2008 and January 2009, inclusive.

Feedback from both the pilots and information workshops pointed to a perception amongst providers of significant potential benefits of implementing the quality, safety and risk management framework, including:

- Improved patient safety
- Structure & standardisation nationally
- Identify & address inefficiencies & adverse events
- Focus on continuous quality improvement
- Framework for planning services
- Framework to prioritise resources
- Clear understanding of accountability & responsibility
- Structure to share good practice

The feedback also provided a list of potential concerns, including:

- Current climate – poor staff morale
- How to ensure buy-in at all levels?
- Finger-pointing...fear of the 'blame game'
- How do we get senior medical staff involved?
- Increased workload – no extra resources
- Will this be just a paper exercise?
- Visibility of risk but no resource to correct
- Linkages with HIQA – will the framework meet their requirements?

The self-assessment training events in January 2009 attempted to deal with the concerns raised. But in the current climate it is fully recognised there will be challenges for some in fully implementing this framework – a 'journey' that may take 3-5 years. Consequently, a key concern for the HSE during self-assessment and implementation is that, wherever possible, providers who identify what they believe to be examples of good practice in quality, safety and risk management within their own organisations should make these available to other provider units for learning and improvement purposes. As Scally and Donaldson¹ proposed for the National Health Service in England, it should be possible to spread good practice in order to help others improve and, in so doing, 'shift the mean' of quality performance across all aspects of HSE funded service provision (Figure 1).

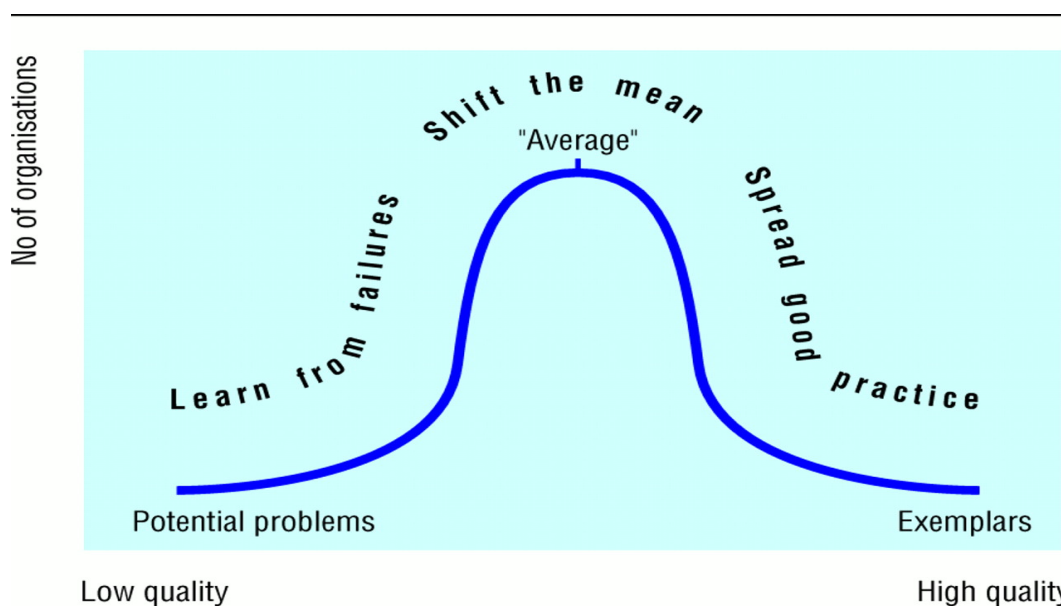


Figure 1 – Spreading good practice and shifting the mean quality performance

¹ Scally G and Donaldson L (1998). Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ* 1998;317:61-65 (4 July).

It should be noted that examples of verification provided in this document are illustrative in nature and should not be considered as a check list for compliance or as an exhaustive list of examples. Each service provider should consider the most appropriate verification criteria that best reflects their own context. It is hoped that verification criteria and other information can be shared with relevant corporate HSE functions for the benefit of all service providers. Verification criteria contained within this Companion Guide will be updated in due course to reflect feedback from service providers.

It should also be noted that whilst this Guide aims to provide additional information to managers and clinicians in support of their self-assessment exercise against the *Framework Document*, it is no substitute for having access to expert advice and assistance on quality, safety and risk management matters. Just as in medicine, there is much in the field of healthcare quality, safety and risk management that is, necessarily, subjective and dependent on local factors.

It is anticipated that this *Companion Guide* will be updated regularly in response to suggestions and identified good practice across HSE service providers resulting from detailed self-assessment studies carried out by service providers against the *Framework Document*, as required by the HSE. The HSE is looking at how the Guide can be regularly updated in the most efficient and economic way.

1.2 Undertaking a self-assessment against the quality, safety and risk management framework

Managers and clinicians should, with reference to this document and the main *Framework Document*, assess the extent to which a suitable framework is in place within their hospital or service. A total of 69 'check questions' relating to key aspects of the framework are contained in this document. 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' (see below). Where a no, partial or don't know response is provided, either an action plan or 'Quality Improvement Plan' (QIP) should be developed to implement any requirements. Proper monitoring and review of the action plans and/or QIPs will ensure that actions are carried out leading, ultimately, to better outcomes for patients and others.

The check questions contained in this document are not exhaustive. They aim to facilitate a reasonable, as opposed to a total assessment of the extent to which arrangements are in place that meet the overarching HSE *Quality and Risk Standard*. Indeed, the *Framework Document* and the *Companion Guide*, taken together, are not a 'counsel of perfection.' They are tools to help engender change and build an enhanced culture of quality, safety and risk management across HSE service providers. It is acknowledged that some providers may already excel in this area.

The initial, or baseline assessment should represent an honest and searching analysis of the provider organisation's strengths and areas for improvement in relation to arrangements in place for quality, safety and risk management. At all times, when considering the check questions, those doing the assessment should consider carefully the extent to which arrangements are in place and working effectively. This *Companion Guide* can assist in this regard. In addition, an electronic assessment tool is provided to enable self-assessment to be carried out in relation to the check questions, and this is outlined below.

In preparing the baseline assessment it is important to bring together all key individuals who can contribute to the assessment process². They should be familiar with the

² In a hospital context, this might include any or all of the following: Senior Management representative, Senior Clinician, Senior Nursing, Senior Health &, Social Care Professional, Quality/Accreditation Manager, Risk Manager, Clinical Audit, Health & Safety, Patient/Service User Representative, HR/Finance/ICT/Occupational Health, and relevant others. In an LHO context a facilitated workshop might be held with managers, clinicians and, where available, professionals involved in quality, safety or risk management, representing all the care groups in the LHO

Framework Document and have an understanding of the kinds of information that will be required to complete the assessment. Given the right people and suitable preparation, a reasonable baseline assessment can be produced within a fairly short space of time, measured in days rather than weeks. During this time the individuals participating in the process will, as a group:

1. Briefly review each check question and provide a consensus view of the level of compliance across the organisation or will simply register a 'Don't know' response.
2. Attempt to identify any particular strengths in relation to the question which could lead to determination of examples of good practice that could be shared with others. Detailed information on these can always be gathered as part of a subsequent exercise.
3. Identify weaknesses in relation to the question that will lead to an action plan or Quality Improvement Plan (QIP). Again, detailed information on these can always be gathered as part of a subsequent exercise.

The assessment should draw, where appropriate, on the results of independent audits and the perspectives of a range of stakeholders. It is recognised that there are aspects to the questions contained in this document that are subjective and depend on managers' detailed knowledge of their local context together with an understanding of quality, safety and risk management. It should be remembered, however, that it is not the absolute magnitude of the compliance scores resulting from an assessment against the framework that is the issue here. What is important is that action is taken to rectify weaknesses in quality, safety and risk management and, over time, there is improvement in compliance against the framework as demonstrated by improvements in compliance scores.

In instances where a 'Yes' response is warranted for any check question, indicating, essentially, 100% compliance with the requirements of the question, it should be remembered that this does not mean that future improvement in relation to the issue addressed by the question should not be considered. Healthcare quality, safety and risk management are in a constant state of flux and standards are improving all the time. Thus this year's 100% compliance might, next year, be rather less than 100%. The emphasis is on continual improvement.

1.3 Electronic self assessment tool

An electronic self-assessment tool containing the check questions is available, which can be used to determine compliance scores as key indicators of performance against the questions and the overall framework for quality, safety and risk management.

1.3.1 Running the tool

'Double-click' on 'QSRMFrameworkScoring_V1.3_Feb_2009' to run the tool, which is an Excel spreadsheet³. You will see the following introductory screen (Figure 2), which contains basic instructions on how to operate the tool. Note that there are several worksheets listed at the bottom covering 'data entry', 'good practice', 'actions or QIPs', 'aggregation' and 'analysis'. These are outlined in more detail below.

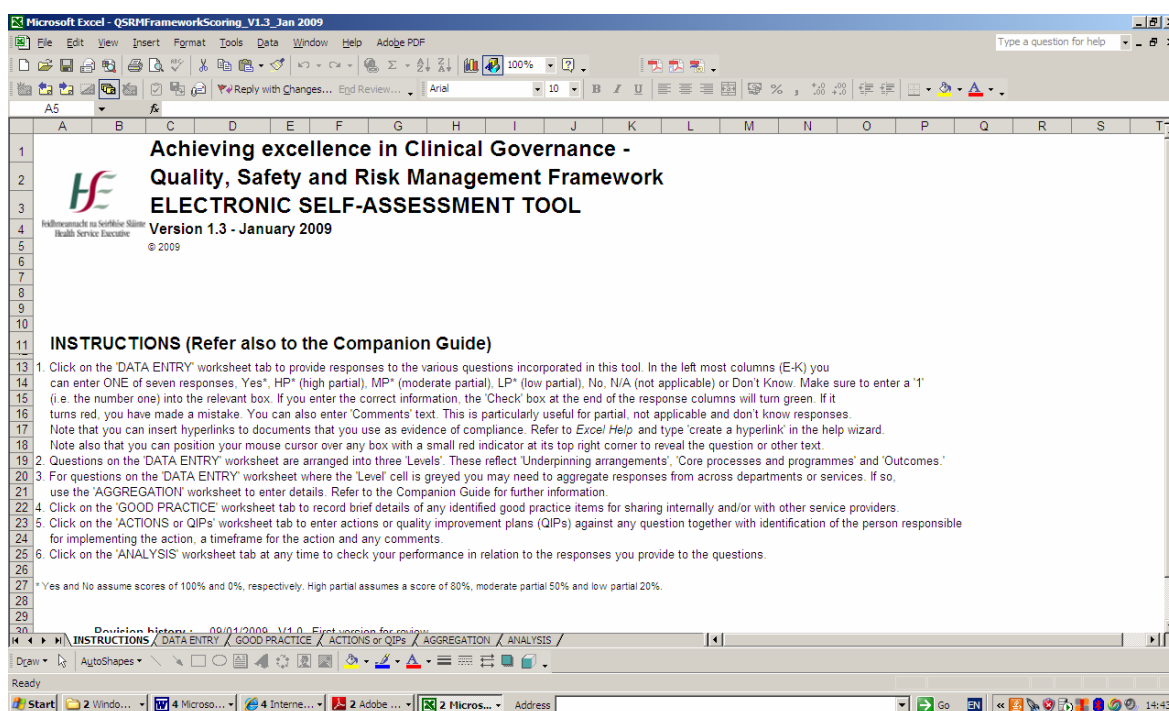


Figure 2 – Introductory screen

³ A demonstration version of the spreadsheet tool is also provided, which is pre-populated with responses to the various questions so that you can get a feel for the analytical capabilities of the tool. The demonstration version is named 'QSRMFrameworkScoring_V1.3_Feb_2009_DEMO'. Some of the screenshots in this document are taken from the demonstration version of the electronic self-assessment tool.

1.3.2. Entering data

Click on the 'DATA ENTRY' worksheet tab. The following screen appears.

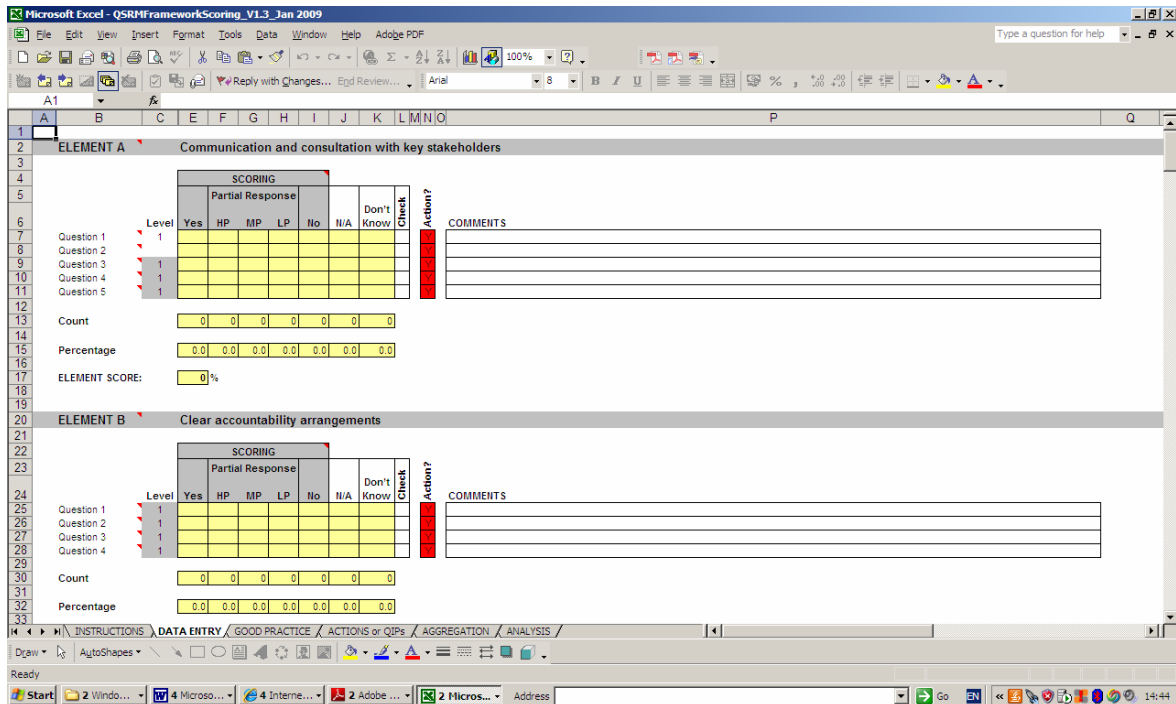


Figure 3 – Data entry screen

The 'check questions' outlined in the quality, safety and risk management framework document have been entered for scoring and analysis purposes. Each question is assigned a 'Level', which is 1, 2 or 3 based on whether the question relates to underpinning requirements (i.e. 1), core processes and programmes (i.e. 2) or outcomes (i.e. 3). Run your mouse cursor over the 'Question' boxes with a small red triangle in the top right corner to reveal each question. You can enter a response, in the form of the number '1', against each question.

In terms of scoring, there are five possible question responses – yes, high partial (HP), moderate partial (MP), low partial (LP) and no. The tool automatically assigns the following scores to your response: Yes=100%, H=80%, M=50%, L=20% and No=0%. The scoring follows the same approach as for the Health and Safety Authority's (HSA) Health and Safety Management Audit system for health services. One way to think about a high partial response is consider it a 'yes, but.....' i.e. you meet many of the requirements of the question, but are not quite there yet. Similarly, a low partial can be thought of as a 'no, but.....' i.e. there is little in place but you can point to evidence of some aspects of compliance.

You must enter ONE response for each question. This can include a 'not applicable' (N/A) or a 'don't know' (D/K) response. If the 'Check' box is green then you have entered a response. If it is white you have yet to enter a response. If it is red, you have entered too many responses and must ensure you have only one response entered. If the 'Action' box is red, this flags up that you have not scored 100% on the question and, therefore, action(s) or a Quality Improvement Plan (QIP) may be needed.

The 'Count' line simply counts the number of each type of response and this is then converted to a 'Percentage' response immediately below. Thus you can immediately get a 'feel' for the response profile in relation to the questions comprising the element.

The 'ELEMENT SCORE (%)' gives the overall score for the element, taking account of any not applicable questions.

Note that scores are based on professional judgment made in relation to responding to the various questions in the DATA ENTRY worksheet. Scoring is relative and not absolute. The objective is to provide a profile, not to suggest precision.

1.3.3 Recording good practice

Click on the 'GOOD PRACTICE' worksheet tab. The following screen appears.

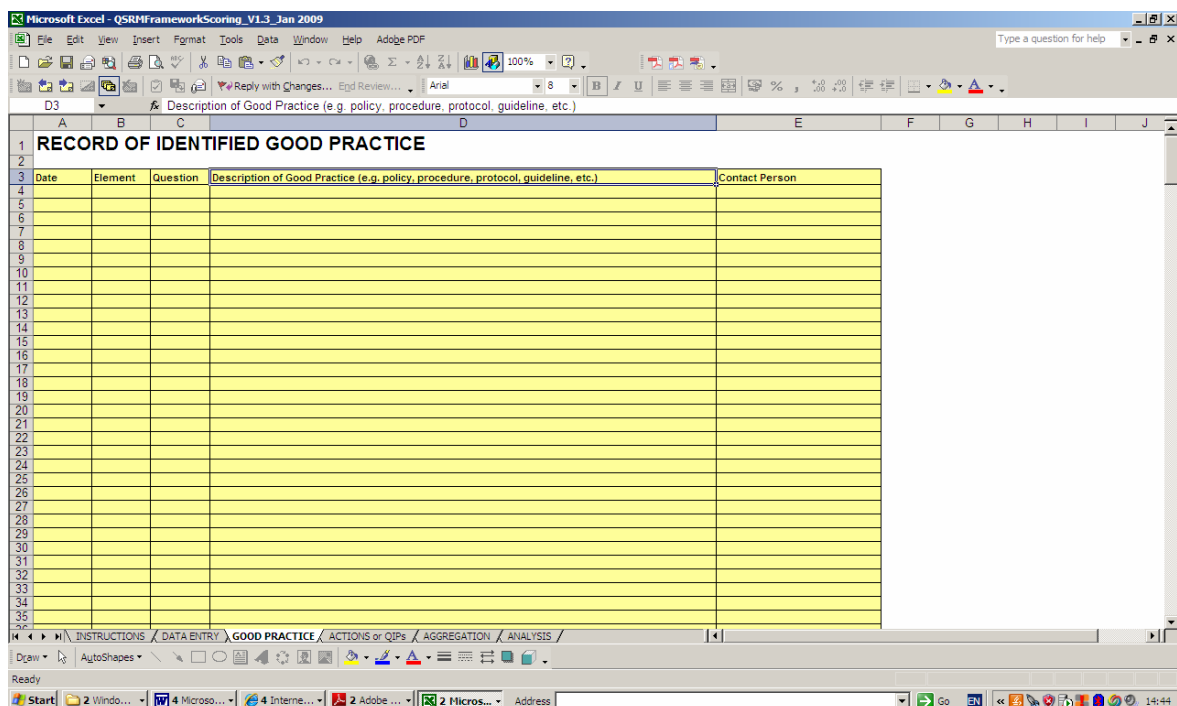


Figure 4 – Good practice screen

The 'GOOD PRACTICE' worksheet allows you to build a simple list of what you consider to be good practices in your organisation. These will be determined from the strengths you identify as part of your self-assessment against the framework. You can then share this information, and your scoring information, with other organisations to build a learning, sharing and benchmarking culture. Over time, this will help you improve quality and safety and reduce risk.

1.3.4 Recording actions or Quality Improvement Plans (QIPs)

Click on the 'ACTIONS or QIPs' worksheet tab. The following screen appears.

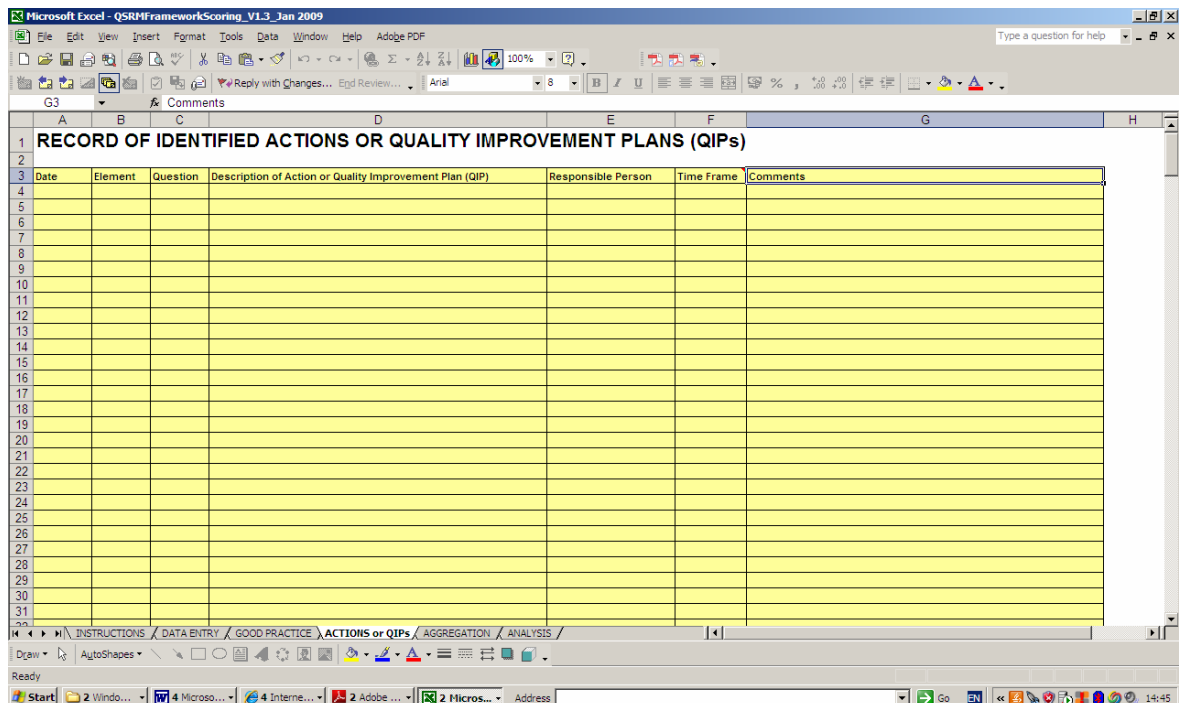


Figure 5 – Actions or quality improvement plans screen

You can type in the relevant details under the various headings to build a comprehensive action plan in relation to compliance with the quality, safety and risk management framework. Alternatively, you can use your own local action planning approach.

1.3.5 Aggregating data across departments, service areas, etc.

Should you need to aggregate data for individual questions across departments, service areas, etc. to establish an overall question response, click on the 'AGGREGATION' worksheet. You will see the following screen.

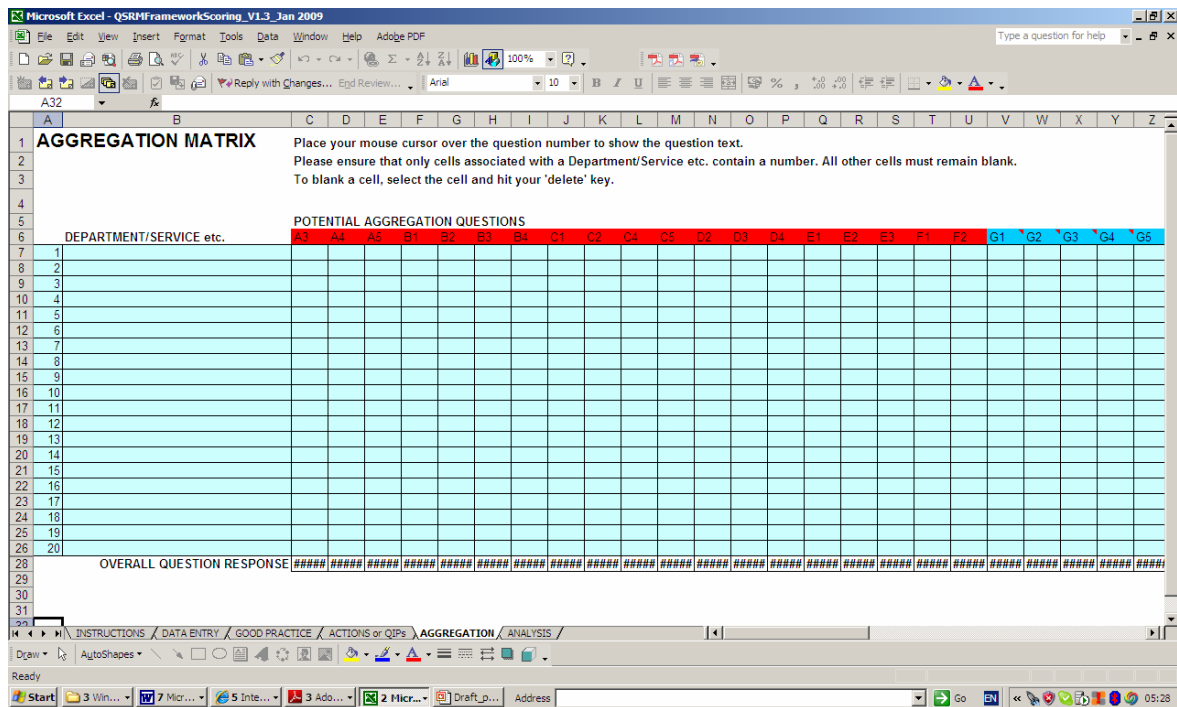


Figure 6 – Aggregation matrix screen

The quality, safety and risk management framework set out in the framework document is applicable at an **organisational** level. An 'organisation' is defined as a collection of services, departments and/or functions under the actual or assumed overall direction and control of a senior management team or governing body. In practical terms, this definition is intended to cover both statutory and voluntary hospitals together with local health offices (LHOs).

In both hospitals and LHOs there are a range of services, departments and/or functions that 'aggregate up' to provide a picture of the whole organisation. In a hospital you would have various services such as Accident and Emergency, Cardiology, Care of the Elderly, General Surgery, Paediatrics, Radiology, and so on. Similarly, in an LHO you would have various services such as mental health, disability services, primary care services, children and families, social inclusion, and so on.

Many of the framework 'check questions' may require aggregation across the organisation to determine the overall question response (i.e. Yes, high partial, moderate partial, low partial or no). With reference to the questions contained within the *Framework Document*, and reiterated in this *Companion Guide*, a shaded question number box indicates that the question requires possible aggregation across the organisation. It is up to senior organisational managers to collect and collate, where appropriate, sufficient information at 'lower levels' within the organisation in order that a judgement can be made about the level of **organisational** compliance with each framework check question.

As an example, consider question A.3 - *Is there effective communication and consultation with internal stakeholders in relation to the purpose, objectives and working arrangements for quality, safety and risk management?* Here you would ensure that all internal (i.e. within the organisation) stakeholders had been identified (from question A.1) and that there was documented evidence of communication and consultation on purpose, objectives and working arrangements for quality, safety and risk management with each service and other stakeholder groups (e.g. finance department, estates & facilities, infection control, etc.). In looking at the evidence, ask yourself the question "Does communication and consultation appear to be working effectively?" You might have to ask specific questions of a number of people representing different internal stakeholder groups in order to gain a better 'picture' of communication and consultation effectiveness. In doing this work, you might deduce that there appears to be evidence of compliance in around half of all services/departments, and limited or no compliance in the remainder. Given the compliance rating options of no, low partial, moderate partial, high partial and full compliance, you would select 'moderate partial' as your level of compliance and produce an action plan accordingly.

It is helpful to produce a matrix of 'relevant questions' against various services, departments, etc. so that you can identify compliance, using the yes, high partial, moderate partial, low partial and no response approach, for each relevant question against each service. Figure 7, overleaf, shows a simple illustrative example using the aggregation matrix contained in the *Electronic Self-Assessment Tool*. It can be seen that for each of the departments listed a numerical response has been provided for each question that identifies the degree of compliance with the question within the department. This numerical response is based on the Yes=100%, H=80%, M=50%, L=20% and No=0% approach, i.e. 100 is entered for a Yes response, 80 for a high partial response, and so on. When the response data has been entered for each department/question combination, the overall question response (Yes, HP, MP, LP, or No) is presented at the

bottom of the matrix. This is used to determine the overall response to the question on the DATA ENTRY worksheet (see section 1.3.2, above).

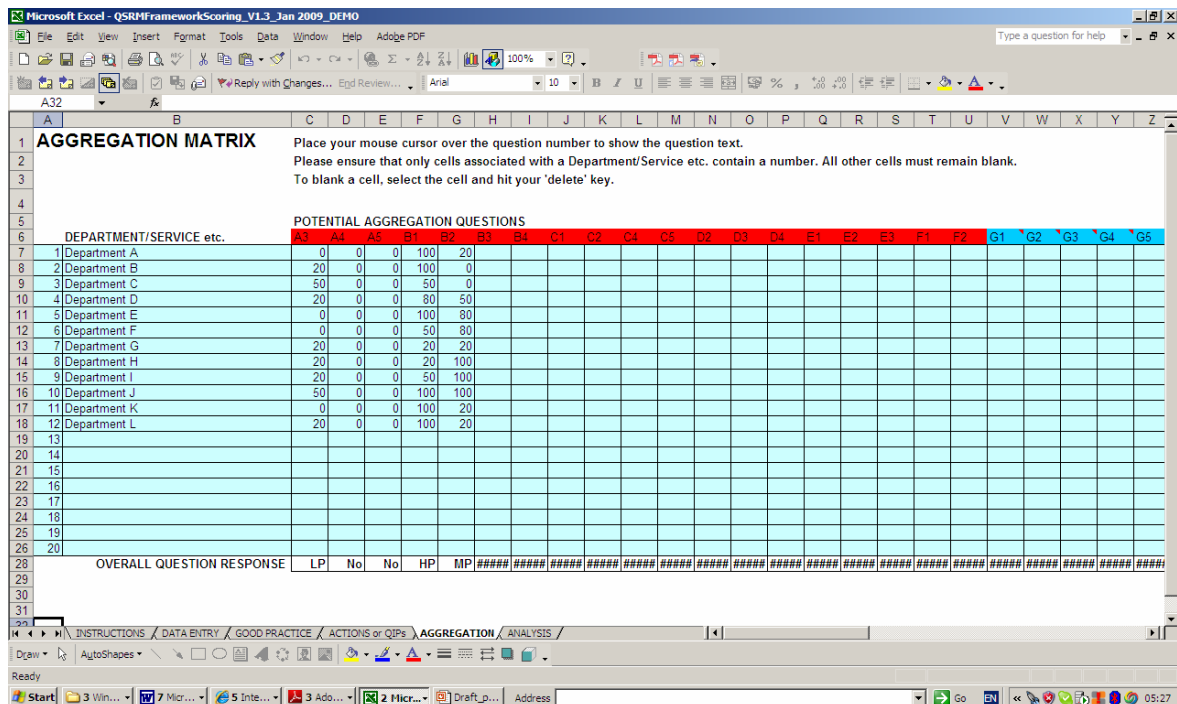


Figure 7 – Specimen aggregation matrix

1.3.6 Analysing the data

Click on the 'ANALYSIS' worksheet tab. A screen similar to Figure 8, overleaf, appears (this particular screen shows that some data has been entered). This shows a table containing a summary of responses to the questions in each element of the framework, together with the element scores.

If you scroll down the worksheet you will find three graphical analysis presentations. Figure 9 shows a bar chart containing element scores. Figure 10 shows a pie chart containing a breakdown of responses to self-assessment questions. And Figure 11 shows a bar chart containing a 'Level' analysis depicting summary scores for underpinning requirements (level 1), core processes and programmes (level 2) and outcomes (level 3).

You can highlight and copy any of the above analysis options using standard Windows™ copy facilities and paste them into, for example, a WORD document for reporting purposes. You can also print them directly from the Electronic Self-Assessment Tool to a printer.

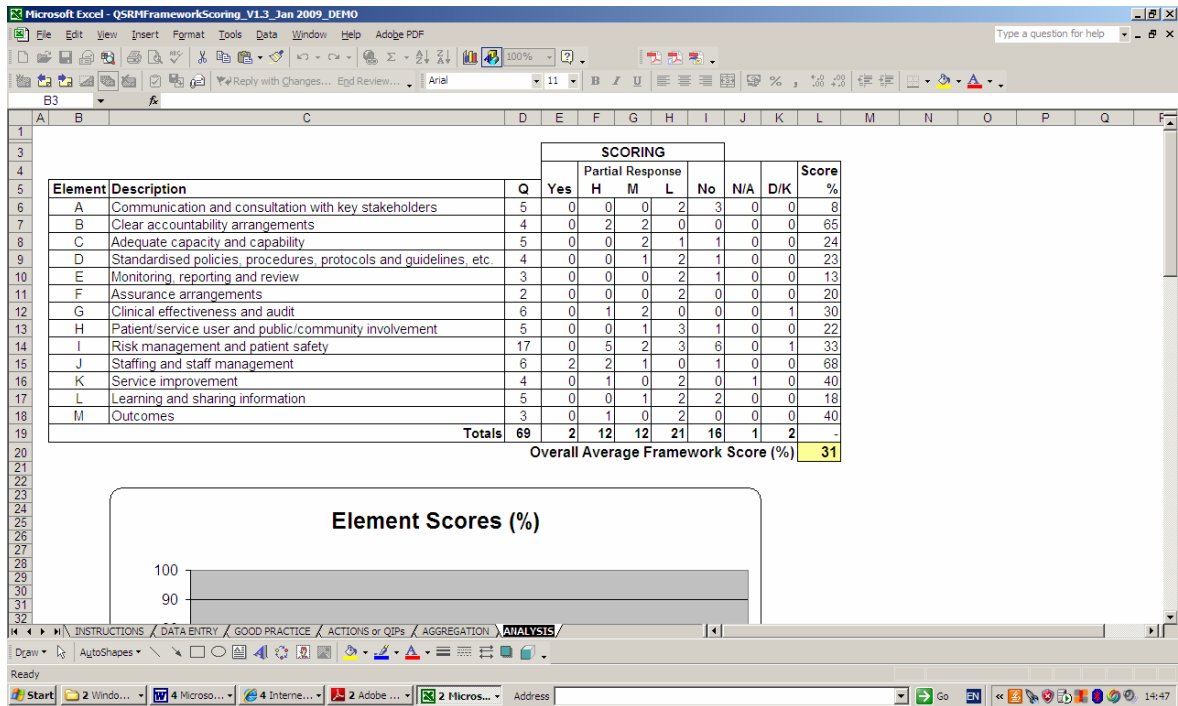


Figure 8 – Analysis: Table of element scores

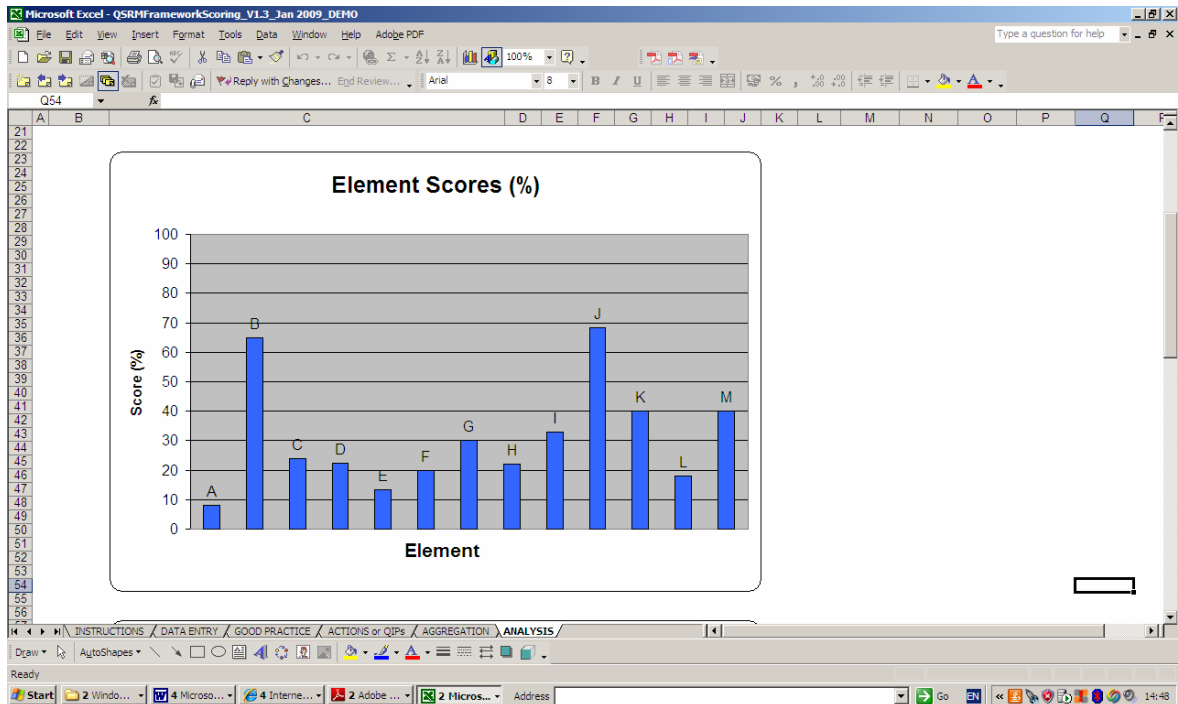


Figure 9 – Analysis: Bar chart showing element scores (%)

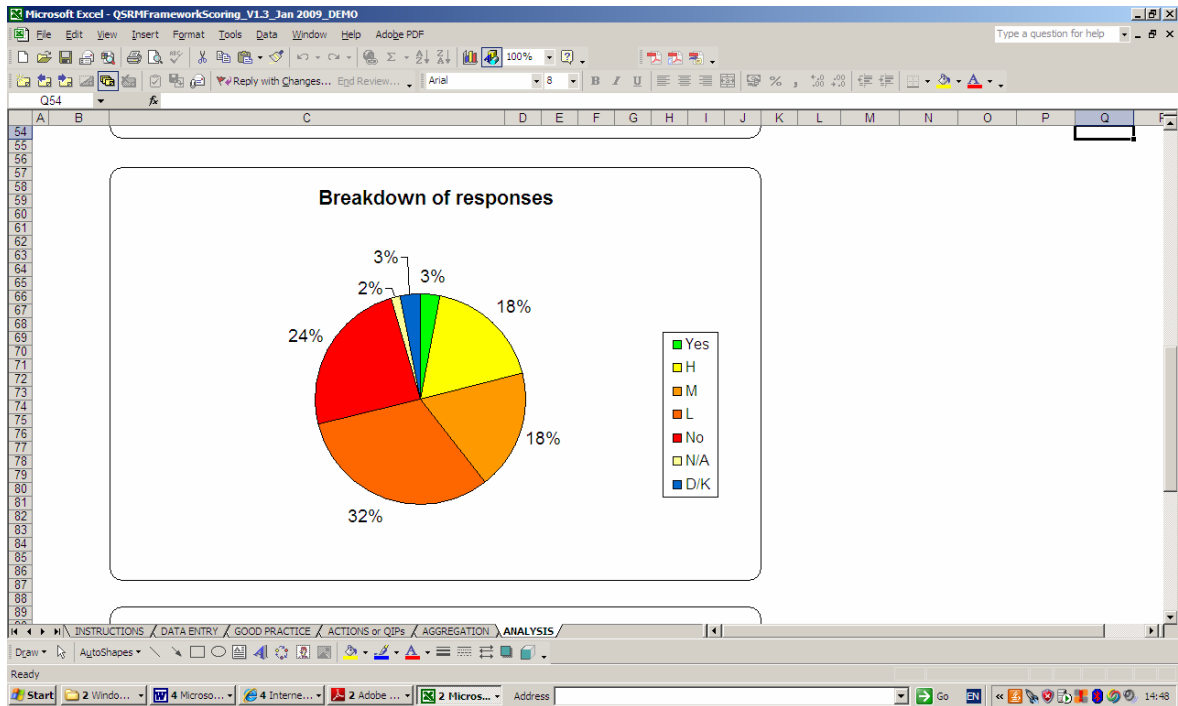


Figure 10 – Analysis: Breakdown of responses to self-assessment questions

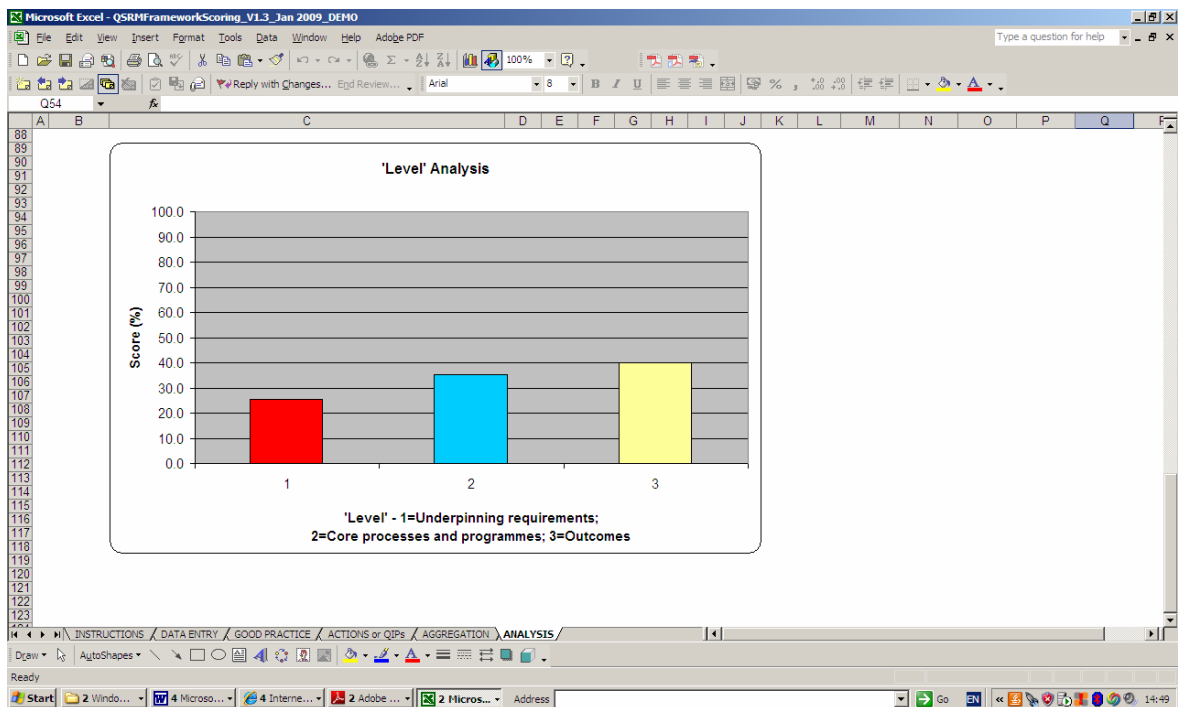


Figure 11 – Analysis: 'Level' analysis depicting score for underpinning requirements (level 1), core processes and programmes (level 2) and outcomes (level 3)

1.4 Beyond self-assessment I - Improving quality, safety and risk management using the Plan-Do-Study-Act (PDSA) improvement model

The PDSA improvement model (Figure 12) is widely used in healthcare internationally, including in Ireland. This model can be usefully applied in the context of the Quality, Safety and Risk Management Framework to help identify, implement and evaluate improvements. Further information on practical application of the PDSA model in healthcare can be found on the website of the Institute for Healthcare Improvement (IHI) at www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/HowToImprove/

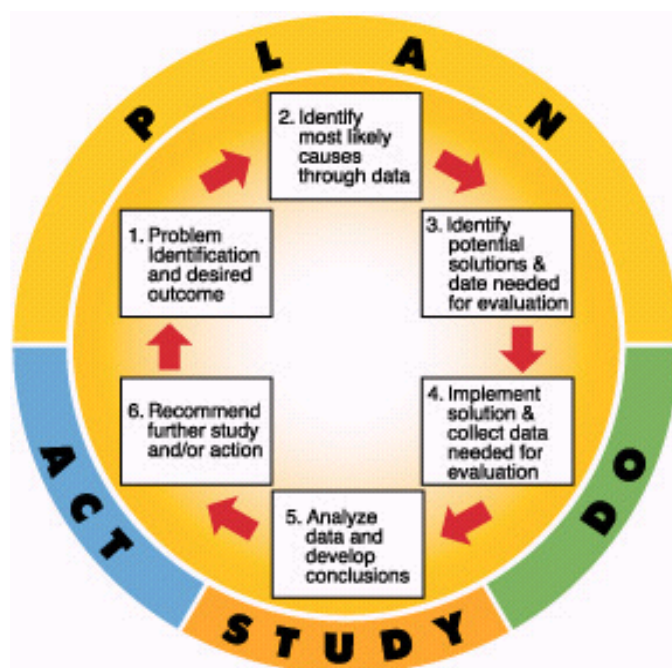


Figure 12 – The PDSA model

1.5 Beyond self-assessment II - Improving quality, safety and risk management using the HSE Change Model

The HSE has recently produced a very useful publication titled *Improving Our Services – A User’s Guide to Managing Change in the Health Service Executive*. The guide sets out a comprehensive ‘change model’ for improving services based on extensive research (Figure 13).

A summary of the guide can be downloaded at:

www.hse.ie/eng/Publications/Human_Resources/Improving_Our_Services_Summary.pdf

The full guide can be downloaded at:

www.hse.ie/eng/Publications/Human_Resources/Improving_Our_Services.pdf

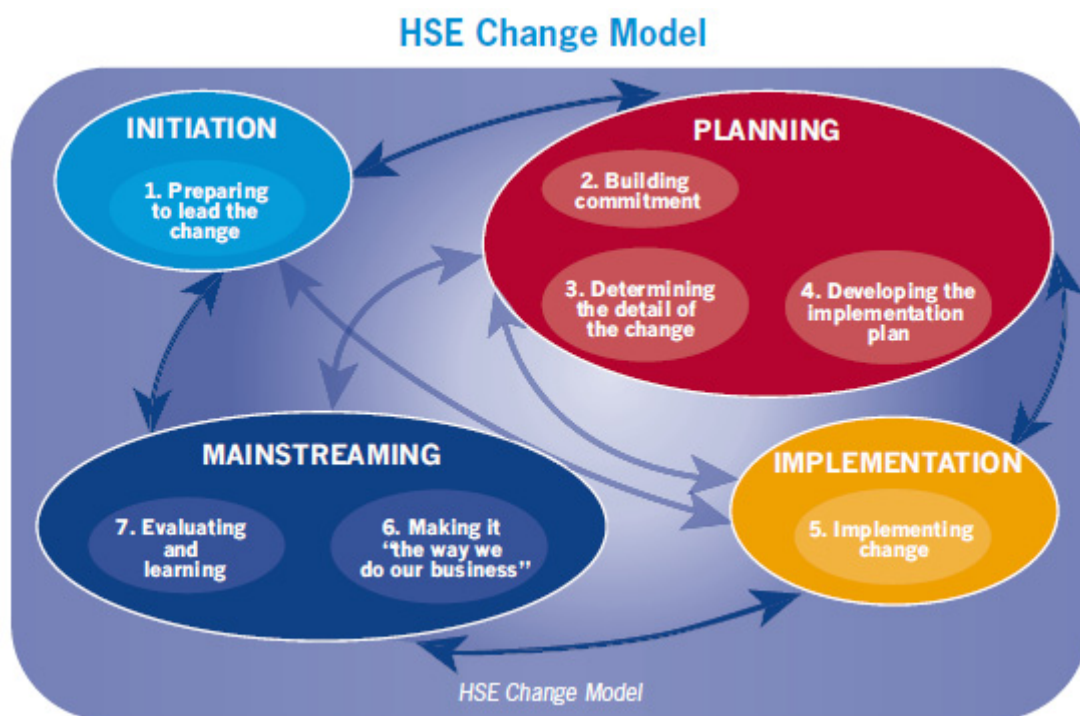


Figure 13 – The HSE Change Model

2. Essential underpinning requirements

A	<p>Communication and consultation with key stakeholders</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>																				
1.	<p>Has a ‘stakeholder analysis’ been carried out to identify all internal and external stakeholders relating to quality, safety and risk management?</p> <p>GUIDANCE</p> <p>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). 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> <p>SPECIMEN STAKEHOLDER ANALYSIS (ILLUSTRATIVE)</p> <table border="1"> <thead> <tr> <th>STAKEHOLDER</th> <th>INTERNAL/ EXTERNAL</th> <th>COMMUNICATION/ CONSULTATION STRATEGIES</th> <th>FREQUENCY</th> </tr> </thead> <tbody> <tr> <td>Staff</td> <td>INTERNAL</td> <td> <ul style="list-style-type: none"> • Staff handbook • Annual report • Induction programme • Newsletter • Communications boards • Staff survey • Internet-based podcast • etc. </td> <td> <ul style="list-style-type: none"> • Annually • Annually • Monthly • Quarterly • Weekly • Bi-annually • Quarterly • etc. </td> </tr> <tr> <td>Patients/Service Users</td> <td>INTERNAL</td> <td> <ul style="list-style-type: none"> • Annual report • Focus groups • Patient/Service User survey • Newspaper/magazine • Conferences • Mailshots • etc. </td> <td> <ul style="list-style-type: none"> • Annually • Ad-hoc • Annually • Quarterly • Annually • Ad hoc • etc. </td> </tr> <tr> <td>HIQA</td> <td>EXTERNAL</td> <td> <ul style="list-style-type: none"> • Senior management feedback to HIQA consultations </td> <td> <ul style="list-style-type: none"> • As required by HIQA </td> </tr> <tr> <td>etc.</td> <td></td> <td>etc.</td> <td>etc.</td> </tr> </tbody> </table> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Stakeholder analysis documentation • Strategic framework document • Risk management strategy • Public engagement strategy • HR strategy • Training needs analysis • Staff survey • Patient survey 	STAKEHOLDER	INTERNAL/ EXTERNAL	COMMUNICATION/ CONSULTATION STRATEGIES	FREQUENCY	Staff	INTERNAL	<ul style="list-style-type: none"> • Staff handbook • Annual report • Induction programme • Newsletter • Communications boards • Staff survey • Internet-based podcast • etc. 	<ul style="list-style-type: none"> • Annually • Annually • Monthly • Quarterly • Weekly • Bi-annually • Quarterly • etc. 	Patients/Service Users	INTERNAL	<ul style="list-style-type: none"> • Annual report • Focus groups • Patient/Service User survey • Newspaper/magazine • Conferences • Mailshots • etc. 	<ul style="list-style-type: none"> • Annually • Ad-hoc • Annually • Quarterly • Annually • Ad hoc • etc. 	HIQA	EXTERNAL	<ul style="list-style-type: none"> • Senior management feedback to HIQA consultations 	<ul style="list-style-type: none"> • As required by HIQA 	etc.		etc.	etc.
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etc.		etc.	etc.																		

A	<p>Communication and consultation with key stakeholders</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
2.	<p>Are arrangements in place to ensure that the ‘stakeholder analysis’ is maintained up-to-date?</p> <p>GUIDANCE</p> <p>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 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.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Relevant policy
3.	<p>Is there effective communication and consultation with internal stakeholders in relation to the purpose, objectives and working arrangements for quality, safety and risk management?</p> <p>GUIDANCE</p> <p>The test of an ‘effective’ communication and consultation mechanism is ‘does it work and, as such, services should aim to provide clear evidence of effectiveness. 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Stakeholder surveys • Apparent impact of communication strategies on key performance indicators

A	<p>Communication and consultation with key stakeholders</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
4.	<p>Are internal and, where appropriate, external stakeholders kept fully informed on progress to achieve quality, safety and risk management objectives?</p> <p>GUIDANCE</p> <p>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 question1, 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Stakeholder communication logs
5	<p>Is there effective communication and consultation with external stakeholders in relation to quality, safety and risk management?</p> <p>GUIDANCE</p> <p>As identified above, the test of an ‘effective’ communication and consultation mechanism is ‘does it work and, as such, services should aim to provide clear evidence of effectiveness. Check firstly that there is communication/consultation with relevant external stakeholders, and secondly that such communication/consultation can be considered to be effective. For example, if you have responded to a HIQA consultation process, is there evidence that your response has been taken on-board.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Stakeholder surveys

Clear accountability arrangements

B NB – Shaded number box indicates question requires possible aggregation across the organisation.

1 Are clearly documented accountability arrangements in place to support the organisation's most senior accountable manager to discharge his/her responsibility for quality, safety and risk management?

GUIDANCE

There should be an 'organisation chart' or 'organogram' and, possibly, an 'accountability framework' 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. hospital manager, LHO manager, etc.). In some instances, however, the accountability arrangements might reflect a more 'matrix working' environment with a number of 'dotted line' accountabilities. This guide does not presume to know the best arrangements for any particular service provider. The maxim "What matters is what works" should be followed.

In a hierarchical accountability framework there will be a hierarchy of job functions and committees or groups leading up to the senior accountable manager. The organisational chart might identify, for example, and in no particular order:

- Executive management team
- Clinical governance committee
- Director of Quality and Risk
- Health and Safety Office
- Risk Manager
- Quality Manager
- Internal Audit Department
- Ethics and Research Office
- Audit Committee
- Radiation Safety Committee
- Quality, Risk and Safety Committee
- Medication Safety Committee
- Clinical Audit Committee
- Individual directorates
- Individual service providers
- etc.

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.

EXAMPLES OF VERIFICATION

- Organogram
- Job descriptions
- Committee/Group terms of reference
- Accountability framework document
- Quality/Safety/Risk Management strategy

RESOURCES

	<p>Clear accountability arrangements</p> <p>B NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<ul style="list-style-type: none"> • The HSE’s Corporate Safety Statement document provides a good example of clearly set accountability arrangements. • See the following link for a specimen ‘Accountability Framework’ for risk management in Worcestershire Mental Health Partnership NHS Trust in England: www.worcestershirehealth.nhs.uk/SWPCT_Library/Policies_and_Procedures/Risk_Management/Risk%20Management%20Strategy.pdf
2	<p>Do the documented accountability arrangements ensure that that the organisation’s most senior accountable manager is fully informed in relation to key areas of quality, safety and risk performance?</p> <p>GUIDANCE</p> <p>The arrangements should cover all areas of quality, safety and risk management deemed key by the organisation/service provider. For example, if radiation protection is a consideration for the organisation, then there will most likely be a radiation safety committee (however named). 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 functions with expert knowledge of quality, safety and risk management is essential. 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Organogram • Job descriptions • Committee/Group terms of reference • Accountability framework document • Quality/Safety/Risk Management strategy • Key performance indicators
3.	<p>Are the roles and responsibilities played by any committees or groups described clearly within the accountability arrangements?</p> <p>GUIDANCE</p> <p>Check all relevant documentation for clear descriptions of the roles and responsibilities for committees or groups.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Organogram • Committee/Group terms of reference • Accountability framework document • Quality/Safety/Risk Management strategy
4.	<p>Do committee structures and reporting arrangements provide for coordination and</p>

B	<p>Clear accountability arrangements</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<p>integration of quality, safety and risk activities and priorities?</p> <p>GUIDANCE</p> <p>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 board’, 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? Further, is there evidence that priorities are being set ‘across the board’?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Organogram • Committee/Group terms of reference • Accountability framework document • Quality/Safety/Risk Management strateg

C.	<p>Adequate capacity and capability</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
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<p>C.</p>	<p>Adequate capacity and capability</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>1.</p>	<p>Do managers at all levels fulfil their responsibility by demonstrating commitment to the management of quality, safety and risk?</p> <p>GUIDANCE</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 organisation 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 organisation 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Minutes of meetings of relevant committees or groups • Notes associated with walkarounds, etc. showing evidence of managerial engagement • Manager’s job descriptions • Evidence of managers’ attendance at educational and training events, e.g. Root Cause Analysis • Evidence of managers’ involvement in complaints and incident investigations • Notes associated with walkarounds, etc. showing evidence of managerial engagement
<p>2.</p>	<p>Do service planning and other business planning arrangements take into account the quality, safety and risk management goals and priorities of the service provider when developing budgets and other financial strategies?</p> <p>GUIDANCE</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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Minutes of meetings of relevant committees or groups • Notes associated with relevant project groups, e.g. capital development

<p>C.</p>	<p>Adequate capacity and capability</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>3.</p>	<p>Is a defined percentage or allocation of the organisation’s annual budget committed to achieving defined quality, safety and risk management goals?</p> <p>GUIDANCE</p> <p>Often, financial resources need to be ‘ring fenced’ in order for quality, safety and risk management goals to be achieved. Look to see whether senior 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"> • Minutes of relevant meetings • Details of budgets, including education/training.

<p>C.</p>	<p>Adequate capacity and capability</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>4.</p>	<p>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.?</p> <p>GUIDANCE</p> <p>No organisation has infinite resources to deal with quality and risk management, or any other matter. The resources that are provided need to be realistic, i.e. in line with issues such as the organisation’s risk profile.</p> <p>Financial resources is partly dealt with in question 3, above, and can be a ‘thorny’ issue. Service providers 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. 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.</p> <p>What is potentially more challenging to assess is the extent to which an organisation has access to appropriate staffing resources for quality, safety and risk management. Larger hospital organisations 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, organisations 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 (e.g. from the HSE’s own corporate quality and risk management function) 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"> • Resource matrix

<p>C.</p>	<p>Adequate capacity and capability</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>5.</p>	<p>Are all staff provided with adequate quality, safety and risk management information, instruction and training appropriate to their role?</p> <p>GUIDANCE</p> <p>All staff will need some form of quality, safety and risk management training – but <u>only as appropriate</u> to their role. For some staff, all of their information, instruction and training requirements will be satisfied in relation to induction and ongoing training processes. Other staff may require additional information, instruction and training. The difference between ‘instruction’ and ‘training’ can sometime be debatable. For practical purposes, ‘instruction’ relates to showing somebody how to carry out a practical activity, whereas ‘training’ is regarded as a more formal process that includes theory as well as practice.</p> <p>One way of assessing compliance with this question is for organisations to conduct an overall information, instruction and training needs analysis. Many organisations will already be familiar with conducting a training needs analysis. Such an analysis should be informed by the organisation’s risk profile (see Element I, below).</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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Documented analysis of information, instruction and training needs • Documented assessment of whether need have been, or are being met • Training records for staff • Events log (conferences, seminars, etc.) • Information publications for staff

<p>D.</p>	<p>Standardised policies, procedures, protocols and guidelines</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>1.</p>	<p>Does the organisation operate a standardised document control process for all policies, procedures, protocols and guidelines?</p> <p>GUIDANCE Health and social care organisations typically have large numbers of policies, procedures, protocols and guidelines, A medium sized hospital, for example, can have several hundred policy document alone. Likewise, the combined service providers making up a local health area could have several hundred policies. Thus, 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 organisation operates a standardised document control process.</p> <p>The document control process could be manually implemented or, ideally, will be computer-based.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Document control policy/procedure <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE Procedure for developing Policies, Procedures, Protocols and Guidelines

D.	<p>Standardised policies, procedures, protocols and guidelines</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
2.	<p>Are arrangements in place to train staff in appraising and developing policies, procedures, protocols and guidelines and identifying evidence-based best practice?</p> <p>GUIDANCE</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 organisations may have a policy on developing policies etc. (for example, University College Hospital Galway has a policy titled <i>Development, Management, Maintenance & review of Policies, Procedures and Guidelines at GUH – GRH/NM000</i>).</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Policy on policies • Staff training records <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE Procedure for developing Policies, Procedures, Protocols and Guidelines • The following article from New Zealand provides a useful introduction to clinical guidelines and evidence-based medicine: www.nzgg.org.nz/download/files/Didsbury_Oct03.pdf
3.	<p>Are policies, procedures, protocols and guidelines standardised throughout the organisation and, where appropriate, are they evidence-based?</p> <p>GUIDANCE</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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Random sampling of policies to ensure compliance.

D.	<p>Standardised policies, procedures, protocols and guidelines</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
4.	<p>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?</p> <p>GUIDANCE</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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check service development plans and actions taken to develop policies, etc..

E.	<p>Monitoring and review arrangements</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
1.	<p>Are all aspects of the framework 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?</p> <p>GUIDANCE</p> <p>Each aspect of the quality, safety and risk management system described by the Framework Document should be periodically monitored and reviewed by local 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"> • Communication and consultation with key stakeholders • Clear accountability arrangements • Adequate capacity and capability • Standardised policies, procedure and guidelines • Monitoring and review arrangements • Assurance arrangements • Clinical effectiveness and audit • Patient and public involvement • Risk management and patient safety • Staffing and staff management • Service improvement • Learning and sharing information • Key Performance Indicators (KPIs)

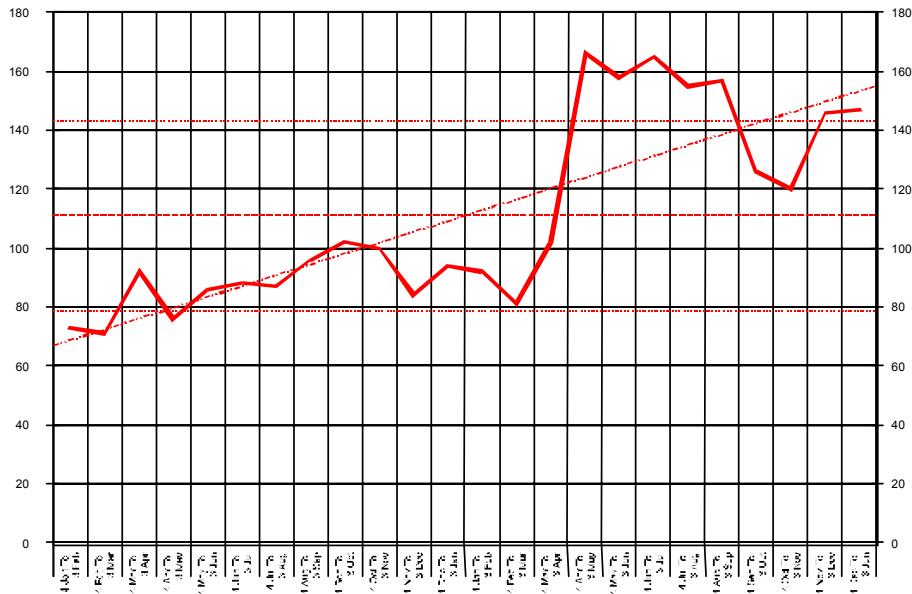
E.	<p>Monitoring and review arrangements</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<p>As part of the review process, any identified weaknesses in any aspect of the framework should be rectified.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Relevant meeting minutes that highlight reviews carried out and any actions required/taken • Relevant review reports
2.	<p>Are the results of independent and other audits used to inform improvements in quality, safety and risk management systems?</p> <p>GUIDANCE</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 organisation that is not directly associated with the service provider. For example, independent audits might be carried out by HIQA, the Mental Health Commission or the Health and Safety Authority. They may be carried out by the HSE itself either through internal audit or through an internally convened independent panel. And there are various reviews and audits carried out by others across the HSE, and outside the HSE, including internationally (e.g. audits in the UK National Health Service), the results of which could be used by any HSE service provider to inform improvements in quality, safety and risk management systems.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Action plans showing improvement actions linked to audits, reports, etc. • Minutes of relevant meetings • KPIs demonstrating performance improvement(s) linked to improvements in the systems for quality, safety and risk management
3.	<p>Are key performance indicators reviewed regularly to identify and correct anomalies and to drive continuous improvement in quality, safety and risk management?</p> <p>GUIDANCE</p> <p>See also guidance associated with questions M.1 – M.3, below.</p> <p>KPIs can be ‘tracked’ over time to determine anomalies, which can be investigated to determine whether system improvements need to be made.</p> <p>Consider, for example, the figure below which is illustrative. This shows a trend for adverse events, i.e. incidents involving harm to patients, for a hospital in the UK for a whole year (1996). The doubling in the number of reported adverse events around August/September can be clearly seen. This ‘anomaly’ was subjected to a root cause analysis and it was found to be caused by management weaknesses around the handling</p>

E. Monitoring and review arrangements

NB – Shaded number box indicates question requires possible aggregation across the organisation.

of new junior doctors. The junior doctors would come in to the hospital at this time while many of the senior staff doctors were on summer holidays. With the lack of clinical supervision, junior doctors would be allowed to literally do their own thing. The result was an increase in the number of reported incidents involving harm to patients.

Trend for Adverse Events, Start Date: 04/01/96



EXAMPLES OF VERIFICATION

- Action plans showing improvement actions
- Minutes of relevant meetings

RESOURCES

- The Institute for Healthcare Improvement in the USA has an excellent range of resources available freely to help healthcare organisations improve through tracking key performance indicators. See www.ihl.org/IHI/Topics/Improvement/

F.**Assurance arrangements**

NB – Shaded number box indicates question requires possible aggregation across the organisation.

1.

Does senior management receive sufficient assurance on the systems in place for quality, safety and risk management?

GUIDANCE

The determination of what constitutes ‘sufficient’ 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.

One approach to determining sufficiency of assurance is to construct a matrix of all actual sources of assurance available from within and outside the organisation and determine, based on the organisation’s 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 “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?”

SPECIMEN ASSURANCE MATRIX (ILLUSTRATIVE)

KEY RISK (From Risk Register)	SOURCE OF ASSURANCE	INTERNAL/ EXTERNAL
Infection control	Internal Audit report on compliance with HIQA draft infection control standards, October 2008	Internal
Infection control	Outside consultant’s report on infection control arrangements, November 2008	External
Information management	Internal Audit report on compliance with information management standards, July 2008	Internal
etc.	etc.	etc.

EXAMPLES OF VERIFICATION

- Internal audit reports
- Clinical audit reports
- Management reports
- Minutes of the committee(s) responsible for overseeing quality, safety and risk management
- Reports from HIQA, Mental Health Commission and other review bodies.
- Reports from Professional bodies
- Reports from external audit
- Reports from multi-professional audit

<p>F.</p>	<p>Assurance arrangements</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>2.</p>	<p>Do the assurances received by senior management form an integral part of their ongoing monitoring and review processes?</p> <p>GUIDANCE</p> <p>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 organisation?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Minutes of relevant meetings • Reports to the board • Reports to HSE corporate functions

3. Core processes and programmes

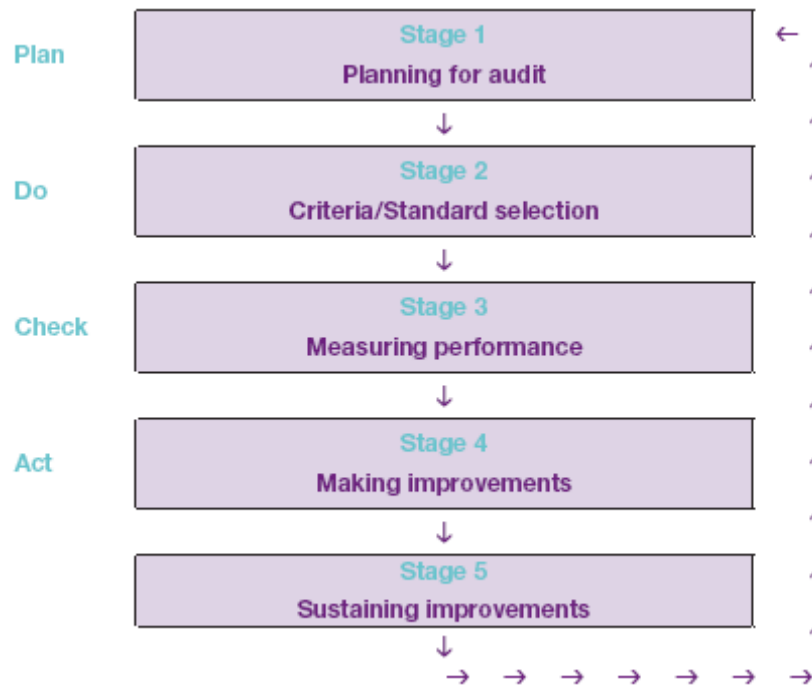
<p>G.</p>	<p>Clinical effectiveness and audit</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>1.</p>	<p>Is there a structured programme, or programmes, in place to systematically monitor and improve the quality of clinical care provided across all services?</p> <p>GUIDANCE</p> <p>The Framework Document states “A structured programme, or programmes, 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 guidelines; systems to disseminate relevant information; and use of supporting information systems.”</p> <p>The ‘clinical effectiveness cycle,’ which includes clinical audit, is presented in the Figure below.</p> <div data-bbox="383 974 1316 1803" style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> <p>The diagram illustrates the 'clinical effectiveness cycle' as a continuous loop of three stages, each represented by an inverted triangle:</p> <ul style="list-style-type: none"> INFORM (top, blue triangle): <ul style="list-style-type: none"> Access to evidence-based knowledge base Evidence Based Practice Critical Appraisal National Standards and Guidelines MONITOR (bottom-left, light blue triangle): <ul style="list-style-type: none"> Clinical audit KPIs Clinical Indicators <p><i>MAKING SURE IT WORKS</i> (written vertically along the left side of the triangle)</p> CHANGE (bottom-right, grey triangle): <ul style="list-style-type: none"> Care Pathways Clinical Guidelines Quality Improvement Change Management Project Management <p><i>EVIDENCE INTO PRACTICE</i> (written vertically along the right side of the triangle)</p> <p>Curved arrows indicate a clockwise flow from INFORM to MONITOR, from MONITOR to CHANGE, and from CHANGE back to INFORM.</p> </div>

G.

Clinical effectiveness and audit

NB – Shaded number box indicates question requires possible aggregation across the organisation.

The clinical audit process is presented below. This figure is reproduced from *Building a Culture of Patient Safety* – see **Resources** section, below. The figure is adapted from guidance on Principles for Best Practice in Clinical Audit published by the National Institute for Health and Clinical Excellence in the UK (NICE) – again, see **Resources** section, below.



The key requirement under this question is to check whether there is a structured programme, or programmes, in place to systematically monitor and improve the quality of clinical care provided across all services. The programme, or programmes, should be based around clinical effectiveness and clinical audit approaches as briefly outlined in the figures above, and set out in detail in the **Resources** listed below. The Department of Health & Children publication *Building a Culture of Patient Safety* provides a particularly good introduction to clinical effectiveness and clinical audit in chapter 7. The NICE guidance *Principles for best practice in clinical audit* explores clinical audit in detail.

EXAMPLES OF VERIFICATION

- Programme documentation
- Relevant policy/procedure
- Minutes of relevant meetings (e.g. clinical effectiveness or clinical audit committee meetings)
- Action/Improvement plans

G.	<p>Clinical effectiveness and audit</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<p>RESOURCES</p> <ul style="list-style-type: none"> • Department of Health & Children (2008). <u>Building a Culture of Patient Safety</u>. Report of the Commission on Patient Safety and Quality Assurance • NICE (2002). <u>Principles for best practice in clinical audit</u>. Free download at www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf
2.	<p>Are arrangements in place to monitor clinical effectiveness activity, including clinical audit?</p> <p>GUIDANCE</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 programme, or programmes, 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Relevant policy • Minutes of relevant meetings (e.g. clinical effectiveness or clinical audit committee meetings) • Clinical audit plan(s) • Completed clinical audit reports • Action/Improvement plans • Management reports outlining evidence of improvements in clinical care
3.	<p>Is the implementation of evidence-based practice through use of recognised standards, guidelines and protocols promoted?</p> <p>GUIDANCE</p> <p>The implementation of evidence-based practice through use of recognised standards, guidelines and protocols should be promoted by the organisation 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Relevant policies, e.g. quality, clinical effectiveness/audit, risk management, etc. • Minutes of relevant meetings, e.g. clinical effectiveness/audit committee • Ask relevant staff

G.	<p>Clinical effectiveness and audit</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
4.	<p>Are information systems being properly exploited to support clinical effectiveness activity?</p> <p>GUIDANCE</p> <p>The determination of whether information systems are being ‘properly exploited’ is a judgment call by those carrying out the self-assessment, assisted where necessary by those with specialist clinical effectiveness knowledge and expertise.</p> <p>In some cases the information systems may not be there to exploit. 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Clinical effectiveness policy/procedures • Ask staff engaged in clinical effectiveness activity
5.	<p>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)?</p> <p>GUIDANCE</p> <p>Given limited resources, it is usually necessary to prioritise 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Clinical audit policy/procedure • Documented clinical audit work plan <p>RESOURCES</p> <ul style="list-style-type: none"> • NICE (2002). <u>Principles for best practice in clinical audit</u>. Free download at www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf

6.	<p>Is there evidence that clinical effectiveness activities result in changes in clinical practice and improvements in the standards of care?</p> <p>GUIDANCE</p> <p>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 have care standards improved as a consequence of clinical effectiveness activity?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Clinical effectiveness/audit reports • Minutes of relevant meetings e.g. clinical effectiveness/audit committee • Ask staff
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H.	<p>Patient/service user and public/community involvement</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation. (NB –questions are adapted from the Victorian Safety and Quality Improvement Framework, Australia)</p>
1.	<p>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?</p> <p>GUIDANCE</p> <p>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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Survey report • Focus group reports • Suggestion reports • Minutes of relevant meetings • Action/improvement plans <p>RESOURCES</p> <ul style="list-style-type: none"> • See Victorian Safety and Quality Improvement Framework, Australia. www.health.vic.gov.au/qualitycouncil/pub/improve/framework.htm

H.	<p>Patient/service user and public/community involvement</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation. (NB –questions are adapted from the Victorian Safety and Quality Improvement Framework, Australia)</p>
2.	<p>Is sufficient information and opportunity provided for patients/service users to meaningfully participate in their own care?</p> <p>GUIDANCE</p> <p>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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Patient surveys • Examination of Care Plans • Check role of clinical nurse specialists • Information guides for patients/service users
3.	<p>Are patients/service users and the public involved in the development of patient information?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check minutes of meetings, relevant reports, etc.
4.	<p>Are arrangements in place to train and support patients/service users, staff and the public involved in the patient and public involvement process?</p> <p>GUIDANCE</p> <p>At the time of writing this Guide, there was mention of a possible toolkit being produced to assist with training and support.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Evidence of completed training
5.	<p>Are patients/service users and the public invited to assist in planning new services?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check arrangements for planning new services • Check attendance at relevant meetings (meeting minutes)

<p>I.</p>	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
<p>1.</p>	<p>Are risks of all kinds systematically identified and assessed in accordance with HSE guidance?</p> <p>GUIDANCE</p> <p>Substantial guidance exists on risk management in support of the HSE’s policy on adopting an integrated approach to quality, safety and risk management. Refer to HSE guidance (see Resources, below).</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Risk management policy • Risk register(s) • Evidence of risk identification workshops • Incident reviews • Complaints review • Business plans <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE guidelines on managing risk • AS/NZS 4360:2004 – the Australian/New Zealand risk management Standard
<p>2.</p>	<p>Are risks of all kinds managed in order of priority in accordance with HSE guidance?</p> <p>GUIDANCE</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 HSE guidance for additional information.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Risk register(s) • Risk action plan(s) <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE guidelines on managing risk • AS/NZS 4360:2004 – the Australian/New Zealand risk management Standard

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
3.	<p>Are risk registers used for the purpose of managing and communicating risk at all levels?</p> <p>GUIDANCE</p> <p>The key requirement of this question is to determine whether risk register are used at all levels in the organisation, i.e. at departmental or service level and up to senior management level. Risk registers are, essentially, communication tools. They help ensure sufficient information on risks is communicated to the appropriate level in an organisation to allow the risk to be properly managed.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Evidence of risk registers at all levels in the organisation • Evidence of decision-making in relation to risk at all levels <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE guidelines on managing risk • AS/NZS 4360:2004 – the Australian/New Zealand risk management Standard

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
4.	<p>Are arrangements in place to manage known high priority risk issues?</p> <p>GUIDANCE</p> <p>Notwithstanding the need to systematically identify, assess and manage risks of all kinds, service providers 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"> – 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 absconsion – Management of patient information – Lone working – etc. <p>High priority risk issues will typically have been previously identified from local experience and national initiatives. The risk register will also contribute to an understanding of local high priority risk issues.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Dedicated policies covering specific high priority risk issues • Relevant programmes to address high priority risk issues • Relevant action plans

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
5.	<p>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?</p> <p>GUIDANCE</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 set out above. Appropriate systems and processes should be in place to ensure the management of occupational safety, health and welfare. The Health and Safety Authority’s (HSA) Health Services Health and Safety Audit tool should be used to assist with implementing suitable systems. The questions from the HSA tool have been incorporated into a version of the Electronic Self-Assessment Tool that accompanies the quality, safety and risk management framework. 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"> • Use of HSA audit tool • Inclusion of a range of occupational safety, health and welfare risks in risk register(s) • Action plans incorporating actions to address occupational safety, health and welfare risk issues
6.	<p>Are environmental and fire safety risks identified, assessed and managed and are arrangements in place to ensure that environmental and fire risks are minimised through meeting legislative and mandatory requirements?</p> <p>GUIDANCE</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 minimised 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"> • Environmental and fire safety audit and/or inspection records • Inclusion of a range of environmental and fire risks in risk register(s) • Action plans incorporating actions to address environmental and fire safety risk issues

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
7.	<p>Is an ongoing programme of patient safety improvement in operation?</p> <p>GUIDANCE</p> <p>Achieving significant improvements in patient safety is currently seen as a major imperative for healthcare internationally. This is evidenced by the relatively recent establishment of the World Health Organisation (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"> • Evidence of ongoing implementation of a programme of patient safety. <p>RESOURCES</p> <ul style="list-style-type: none"> • WHO World Alliance for Patient Safety - www.who.int/patientsafety/en/ • HIQA – www.higa.ie • UK National Patient Safety Agency – www.npsa.nhs.uk • USA Joint Commission - www.ccforspatientsafety.org/ • ECRI Institute – www.ecri.org • Institute for Healthcare Improvement (IHI) - www.ih.org/IHI/Topics/PatientSafety/ • US Department of Veterans Affairs National Center for Patient Safety - www.va.gov/ncps/ • US Agency for Healthcare Research and Quality - www.ahrq.gov/qual/
8.	<p>Are arrangements in place to ensure that Medical Device Alerts/Safety Notices are circulated to all relevant staff and are acted on?</p> <p>GUIDANCE</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"> • Policy/procedure for dealing with medical device alerts and safety notices • Software system in use for identifying and circulating alerts and notices, and for monitoring whether they have been acted upon.

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
9.	<p>Are incidents properly recorded and reported to management?</p> <p>GUIDANCE</p> <p>Refer to HSE incident management policy and procedure for detailed guidance.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Random sample of local incident reports <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE incident management policy and procedure
10.	<p>Are incidents managed in accordance with an agreed policy?</p> <p>GUIDANCE</p> <p>There should be a locally agreed policy for incident management that takes cognisance of the HSE's overall incident management policy and procedure.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Local incident management policy • Select a sample of incidents and 'trace back' how they were managed to establish degree of compliance with policy • Talk to managers, clinicians and staff <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE incident management policy and procedure

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
11.	<p>Are incidents rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?</p> <p>GUIDANCE</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’). Refer to HSE guidance on systems analysis/root cause analysis for further information.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Incident reports • Risk register information • Incident investigation/RCA report <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE incident management policy and procedure
12.	<p>Are incidents subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?</p> <p>GUIDANCE</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"> • Incident review reports <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE incident management policy and procedure

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
13.	<p>Are complaints, comments and appeals properly recorded and reported to management?</p> <p>GUIDANCE</p> <p>Refer to HSE guidance on complaints, etc.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check a sample of complaints reports <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE guidance on complaints, etc.
14.	<p>Are complaints managed in accordance with an agreed policy?</p> <p>GUIDANCE</p> <p>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 that takes cognisance of HSE guidance.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Local complaints management policy • Select a sample of complaints and 'trace back' how they were managed to establish degree of compliance with policy • Talk to managers, clinicians and staff <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE guidance on complaints

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
15.	<p>Are complaints rated according to impact and reviewed, where appropriate, to determine contributory factors, root causes and any actions required?</p> <p>GUIDANCE</p> <p>All reported complaints should be rated according to impact in order to determine what, if any, further action is required, The key to learning from complaints is ‘root cause analysis’ (sometimes termed ‘systems analysis’), Refer to HSE guidance on root cause analysis/systems analysis for further information.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Complaints reports • Risk register information • Complaints investigation/RCA report <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE complaints guidance
16.	<p>Are complaints and comments subjected to periodic aggregate reviews to identify trends and further opportunities for learning, quality and safety improvement, and risk reduction?</p> <p>GUIDANCE</p> <p>All complaints 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"> • Complaints review reports • Action/improvement plans • Risk register information <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE complaints guidance

I.	<p>Risk management and patient safety</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
17.	<p>Where appropriate, are all claims recorded and analysed to identify opportunities for learning, quality and safety improvement, and risk reduction?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Claims review reports • Action/improvement plans • Risk register information

J.	<p>Staffing and staff management</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
1.	<p>Are arrangements in place to ensure appropriate workforce planning?</p> <p>GUIDANCE</p> <p>Arrangement should reflect national HSE workforce planning policies, strategies, etc.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Workforce planning policies etc. • Evidence of compliance with workforce planning arrangements <p>RESOURCES</p> <ul style="list-style-type: none"> • HSE workforce planning policies, strategies, etc.
2.	<p>Are arrangements in place to ensure appropriate recruitment, induction, and training and development for staff appropriate to their roles and responsibilities?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Relevant policies, procedures, etc. • Induction programmes • Training needs analysis reports • Training records

J.	<p>Staffing and staff management</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
3.	<p>Do the arrangements set out in questions 1 and 2 ensure compliance with related HSE and DOHC policy and guidance, professional and other codes of practice, and employment legislation?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check all relevant arrangement, i.e. policies, procedures, etc. <p>RESOURCES</p> <ul style="list-style-type: none"> • Relevant legislation • Relevant HSE and DOHC policies, codes, guidance, etc.
4.	<p>Are continuing learning and development programmes in place and aimed at meeting the development needs of staff and services?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check learning and development programme details • Training needs analysis • Development needs analysis
5.	<p>Are robust pre-employment checks carried out in line with national policy and the requirements set out in this framework?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Evidence of employment checks <p>RESOURCES</p> <ul style="list-style-type: none"> • Relevant national policies etc.
6.	<p>Are arrangements in place to identify and deal with poor professional performance?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Policy on identifying and dealing with poor professional performance. • Evidence of instances where poor performance has been identified and dealt with in accordance with relevant policy

K.	<p>Service improvement</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
1	<p>Are quality, safety and risk management goals clear, communicated effectively throughout the organisation and reflected in relevant service and business planning processes?</p> <p>GUIDANCE</p> <p>The HSE’s latest guidance on improving services (see below) contains a wealth of guidance relevant to this entire element of the Framework – see Resources, below.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Communication arrangements • Check actual communication • Check relevant service and business planning processes <p>RESOURCES</p> <ul style="list-style-type: none"> • <i>Improving Our Services – A User’s Guide to Managing Change in the Health Service Executive.</i> www.hse.ie/eng/Publications/Human_Resources/Improving_Our_Services.pdf
2	<p>Do local quality, safety and risk management plans take account of identified national priorities?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Check relevant plans
3	<p>Does the organisation participate in relevant external accreditation programmes?</p> <p>GUIDANCE</p> <p>A range of accreditation programmes exist, e.g. CPA, JCI, professional bodies’ own programmes, etc. Some are essentially mandatory (e.g. as in the case of certain laboratory accreditation programmes). Draw up a list of accreditation programmes that your organisation participates in.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Evidence of accreditation programme participation

K.	<p>Service improvement</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
4	<p>Do quality improvement activities utilise a range of quality improvement tools to assist with assessing and diagnosing issues, identifying remedies and measuring improvement?</p> <p>GUIDANCE</p> <p>There are many quality improvement tools available in healthcare that can assist with diagnosing issues, identifying remedies and measuring improvement.</p> <p>The Irish Health Services Accreditation Board standards for acute care, for example, lists the following tools for quality improvement:</p> <ul style="list-style-type: none"> • Performance measures, including clinical indicators and key performance indicators • Adverse event management • Culture and change management • Team Building • Integrated care pathways • Incident monitoring • Clinical audits • Flowcharts • Cause and effect diagrams • Brainstorming • Pareto charts • Histograms • Run charts • Control charts • Scattergrams <p>Other tools include failure mode and effects analysis (FMEA), lean techniques, Plan-Do-Check-Act (PDSA), theory of constraints and six sigma.</p> <p>Six sigma is a particularly powerful tool for measuring and monitoring quality improvement.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Look for evidence of use of a range of quality improvement tools in service improvement projects and in day to day quality improvement activity <p>RESOURCES</p> <ul style="list-style-type: none"> • Irish Health Services Accreditation Board. <u>Acute Care Accreditation Scheme – A Framework for Quality and Safety</u>. 2nd Edition. • Department of Health & Children (2008). <u>Building a Culture of Patient Safety</u>. Report of the Commission on Patient Safety and Quality Assurance. • The US Institute for Healthcare Improvement provides a range of free quality improvement tools at www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Tools/ • A compendium of information on six sigma in healthcare can be found at http://healthcare.isixsigma.com/spotlight/

L.	<p>Learning and sharing information</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
1	<p>Does the organisation routinely learn from patient experience?</p> <p>GUIDANCE</p> <p>Actively seeking patient's, and other service user's 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. A range of resources relating to patient experience are available for download from the Irish Society for Quality & Safety in Healthcare. See Resources section, below. What evidence exists that demonstrates that your organisation routinely learns from patient experience?</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Learning reports from patient survey information • Relevant policies • Risk register • Improvement action plans <p>RESOURCES</p> <ul style="list-style-type: none"> • Various patient satisfaction guidelines and reports from the Irish Society for Quality & Safety in Healthcare are available for download at www.isqsh.ie/docs/default.asp?mnu=8&wglD=&folder=Patient+Participation
2	<p>Does the organisation routinely learn from incidents occurring within the organisation and elsewhere?</p> <p>GUIDANCE</p> <p>Whilst it is unfortunate that incidents should occur in healthcare, particularly in instances where they result in harm to people, nevertheless it behooves organisations to 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 organisation, but also happens in relation to incidents occurring elsewhere – in another service provider in Ireland, for example, or in organisations in other countries. The 'benefits' of learning from incidents occurring elsewhere, of course, include the fact that it has not happened in your own organisation.</p> <p>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. The figure in the guidance associated with question E3 is a case in point.</p> <p>What evidence exists to show that your organisation routinely learns from incidents occurring within your own organisation, and elsewhere?</p> <p>EXAMPLES OF VERIFICATION</p>

L.	<p>Learning and sharing information</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<ul style="list-style-type: none"> • Incident investigation/analysis reports • Action plans resulting from incident review • Risk identification process • Risk register, detailing risks resulting from incident investigation/analysis/review <p>RESOURCES</p> <ul style="list-style-type: none"> • Latest HSE Corporate guidance on incident management (refer to relevant HSE contact) • Department of Health & Children (2008). <u>Building a Culture of Patient Safety</u>. Report of the Commission on Patient Safety and Quality Assurance
3	<p>Does the organisation regularly communicate to patients, staff and other relevant stakeholders improvements that have been made as a consequence from learning from patient experience and incidents?</p> <p>GUIDANCE</p> <p>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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Patient survey reports • Incident reports • Communications policy • Regular newsletters • Annual reports • Internal communication noticeboards
4	<p>Does the organisation share information and learning about serious incidents with other health providers and agencies?</p> <p>GUIDANCE</p> <p>When things go wrong it is important that information and learning is communicated with others. ‘Learning from elsewhere’ should be a key component of any organisation’s risk identification process.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Participation in national incident reporting schemes, e.g. CIS • Reports to HSE corporate • Reports to relevant agencies

L.	<p>Learning and sharing information</p> <p>NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
5	<p>Are arrangements in place for learning and for sharing information in relation to good practice in quality, safety and risk management?</p> <p>GUIDANCE</p> <p>Assuring the safety of patients, staff and visitors is a key priority within the HSE. This requires a collaborative approach to the analysis of quality and risk information so that the lessons learnt from this analysis are shared across the service area or organisation and across the HSE as a whole. It is essential that service providers develop a learning culture and that effective learning and sharing processes are developed to spread good practice and educate/inform others. The electronic self-assessment tool provides a means of capturing information on good practice that can be shared with other organisations and services.</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Seminars. • Briefings. • Workshops. • Education programmes. • Newsletters, journals, publications etc. • Presentation at National/International conferences • Electronic self-assessment tool (Quality, safety and risk management framework)

4. Outcomes

M.	Key Performance Indicators (KPIs) NB – Shaded number box indicates question requires possible aggregation across the organisation.
1.	<p>Have local KPIs been developed for quality, safety and risk management?</p> <p>GUIDANCE</p> <p>The following guidance is adapted from the Audit Commission in England – see Resources, below.</p> <p>A performance indicator (PI) is a clearly defined measurement of one aspect of performance. It literally provides an indication of how well you are performing a given activity. A <u>key</u> performance indicator is one that provides essential organisational level information on the performance of an activity for accountability and performance management purposes. Examples of local KPIs are given below.</p> <p>Performance information on quality, safety and risk management is not an end in itself. It may be used to:</p> <ol style="list-style-type: none"> 1. Measure progress towards achieving local or corporate quality, safety and risk management objectives and targets. 2. Promote the accountability of service providers to patients/service users, the public and other stakeholders. 3. Compare performance to identify opportunities for improvement. 4. Promote service improvement by publicising performance levels. <p>PIs come in all shapes and sizes. It is important that you select the key indicators that reflect your activities and management needs. Examples of PIs currently used, or proposed in Ireland include:</p> <ul style="list-style-type: none"> • % compliance with Quality, Safety and Risk Management Framework (from the electronic scoring tool) • Patient reported satisfaction (e.g. very satisfied, satisfied, somewhat satisfied, somewhat dissatisfied, dissatisfied, very dissatisfied) • Staff satisfaction (composite indicator – e.g. very satisfied, satisfied, somewhat satisfied, somewhat dissatisfied, dissatisfied, very dissatisfied) • Incident reporting rates (injury incidents; ill health incidents; near misses) • % of all reported injury incidents (excluding near misses) categorised as High risk/severity • Hospital Standardised Mortality ratio (HSMR) • ED waiting time (DTA to Admit) • Out-patient waiting lists • In-patient waiting lists (including Day cases) • Hospital Acquired Colonisation: MRSA • Average Length of Stay • Day case rate • Staffing levels • Financial position • Delayed discharges • Number of incidents reported which were escalated though the serious incident process • Number of reported incidents subjected to systems-based review • Number of staff who have received incident reporting/management training. • Presence of fully operational, up-to-date risk register in place in accordance with HSE

M.	<p>Key Performance Indicators (KPIs) NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
	<p>risk management guidance (Yes, No, Partial) by service/department</p> <ul style="list-style-type: none"> • Presence of fully operational, up-to-date risk register in place in accordance with HSE risk management guidance (Yes, No, Partial) by LHO • Presence of up-to-date safety statement, in accordance with requirements, in place (Yes, No, Partial) by service/dept. • Presence of up-to-date safety statement, in accordance with requirements, in place (Yes, No, Partial) by LHO. <p>For a comprehensive introduction to the specification and use of performance indicators, refer to the Audit Commission guidance document specified in the Resources section, below.</p> <p>Much can be learned from the work of the Government Agency for Research in Healthcare Quality (AHRQ) in the USA, who have published comprehensive indicator sets for healthcare quality and patient safety. Refer to the AHRQ indicators specified in the Resources section, below.</p> <p>It is likely that the HSE will specify a national KPI 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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Local performance indicator list or ‘dashboard’. • 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. <p>RESOURCES</p> <ul style="list-style-type: none"> • Audit Commission (UK - 15 June 2000). <u>On Target. The practice of performance indicators</u>. This is a highly recommended resource, which is freely downloadable from www.audit-commission.gov.uk (Search for ‘the practice of performance indicators’). • Agency for Healthcare Research and Quality (AHRQ, USA – March 2008). AHRQ Quality Indicators Version 3.2: Prevention quality indicators; Inpatient quality indicators; and patient safety indicators. www.qualityindicators.ahrq.gov/index.htm

M.	<p>Key Performance Indicators (KPIs) NB – Shaded number box indicates question requires possible aggregation across the organisation.</p>
2.	<p>Are the KPIs monitored as part of ongoing quality, safety and risk management improvement activities?</p> <p>GUIDANCE</p> <p>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 (acting as a ‘can-opener’).</p> <p>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Performance reports, clearly setting out KPI information • Evidence of consideration of reports by relevant committees and senior managers (e.g. see relevant minutes). • Evidence that, where necessary, action is taken by management in response to monitoring (e.g. see relevant minutes).
3.	<p>Do the KPIs demonstrate that there is ongoing improvement in quality, safety and risk management?</p> <p>GUIDANCE</p> <p>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>EXAMPLES OF VERIFICATION</p> <ul style="list-style-type: none"> • Performance reports, clearly setting out improvements in KPIs over time

5. Glossary of terms

The following glossary of terms is a sub-set of terms principally drawn, verbatim, from the HSE's *Quality and Risk Taxonomy Governance Group Draft Report, June 2008*. Each term is listed in alphabetical order and, for each term, a definition is provided and the source of the definition is referenced. The full report should be consulted for a full list of references. Note that there are some definitions in italics. These are taken from a previous draft version of this Framework Document.

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 organisation 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 organisation's operations. It helps an organisation 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 <i>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)</i>
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 <i>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 framework for action in and through the NHS, NHS Executive, January 1996)</i>

TERM	DEFINITIONS AND REFERENCES
<i>Clinical Guideline</i>	<i>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).</i>
Clinical Governance	A Framework through which organisations 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 authorised to have access (International Organisation for Standardisation, 2008a).
Continuous Quality Improvement (CQI)	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 organisation 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 organisation and/or person which can impact positively or negatively on the organisation and/or person (adapted Information Services NHS Scotland, 2004)
Corporate governance	Corporate governance is the system by which organisations 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 (Framework 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 organisation (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 organisation, service, programme, 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)
Framework	A framework is a set of components that provide the foundations and organisational arrangements for designing, implementing, monitoring, reviewing and continually improving (adapted International Organisation for Standardisation, 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 behaviour(s) by which organisations lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations (Department of Health, 2006)

TERM	DEFINITIONS AND REFERENCES
Guideline	A Guideline is a principle or criterion that guides or directs action (Concise Oxford Dictionary, 1995)
Harm	A detrimental impact on the organisation'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 organisation define and measure progress towards organisational 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 organisation 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 organisational 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)).

TERM	DEFINITIONS AND REFERENCES
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 Framework	Set of elements of an organisation'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 organisation to identify, assess, decide on responses to and report on opportunities and threats that affect the achievement of the organisation's objectives (Institute of Internal Auditors UK and Ireland, 2007).
Risk Register	A risk register is a management tool that enables an organisation 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, organisations 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 organisation 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).

6. Frequently Asked Questions

The following are a selection of key questions that have been asked relating to the Framework for Integrated Quality, Safety and Risk Management across HSE Service Providers.

What is the fundamental purpose of the Framework?

Fundamentally, the Framework exists ensure to:

1. there is an appropriate framework for quality, safety and risk management in place across all HSE service providers in health, personal social care to support and drive improvements in the provision of safe, effective, high quality services;
2. drive core programmes 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
3. 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, the CEO of the HSE and to the HSE Board.

Will the Framework be replaced by any standards for quality, safety and risk management that HIQA might issue?

The HSE is working with HIQA to ensure that the Framework will meet whatever requirements HIQA place on HSE service providers.

How does the Framework relate to the report by the Commission on Patient Safety and Quality Assurance - *Building a Culture of Patient Safety?*

The Framework has been mapped against the recommendations contained in the Commission report. We found that 70 of the 134 recommendation should be met by proper implementation of the Framework. The remaining recommendations are outside of the scope of the Framework (e.g. requiring legislation, etc.).

Why do some of the Framework questions seem a bit ‘wooly’? Can you not make them more specific?

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

Why are staff not represented along with patients and service users at the heart of the Framework diagram (the diagram containing concentric circles diagram showing patient/service user at the centre together with underpinning requirements, core processes and programmes and outcomes – see Figure 1 in the Framework Document)?

The Framework relates to the core purpose of the HSE’s existence, which is about helping patients and service users live healthier, more fulfilled lives. The HSE does take the issue of staff health, safety and wellbeing very seriously and this is reflected in the core processes and programmes aspect of the Framework.

How does risk registers related to the Framework?

Risk management and, in particular, use of risk registers is an important aspect and is described in the core processes and programmes component of the Framework. It should be borne in mind that any assessment made against the Framework can be considered as forming part of a risk identification exercise, and any weaknesses found can be considered as risks to the service provider and treated within their local risk management process as such.

Will additional resources be made available to implement the Framework?

There are unlikely to be additional resources made available. It is important that service providers use some of the techniques espoused by the Framework (e.g. risk management prioritisation methodologies) to ensure optimal deployment of existing resources to improve the safety and quality of services.