



*Litigation Authority*

# NHSLA Risk Management Standards 2013-14

for NHS Trusts providing  
Acute, Community, or Mental Health & Learning  
Disability Services  
and Non-NHS Providers of NHS Care



MANAGING RISK

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The format and layout of the NHSLA Risk Management Standards 2013-14 manual has been revised to make it simpler and easier to understand by all. The manual now includes more information than ever before about the assessment process and how to prepare. The introduction to the manual, and the appendices, include essential information and guidance about the assessment process, which is relevant to everyone participating in an assessment.

We would therefore encourage organisations to share the manual in its entirety with criterion leads rather than extracting sections which are believed to be of specific relevance. For those organisations wishing to extract information or to create action plans, this separate Word version has been made available. However, organisations are referred to the evidence template as the recognised working document for the purposes of self-assessment and assessment preparation.

For printing, and using the hyperlinks within the document, the PDF version of the standards, available on the NHSLA website, is recommended.

# Addendum 2013–14: Standards and Assessment Process

## Introduction

The NHS LA is changing its approach to the risk management standards and assessment process. From 1 April 2013 to 31 March 2014, the NHS LA will undertake a limited assessment programme.

During this time the NHS LA will continue to work with members to ensure that any revised process is focused on helping organisations reduce harm to patients and the number and cost of claims that they receive.

Feedback from a recent risk management survey conducted in 2012 was extremely valuable.

The headline findings are that although the NHS LA has a generally high level of satisfaction, there are opportunities for us to improve our approach to the standards and assessment process, in particular by:

- sharing more data and learning with members;
- ensuring that any standards we look at are focused on outcomes;
- minimising burden and duplication; and
- ensuring that any assessments are proportionate to the organisation's risk.

The frequently asked questions (FAQs) in the Addendum 2013-14 aim to address any queries in relation to the revised process. The addendum supersedes information about the standards and assessment process included in this manual, and the content within the individual criteria has not changed.

The limitations of the standards and assessments process have also been recognised. The assessment process checks for compliance against a set of standards that aim to drive improvements in processes and risk management systems. The existence of a risk management system, even one complying with the NHS LA standards, does not of itself mean that a trust is safe. There are lots of other factors that are relevant when considering safety. Although effective risk management processes are important, they are only one of the many things that should be considered when assessing whether practices are safe for staff and patients.

If you have any questions, please contact a member of the NHS LA Risk Management Team on 020 7811 2826 or [riskmanagement@nhsla.com](mailto:riskmanagement@nhsla.com).

Best wishes,

Catherine Dixon  
**Chief Executive**

Suzette Woodward  
**Director of Safety, Learning & People**

# 2013-14 Risk Management Standards and Assessments

## Frequently Asked Questions (FAQs)

### What are the plans for assessments?

Assessments will be undertaken in the following circumstances:

- where a trust wants an assessment;
- where a trust has failed an assessment in 2012-13 and dropped to Level 0; or
- for a trust for which we have significant concerns.

### What should we do if we want an assessment?

If your trust is due a mandatory assessment, DNV will be in touch with you to book a date.

If you wish to have an optional assessment, please notify DNV of your intention to be assessed by no later than 31 May 2013 by emailing [nhsla@dnv.com](mailto:nhsla@dnv.com).

### What about maternity services?

Because of the high risk nature of the service, maternity services due for an assessment will continue to be assessed at Levels 2 and 3 within the CNST maternity standards.

In the coming months the CNST maternity standards and assessments will be reviewed. This review will not impact on assessments due between 1 April 2013 and 31 March 2014.

### Why are you not undertaking assessments for maternity services at Level 1?

Nearly all maternity services have achieved Level 1, so it is recognition that most already have the documentation in place to manage clinical risks, whereas at Levels 2 and 3 we are more directly supporting better outcomes. Additionally, maternity services at Level 1 will have last been assessed only two years ago, whereas in most cases those at the higher levels will not have been assessed for three years.

### Will we still have our named assessor?

Our contract with DNV to provide risk management services has been extended for a year, but on a significantly reduced basis covering assessments that will be carried out in 2013-14.

As a result, the assessment team will be smaller, and this will mean a change of assessor for some trusts. All assessments will now be booked centrally and a named assessor will be allocated when assessment dates have been confirmed.

Named assessors will only be allocated to trusts being assessed in 2013-14.

### What will happen to informal visits?

If you are a trust going to be assessed, you will still be offered an informal visit. We do not plan to offer informal visits where a trust will not be assessed, as the primary purpose of an informal visit is to provide guidance in preparing for an assessment. If, however, you do require the support of an assessor, please email [nhsla@dnv.com](mailto:nhsla@dnv.com) and we can discuss your requirements.

## Should we continue to work towards meeting the standards even though they are changing?

Any activity you are currently doing in working towards achieving the requirements set out in the standards will not be wasted effort. They remain good practice and will ensure you are still contributing towards safer care.

## We are in the process of going through a merger or acquisition. What should we do?

A new approach has been agreed for dealing with risk management discount in these circumstances. Our commitment is that trusts will no longer be financially disadvantaged by losing a risk management discount.

In most cases the component parts of the new trust will retain their assessment level and discounts in proportion to their gross contributions.

### For example:

Trust A and B merge to form C. At the time the merger takes place:

- trust A is at Level 1 (10% discount) in the NHS LA standards and its gross contributions represent 40% of the new organisation; and
- trust B is at Level 2 (20% discount), with 60% of contributions.

Therefore, trust C will receive a discount of 10% on 40% of its contributions and 20% on the balance of 60%.

The new trust will be in the same financial position in respect of its net contributions paid to the schemes as if the organisational changes had not taken place.

This will apply until the NHS LA revised approach to standards and assessment has been agreed. If you have any additional queries, please email [riskmanagement@nhsla.com](mailto:riskmanagement@nhsla.com).

## What will happen to my contribution discount if I apply for assessment at a higher level and fail?

Under usual scheme rules, trusts and maternity services that fail to achieve compliance at the level assessed are required to be assessed in the following financial year at the level attained or a lower level.

Due to the changes the NHS LA is making to the standards and assessment process, this rule no longer applies. If a trust or maternity service fails an assessment in 2012-13 or 2013-14 it will not need to be re-assessed.

The exceptions to this rule are trusts or maternity services that fail to achieve compliance and drop to a Level 0 in which case an assessment at Level 1 will take place within six months of the unsuccessful assessment.

## What will happen to the contribution discount?

Any risk management discount which has been earned as at **1 April 2013** will continue to be applied until a new process has been agreed. If for any reason a trust drops to Level 0 the risk management discount to be applied will be reviewed by the NHS LA.

## **If we pass a Level 2 or 3 assessment before 1 April 2014 will the 2/3 year assessment period and discount hold, regardless of the new standards coming in?**

The NHS LA will ensure that any changes to the assessment process including periods of discount are transitioned appropriately and with due notice.

## **What will happen to assessment levels from 1 April 2014?**

The future of assessment levels is currently being reviewed. Once the revised approach has been agreed and subsequently tested, we will communicate with members to explain any changes.

## **What will the assessment process be like from April 2014?**

A number of options are being considered for the future. These will be tested to ensure they meet our aim of focusing on improving outcomes of care, reducing harm, reducing claims and costs associated with claims, together with ensuring a reduction in duplication and bureaucracy.

The aim is to test the revised process in the autumn, provide as much advance notice as we are able, and introduce the new approach from 1 April 2014.

## **Can we register to become a pilot site?**

We welcome interest from organisations willing to test our new approach. If you are interested, please contact [riskmanagement@nhsla.com](mailto:riskmanagement@nhsla.com). Please note that expressing an interest does not guarantee you to be chosen, nor does it commit you to participating in the testing phase when it has been decided.

## **I have a question – who should I contact?**

Please contact your named assessor or DNV as usual for all matters relating to an assessment, including an informal visit and queries about the standards and assessment process. Please direct all other risk management enquiries to the NHS LA Risk Management Team by emailing [riskmanagement@nhsla.com](mailto:riskmanagement@nhsla.com) or call 020 7811 2826.

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# 1. Contacts

If you have a query on the standards or assessment process, which is not covered by this manual, please contact your named assessor in the first instance. An up to date list of assessors and other contacts from the DNV and NHSLA teams can be obtained from [www.nhsla.com](http://www.nhsla.com) or from the DNV Healthcare Support Team.

## DNV Healthcare UK - Healthcare Support Team



**General Enquiries:** 0161 477 3818  
[nhsla@dnv.com](mailto:nhsla@dnv.com)

DNV Healthcare  
 Highbank House  
 Exchange Street  
 Stockport  
 Cheshire  
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**Website:** [www.dnv.com/healthcare](http://www.dnv.com/healthcare)

## NHSLA Risk Management



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## 2. Introduction

*This section provides you with background information on the NHS Litigation Authority (NHSLA) and the standards.*

### What is the NHSLA?

The NHS Litigation Authority (NHSLA) is a Special Health Authority that was set up in 1995. The NHSLA handles negligence claims made against NHS organisations and works to improve risk management practices in the NHS. It manages the:

- Clinical Negligence Scheme for Trusts (CNST);
- Liabilities to Third Parties Scheme (LTPS); and
- Property Expenses Scheme (PES).

All NHS organisations in England can apply to be members of these schemes. Members pay an annual contribution (premium) to the relevant schemes, which are similar to insurance.

At present, the NHSLA cannot cover non-NHS providers of NHS care directly under CNST, but can offer cover for their NHS work via a Primary Care Trust's membership in certain limited circumstances. Any enquiries should be directed to the [NHSLA Risk Management Team](#). This applies to independent sector providers, social enterprises and community interest companies. They can however opt into the assessment process and will be charged.

For more information on the NHSLA and the schemes please go to [www.nhsla.com](http://www.nhsla.com).

### What risk management standards have been developed?

The NHSLA has produced risk management standards for:

- NHS organisations providing acute, community or mental health & learning disability services; and
- non-NHS providers of NHS care.

The standards for these organisations are included within this manual.

Similar standards for ambulance trusts have also been produced which can be found in a separate manual.

All of these standards have been designed to address organisational, clinical, and non-clinical or health and safety risks.

All members of the NHSLA schemes that provide healthcare must be assessed against the relevant standards.

The NHSLA has also produced clinical (CNST) maternity standards and organisations providing maternity services are assessed against these too.

NHS organisations that demonstrate compliance with the standards at assessment receive a discount on their contributions to the NHSLA schemes. Non-NHS providers of NHS care are not eligible for discounts.

There are no NHSLA risk management standards for organisations that commission care.

### Why have the standards been developed?

The standards and assessment process are designed to:

- improve the safety of patients, staff and others;
- provide a framework within which to focus risk management activities in order to support the delivery of quality improvements in patient care, organisational governance, and the safety of patients;
- assist in the identification of risk;
- contribute to embedding risk management into the organisation's culture;
- focus organisations on increasing incident reporting whilst decreasing the overall severity of incidents;
- encourage awareness of and learning from claims;
- reflect risk exposure and enable organisations to determine how to manage their own risks;
- encourage and support organisations in taking a proactive approach to improvement; and
- provide information to the organisation, other inspecting bodies and stakeholders on how areas of risk covered by the standards are being managed at the time of the assessment.

The NHSLA is committed to supporting improvements in health services while minimising the disruption and duplication of inspection.

### Who develops the standards and conducts assessments on behalf of the NHSLA?

The NHSLA has a contract with Det Norske Veritas Ltd (DNV) to develop and maintain the risk management standards, conduct assessments, and provide education services.

DNV may do other work for organisations that are assessed against the NHSLA standards. A clause on managing conflicts of interest is included in the contract between the NHSLA and DNV. For more information on this please contact the [NHSLA Risk Management Director](#).

### How are the standards updated and reviewed?

The standards contained within this manual are updated on an annual basis. A revised version is published on the NHSLA website every January, and this is used for assessments from the following April to March.

With DNV, the NHSLA has set up two working groups to coordinate the maintenance of existing standards and, where necessary, the development of new standards. One group leads the maternity standards with the second leading all others. Clear terms of reference have been developed for each group detailing accountability and reporting arrangements, roles and responsibilities.

Each group is made up of assessors who have either a clinical background or interest in the specialist area. Individual standard leads have been appointed to each group, and they are responsible for advising on the technical aspects of the relevant standard. A member of the NHSLA Risk Management Team sits on each of the project groups and they are fully involved in the standards review process.

For each set of standards a project plan covering their on-going maintenance has been produced. These plans detail objectives, timescales and responsibilities.

Each set of standards is reviewed annually to ensure that they continue to meet their key objectives. The review process is continuous with an important aim being to ensure that the standards are published on time, which allows scheme members time to prepare for assessment.

Throughout the year the project groups and standard leads review national guidance, consult with stakeholders and review feedback on the standards and assessment process. Feedback from scheme members and the assessment team has the most significant impact on the standard review process. In addition assessment data is reviewed to identify trends.

## Stakeholder involvement in the review process

A wide range of NHS and other organisations, risk managers and healthcare professionals contributed to, and are consulted on, the development of these standards and the assessment process.

The NHSLA has set up two Risk Management Forums to provide advice on the future development of the risk management standards, assessment process and support available for organisations.

In addition, DNV has established regional forums to facilitate networking and sharing between organisations.

More information on the NHSLA and DNV forums is contained in [section 8](#).

All organisations that have an assessment are invited to complete a web based survey to provide feedback on the experience. Feedback from the survey is used to inform the development of the standards, assessment process and educational support.

The NHSLA would welcome your feedback on this manual. Please email [nhsla@dnv.com](mailto:nhsla@dnv.com) to tell us of known or suspected errors or omissions, suggestions for improvement, general comments or queries relating to any of the standards, criteria, or supporting information. Any resulting changes will be incorporated into the next version of the manual.

The NHSLA gratefully acknowledges the valuable input of all its stakeholders and scheme members.

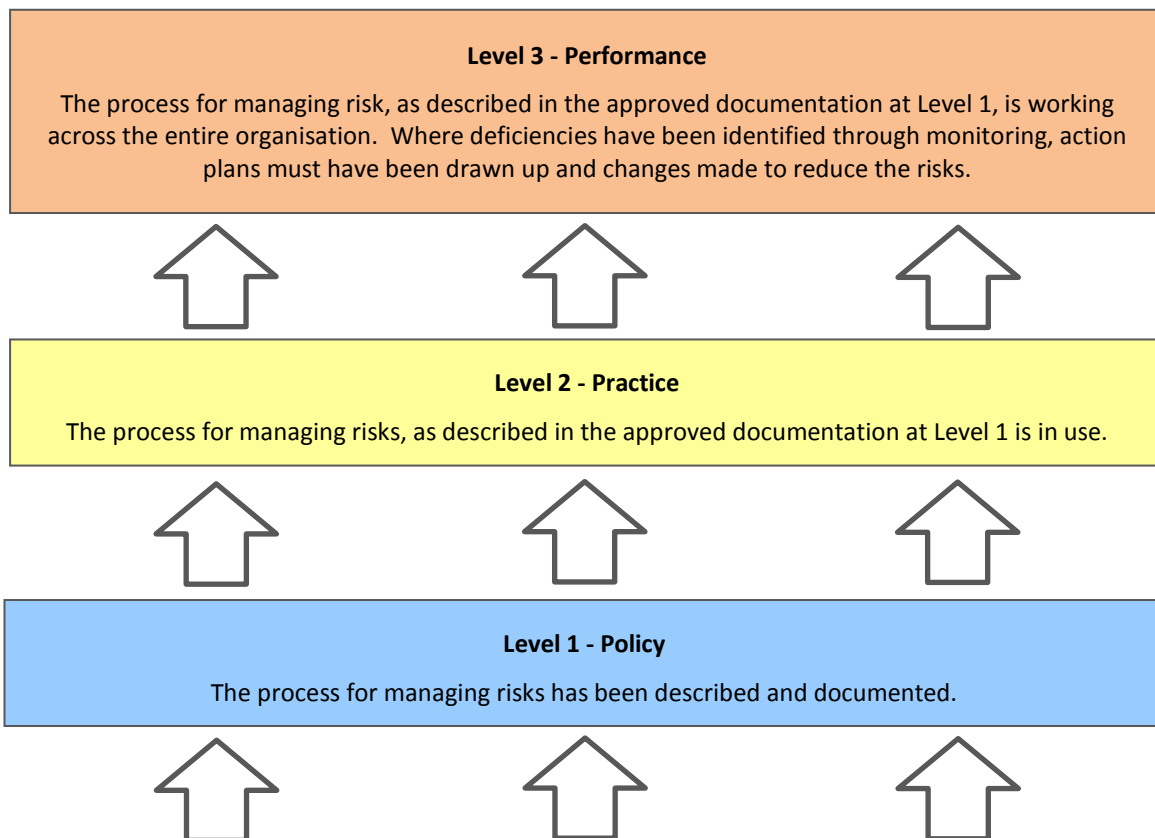
## 3. Assessment levels and dates

*This section guides you through the options available to you for selecting a date and level for your assessment. Assessment against the standards, in accordance with the principles included within this section, is a mandatory requirement of scheme membership for most organisations.*

### At what level should your organisation be assessed?

There are three assessment levels and these are explained below.

The progression of organisations through the standards is logical and follows the development, implementation, monitoring and review of policies and procedures.



The level at which your organisation can be assessed will depend upon:

- Whether your organisation is new or has undergone significant external restructuring.
- Whether your organisation has been assessed before, and if so whether it was successful at its chosen level.

## New organisations

All new organisations will be assessed at Level 1.

## Organisations that have undergone significant restructuring

Restructuring in the context of this manual involves more than one organisation (including mergers, acquisitions of services, etc.) and not internal restructuring. Organisations undergoing significant restructuring will be allocated an assessment level by the NHSLA immediately post event.

To assist the NHSLA in determining the level to be allocated and future arrangements for assessment, organisations undergoing restructuring are asked to write to the [NHSLA Risk Management Director](#), copying in their named assessor, and provide information on the scope and nature of the restructuring.

## Organisations that have been assessed before\*

If your organisation was successful at its last assessment then the following options apply:

- Level 1 organisations may be assessed at Level 1 or 2
- Level 2 organisations may be assessed at Levels 1, 2 or 3
- Level 3 organisations may be assessed at Levels 1, 2 or 3

If your organisation was unsuccessful at its last assessment then the following options apply:

- Level 0 organisations may only be assessed at Level 1
- Level 1 organisations may only be assessed at Level 1
- Level 2 organisations may be assessed at Levels 1 or 2

*\*These options apply to the level held by the organisation.*

### Points to note before deciding on an assessment level

- ✍ Organisations are strongly recommended to discuss the level at which they are planning to be assessed with their named assessor to determine the organisation's readiness for assessment.
- ✍ To make sure that systems are embedded and being implemented at Level 2 and monitored at Level 3, organisations are advised to wait at least 18 months before being assessed at the next level.
- ✍ Organisations that perform badly at assessment will drop to a lower level and can drop to Level 0.

## When should your organisation be assessed?

The timescales for when assessments should take place vary and these will depend upon:

- Whether your organisation is new or has undergone significant external restructuring.
- Whether your organisation has been assessed before, and if so whether it was successful at its chosen level.

### New organisations

In the first 12 months following establishment new organisations have the option of an assessment or informal visit. If an informal visit is chosen, a formal assessment must take place within 24 months of establishment and must include all services.

### Organisations that have undergone significant restructuring

Arrangements for the assessment of organisations that have undergone restructuring will be determined by the NHSLA based on the specific circumstances. Whenever an assessment is to take place, such organisations will normally be required to have an informal visit within the first six months of the restructuring.

### Non-NHS providers of NHS care

Non-NHS providers of NHS care must inform the NHSLA if they wish to opt in to the assessment cycle and be assessed during 2012/13.

Those non-NHS providers with an existing assessment level that will remain valid throughout 2012/13 need only inform the NHSLA if they wish to be assessed at a higher level.

As they are not members of the NHSLA schemes, non-NHS providers will be charged for an assessment. Please contact your named assessor or the DNV support team for details of the cost of an assessment and associated support.

Organisations wishing to be assessed must send an email to [nhsla@dnv.com](mailto:nhsla@dnv.com) as early as possible in the financial year.

### Organisations that have been assessed before

#### Mandatory assessments

These are assessments that the NHSLA has stated must take place. They normally take place when an organisation has dropped to Level 0 or when the NHSLA has concerns about an organisation.

- Your assessor will contact you to arrange an assessment date.
- If your organisation has dropped to Level 0, your assessment will normally take place within 6 months of your last unsuccessful assessment.

#### Due assessments

These are assessments which must be undertaken to ensure that your organisation's level and discount do not expire.

- Your assessment must take place before the anniversary of your last assessment. Please refer to your last assessment report for more information on your organisation's reassessment date.
- Level 2 and 3 assessments cannot take place in March.
- Your assessor will normally contact you around 10 months prior to your assessment anniversary to arrange a date. You may contact your assessor directly, but assessments cannot be booked more than 12 months in advance.

- Your assessment date and level must be agreed by 31 May of the financial year in which your organisation is due to be assessed.
- If your organisation is not assessed before its anniversary date it will drop to Level 0 and lose its discount.

### Early assessments

These are assessments that take place between due assessments. They normally take place when an organisation believes it is ready to be assessed at a higher level.

- You can ask for your assessment to take place in any month; however Level 2 and 3 assessments cannot take place in March.
- You should contact your assessor as early as possible to book an assessment date, but assessments cannot be booked more than 12 months in advance.

### Points to note before booking an assessment

- ✎ Organisations at Level 1 must be assessed against the standards at least once in any two year period.
- ✎ Organisations at Level 2 or 3 must be assessed against the standards at least once in any three year period.
- ✎ Organisations that fail an assessment must be assessed at the level attained or a lower level in the following financial year
- ✎ In most circumstances assessments may only be undertaken once in a financial year.
- ✎ Assessment against the standards is a requirement of scheme membership and refusal by an organisation to be assessed in line with the principles outlined within this manual may result in the organisation being deemed to be at Level 0 and may lead to a refusal by the NHSLA to provide indemnity.
- ✎ In exceptional circumstances, such as when there are concerns about performance, the NHSLA may visit or require organisations to be assessed outside the specified schedule.
- ✎ All requests for a change to a lower level assessment will be accepted, but must be notified to the assessor at least 20 working days before the assessment.
- ✎ Organisations wishing to change to an assessment at a higher level must put their request in writing to their assessor for consideration a minimum of three months prior to the assessment date.
- ✎ Assessors will do their best to carry out assessments at a time that is convenient for the organisation, but to improve the choice of dates you should discuss this with your named assessor as early as possible.
- ✎ If an organisation cancels an assessment visit without good reason and/or giving reasonable notice, the NHSLA reserves the right to recharge non-refundable accommodation and travel expenses incurred by the assessor(s).

## 4. Assessment principles

*This section guides you through the general principles that apply to all assessments.*

### Standard terms

Throughout the standards the term “organisation” includes the following:

- NHS organisations providing acute, community or mental health & learning disability services; and
- Non-NHS providers of NHS care including independent sector providers, community interest companies and social enterprises.

The term “patient” is used generically within the standards and refers to service users, clients and residents. Unless specified, the term includes all patient groups such as inpatients, outpatients, etc.

Within this manual you will find [Appendix G - Clarification of Terms](#), which defines the words and phrases used in this manual that have a specific meaning in the context of the standards. In the manual, these terms appear in blue and are underlined.

### Changes to the standards

On occasion, criteria may be removed from the standards. This may be due to:

- the risk being well controlled by scheme members;
- management of the risk area being looked at by other bodies; or
- the need to allow the inclusion of increasing or emergent areas of risk.

Where a criterion is removed from the standards the NHSLA would still expect an organisation to have in place appropriate systems to manage the relevant area(s) of risk.

When significant changes are made to an existing criterion, for example a new minimum requirement is added, the new minimum requirement(s) will be piloted for one year.



Pilot minimum requirements are clearly identified within the standards using this symbol.

Organisations will be encouraged to submit evidence for the pilot minimum requirement to ensure that it can be rigorously tested, but failure to submit evidence or submitting evidence that is non-compliant will not impact upon the outcome of the assessment. Where evidence is submitted the assessor(s) will review the information and comment on it in the assessment report.

Information on risk areas which may be piloted in future years, including the approach to piloting new criteria, and other possible changes to the standards and the assessment process is contained in [Appendix F - Overview of proposed changes to the standards](#).

The NHSLA may change the Level 1 requirements carried forward for assessment at Levels 2 and 3 either wholly or in part at any time in the future. These and other minor changes to individual criteria or minimum requirements will not be piloted.



## The standards your organisation will be assessed against

At each assessment level there are six standards and within each standard there are ten criteria which are equally weighted. An [overview](#) of the criteria can be found at the start of the detailed standards.

Each criterion has a title, which outlines the risk issue to be addressed, followed by a list of the minimum requirements that the assessor(s) would expect to see being met in order to award compliance with the criterion.

The minimum requirements at Level 1 which are carried forward to Levels 2 and 3 are highlighted in **bold**. Minimum requirements which are carried forward to higher levels but with a slightly different emphasis are highlighted in **bold italics**.

### Acute and community providers

Organisations providing acute services, community services, or a mix of acute and community services, will be assessed against Standards 1 to 5. The pass mark at each level is 40 out of 50 criteria with no fewer than seven criteria passed in any one standard. The level of compliance achieved will be determined in accordance with the [assessment scoring table](#).

### Mental health & learning disability providers

Organisations providing mental health & learning disability services only, will be assessed against Standards 1 to 4 and Standard 6. The pass mark at each level is 40 out of 50 criteria with no fewer than seven criteria passed in any one standard. The level of compliance achieved will be determined in accordance with the [assessment scoring table](#).

### Integrated providers

Organisations providing a mix of acute and mental health & learning disability services, or a mix of mental health & learning disability and community services, will be assessed against Standards 1 to 6.

Standards 1 to 4 will be assessed in full. In addition, ten criteria will be selected from Standards 5 and 6 and the organisation will also be assessed against these. The assessor will consult with the organisation over which criteria are most appropriate and select those that are to be assessed in advance of the assessment. The criteria selected will normally reflect the organisation's service and risk profile. It is recommended that the informal visit is used for this purpose.

The remaining ten criteria will not be formally assessed but organisations are advised to self-assess against them to assure themselves as to their level of compliance with the requirements.

The pass mark at each level is 40 out of 50 criteria with no fewer than seven criteria passed in each of Standards 1 to 4. For Standards 5 and 6 the organisation will need to pass seven out of the 10 pre-selected criteria. The level of compliance achieved will be determined in accordance with [assessment scoring table](#).

### All organisations

If your organisation feels that any of the standards or criteria are not applicable to the services provided, the reasons for this should be discussed and agreed with your named assessor prior to assessment.

## Assessment scoring table

Assessment Scoring Table											
		Lower Level			Existing Level			Higher Level			
Existing NHSLA Level		2	3	3	1	2	3	0	1	2	
Level Applied for		1	1	2	1	2	3	1	2	3	
Scoring Range	40 - 50	Outcome	Pass*	Pass*	Pass*	Pass*	Pass*	Pass*	Pass*	Pass*	Pass*
		Level achieved	1	1	2	1	2	3	1	2	3
		Time frame for reassessment	2yrs	2yrs	3yrs	2yrs	3yrs	3yrs	2yrs	3yrs	3yrs
		Level(s) organisation can next be assessed at	1 or 2	1 or 2	1, 2 or 3	1 or 2	1, 2 or 3	1, 2 or 3	1 or 2	1, 2 or 3	1, 2 or 3
	30 - 39	Outcome	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail
		Level achieved	0	0	1	0	1	2	0	1	2
		Time frame for reassessment	6 months	6 months	1yr	6 months	1yr	1yr	6 months	1yr	1yr
		Level(s) organisation can next be assessed at	1	1	1	1	1	1 or 2	1	1	1 or 2
	29 or less	Outcome	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail
		Level achieved	0	0	0	0	0	0	0	0	0
		Time frame for reassessment	6 months	6 months	6 months	6 months	6 months	6 months	6 months	6 months	6 months
		Level(s) organisation can next be assessed at	1	1	1	1	1	1	1	1	1

## Assessment requirements

### All levels

#### Services covered by the assessment

The assessment will cover the whole organisation and all services provided (unless otherwise agreed with the assessor prior to the assessment).

At all levels of assessment organisations should provide evidence for all settings (meaning directorates, divisions, departments, wards, offices, etc.), all staff groups and all patient groups. Where an organisation provides services across more than one site, evidence should be presented from all sites. The onus is on the organisation to highlight to the assessor(s) where the evidence has come from.

Whilst separate CNST standards exist for maternity services, organisations which provide maternity services need to demonstrate application of the relevant NHSLA standards in this manual to all services, including maternity.

#### Approved documents

At all levels, all of the criteria must have an approved document in place. These documents could include strategies, policies, guidelines, standard operating procedures or protocols. Evidence provided in support of a criterion must be in place and effective at the time of assessment and have been approved as per the organisation's policy on procedural documents. Draft documentation, or planned or proposed systems that have not been implemented, will not be admissible.

At all levels the evidence presented at assessment must be in use and reflective of day to day practice within the organisation. To test this, the assessor(s) will randomly select ten documents from the organisation's evidence portfolio and ask to see evidence of their approval. Additionally the assessor(s) will review the organisation's intranet and/or policy folders to ensure that the ten documents are readily available for use by staff. If the organisation is unable to evidence

that a document is approved and in use then it will fail the relevant criterion even if all the minimum requirements for this criterion have been met.

For example, an organisation meeting the requirements of criterion 3.1 – Corporate Induction – would fail that criterion if it were unable to evidence that the document which described the process for corporate induction was in use and available within the organisation.

### At each level

#### What evidence do you need to provide for a Level 1 assessment?

The Level 1 assessment requires all minimum requirements for each criterion to be described in the approved documentation. However, the quality of the processes described in the documentation will not be rigorously tested until the Level 2 assessment. It is important to note therefore that compliance at Level 1 should not be seen as an indication that the organisation will be able to demonstrate compliance at Level 2 or that it is effectively managing risks.

#### What evidence do you need to provide for a Level 2 assessment?

Assessors will need to see practical evidence of processes being implemented. This can be demonstrated through viewing health records, risk assessments, incident reports, meeting minutes, and training records that are used within the organisation. Audits and other monitoring tools can also be provided as evidence to supplement the evidence showing implementation but are not adequate evidence alone.

The assessors will need to see 12 months of evidence to award compliance for most criteria. The 12 month period must reflect one of the following:

1. the financial year immediately preceding the assessment;

2. the calendar year immediately preceding the assessment; or
3. 12 calendar months preceding the assessment.

If option 3 is chosen, the last month in the data collection period must be no later than 12 months before the assessment. For example if the organisation is being assessed in December 2012, the last month in the data collection period must not be before December 2011.

The organisation should indicate on the evidence template the data collection period being used.

The evidence presented must be reflective of the full data collection period, for example, in presenting evidence for a calendar year it would not be acceptable to present training records for September to December only. Failure to provide such evidence will result in the organisation being found non-compliant.

In circumstances where processes are new, evidence of previous processes may be acceptable. The organisation should discuss such instances with the assessors prior to the assessment.

For any of the Level 2 criteria, the assessors may ask to interview staff to seek clarification of the evidence reviewed and will also need to visit clinical and non-clinical areas to verify that systems are in place.

### **What evidence do you need to provide for a Level 3 assessment?**

Assessors will need to see evidence that the organisation has monitored their processes and be assured that the processes for managing the risks have been implemented.

Where deficiencies have been identified action plans must have been drawn up and changes made to reduce the risks.

For any of the Level 3 criteria, the assessors may ask to interview staff to seek clarification on the evidence reviewed and will also need to visit clinical and non-clinical areas to verify that systems are in place and working.

## **Outcome of the assessment**

In most cases the assessor(s) will inform the organisation of the assessment outcome at the end of the two day assessment.

In exceptional circumstances, extra time known as a clarification period may be allowed after the assessment visit to enable the organisation to provide additional evidence to demonstrate compliance. If this is the case, the assessor will discuss the arrangements with the organisation at the time of the assessment.

### **Organisations that attain Level 1, 2 or 3**

Organisations complying with the standards (other than non-NHS providers of NHS care) will receive a discount from both their CNST and RPST contributions. The discounts are:

Level 1	10% and valid for 24 months
Level 2	20% and valid for 36 months
Level 3	30% and valid for 36 months

Discounts will be applied from the beginning of the financial quarter following the date of the assessment.

If a clarification period is allowed, the discount will be applied from the beginning of the financial quarter following the date of the assessment.

Where an organisation drops to a lower level, the discount will be determined by the new level and be applied from the beginning of the following financial quarter.

For non-NHS providers of NHS care that exit the assessment cycle, their level will remain valid for the usual period from the date of their last assessment.

### **Organisations that drop to Level 0**

The aim of the NHSLA risk management standards and assessments is to improve the safety of NHS patients and staff. Therefore where an organisation is deemed to be at Level 0 following an assessment the approach taken will be to encourage, monitor and support the organisation as it works towards achieving Level 1 compliance.

Organisations that drop to Level 0 or do not attain Level 1 will be placed under improvement measures and must undertake a Level 1 assessment within six months of the date of their unsuccessful assessment. The NHSLA Risk Management Director will write to the organisation to explain the timescales and nature of the improvement measures. This would normally necessitate at least one informal visit, but more visits may be deemed necessary by the NHSLA. Organisations will be provided with an interim report which will be

shared with regulatory bodies such as the Care Quality Commission and, where relevant, Monitor, and with the local Strategic Health Authority cluster.

The date of the subsequent assessment will be determined by the NHSLA Risk Management Director but, assuming the organisation achieves Level 1 at the end of the improvement measures, this will normally be two years from the date of the failed assessment.

# 5. Preparation for assessment

*This section guides you through the steps we recommend you take when preparing for an assessment.*

## Preparing for an assessment

The recommended steps are summarised below and then covered in more detail later.

<b>A. Contact with the assessment team</b>	
1. Make sure the assessment team has up to date contact details for your organisation	<input type="checkbox"/>
2. Book an informal visit if you have not already done so – remember these must take place at least 3 months before assessment	<input type="checkbox"/>
3. Consider if additional support is required	<input type="checkbox"/>
4. Send risk management strategy to assessor (10 days before assessment)	<input type="checkbox"/>
<b>B. Plan the assessment</b>	
1. Pull together a team	<input type="checkbox"/>
2. Brief staff	<input type="checkbox"/>
3. Conduct a self-assessment	<input type="checkbox"/>
4. Review self-assessment results	<input type="checkbox"/>
5. Produce an action plan and complete actions	<input type="checkbox"/>
6. Consider whether you need to brief patients about the assessment	<input type="checkbox"/>
<b>C. Gather evidence</b>	
1. Gather evidence	<input type="checkbox"/>
2. Read the evidence template guidance document	<input type="checkbox"/>
3. Populate the evidence template	<input type="checkbox"/>
4. Check that the entire evidence template and all evidence can be transferred to a memory stick (refer to the evidence template guidelines for further details)	<input type="checkbox"/>

## A. Contact with the assessment team

DNV maintain a database with contact details for the person who will lead your organisation's assessment. If this person or their contact details change at any time, please contact [nhsia@dnv.com](mailto:nhsia@dnv.com) with up to date details. This is vital as any important announcements will be sent to this person.

We would recommend that you have an informal visit every year. The purpose of the visit is described further in [section 8](#), but in summary it will provide an excellent opportunity to meet with the assessor and determine how ready the organisation is for assessment.

Further advice and support is available and again this is outlined in [section 8](#).

Assessments at all levels consist of two consecutive days on site. When dates for the assessment have been agreed, your named assessor will write to you confirming the dates and setting out a proposed programme for the assessment.

Documentation will not be reviewed before the assessment visit, but you will need to email your organisation's risk management strategy to the assessor 10 working days prior to the assessment date. This will help the assessor(s) prepare for the assessment.

## B. Plan the assessment

### Pull together a team

Whilst responsibility for coordinating the assessment will normally rest with one person we would recommend that a team is identified and assigned with responsibility for assessment preparation.

Organisations that have performed well at assessment have assigned standard leads who are responsible for self-assessments, collating evidence and addressing any shortfalls.

### Brief staff

It is assumed that responsibility for the assessment will rest with the executive director responsible for risk management within the organisation. The executive director or delegated contact person should make sure that all staff involved are fully briefed on the purpose of the assessment, their specific role, and the role of the assessor(s).

### Self-assessment and action planning

In the year(s) between formal assessments, and in the lead up to an assessment, we would encourage all organisations to undertake a self-assessment against the standards using the appropriate level(s) on the evidence template. This template can be used to create action plans to assist the organisation in preparing for future assessments and/or informal visits.

It is recommended that action plans should be completed following each assessment and/or informal visit, and that these should include realistic timescales and designated responsibilities for taking the actions forward. When the action plan is ready the organisation may want to confirm the actions with their named assessor as these will be reviewed at subsequent assessments and may be requested by other bodies for their reviews. The action plan should therefore be kept up to date and readily available.

The organisation should carefully study the report from the last assessment which will detail areas requiring attention.

The standards are set out in full in this manual, and it is essential that in preparing for assessment you refer to these and the detailed minimum requirements. In addition, you are advised to consider the Level 2 and 3 requirements when addressing the Level 1 criteria, to ensure that the objectives the organisation sets itself at Level 1 are measurable and achievable.

## Brief patients

As part of the assessment process the assessors will need to look at some patient health records. Our assessors have been cleared to look at patient records as part of the assessment process (via Section 251 approval).

This approval is subject to certain conditions. One of the conditions is that the NHSLA should provide some text for organisations to include in their own patient information about how patient records and incident forms are used as part of the NHSLA assessment process. The following words are recommended:

“Use of patient information by the NHS Litigation Authority

The NHSLA has a statutory duty to manage and raise the standards of risk management throughout the NHS. In order to achieve this, all NHS trusts are assessed every few years against a set of risk management standards which are based on those factors which give rise to the greatest number and cost of claims. More information about the NHSLA risk management programme is available on its website at [www.nhsla.com/riskmanagement](http://www.nhsla.com/riskmanagement).

As part of the assessment process, the assessors will look at a number of patient health records and a selection of incident report forms. None of these documents will be removed from the premises. The aim is to ensure that these documents are created and managed in accordance with appropriate policies and procedures: for example whether they are written clearly, signed and dated, stored securely, etc. The assessors are not concerned with individual patient details. They are all professional people who have previously worked in NHS organisations and are now employed on behalf of the NHSLA under strict principles of confidentiality.

If you wish to object to your records being made available during an NHSLA assessment, please just notify the trust”.

## C. Gather evidence

To assist you in preparing for assessment, an evidence template has been produced which is in electronic Excel spreadsheet format. There is a single template workbook encompassing the three assessment levels. The template allows you to conduct self-assessments and is also used by the assessors to record scores and findings at assessment. Further guidance on the use of the template can be found on the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications).

Prior to assessment the evidence template must be completed. Please refer to [section 4](#) and [section 6](#) for more information on the different types of evidence that the assessors might look at.

Each of the three levels is a distinct assessment containing its own individual question sets and scored on a stand-alone basis. Although lower level(s) will not be reassessed as the organisation progresses, a completed evidence template and Level 1 documentation must be available on the assessment days irrespective of the level being assessed. This is to enable the assessor to check that the processes being implemented at Level 2 are those in the approved documentation, and at Level 3 that monitoring of the processes implemented also reflects the approved documentation.

The onus is on the organisation to demonstrate compliance with the risk management criteria and you must draw the assessor(s) attention to the evidence for each of the risk areas. The time available for the assessment will not permit the assessor(s) to search for evidence.

The location of relevant information column of the appropriate evidence template must be completed to alert the assessor(s) to where each of the minimum requirements can be found within the documents submitted.

If the evidence template has not been fully completed, and you are unable to signpost the assessor(s) to the relevant evidence within the time allowed, the assessor(s) may be unable to complete the assessment. This may result in the organisation being deemed



to be at Level 0 and may lead to a refusal by the NHSLA to provide indemnity.

Documentary evidence, where required, may be provided in electronic or paper format (or a combination of both).

Photocopies of health records or the presentation of sections of health records will not be acceptable.

The assessor(s) will not normally need to take paper copies of any evidence away from the site at the end of the assessment. If it is necessary to take copies (for instance, in the case of a borderline assessment), permission will be sought.

Electronic evidence is in many cases transferred to the assessor's laptop with the evidence template. If this is the case, in accordance with good information governance practices, the assessor will delete the evidence once the report has been published on the NHSLA website. Any evidence temporarily stored on assessors' laptops is subject to strict IT and data security protocols. If the organisation has any concerns about evidence being kept by the assessor it should raise these with the assessor in advance of the assessment.

## 6. Assessment process

*This section guides you through the on-site assessment process.*

### The assessment team

Assessors are employed by Det Norske Veritas (DNV) to provide risk management services on behalf of the NHSLA. Assessors will not visit an organisation where they have been employed by the organisation in the past five years or where there is any other apparent or suspected conflict of interest.

The DNV assessors work within regional pools and your organisation will have a named assessor from the relevant regional pool as your main point of contact. DNV will endeavour to have your assessment carried out by the named assessor but in some circumstances this may not be possible.

Your named assessor will:

- be your organisation's primary contact point;
- be responsible for conducting assessments and other visits;
- answer any queries about the standards and assessment process.

You will be notified if your named assessor changes.

Where assessments are carried out by more than one assessor, your named assessor will lead the assessment and make decisions on the outcome. The lead assessor is responsible for making all arrangements for the assessment and ensuring that it is completed within the specified time frames.

Responsibilities of the lead assessor include the following:

- acting as the spokesperson for the team on site;
- managing the assessment;
- encouraging communication among team members;
- evaluating team progress and coordinating meetings with team members and your staff as needed;
- coordinating any ongoing discussions with you and providing feedback, on the status of the assessment;
- facilitating opening and closing meetings; and
- coordinating and preparing the assessment report.

In most circumstances Level 1 assessments will be conducted by one assessor. All Level 2 and 3 assessments will be conducted by two or three assessors. The exact number of assessors will be determined by the size and complexity of your organisation.

As part of the ongoing development and quality assurance process of the assessment team, the assessor(s) may be accompanied by another assessor or manager, or a representative from the NHSLA or other relevant body. If this is proposed you will be notified in advance.

## Assessment team tasks

### Assessment team's off-site preparation

The assessment team will prepare for the assessment off-site by identifying and sharing information. This could include:

- previous NHSLA and CNST assessment reports;
- your organisation's claims history including any solicitors' risk management reports on claims; and
- reports on your organisation produced by external reviewing bodies such as the Care Quality Commission.

### Assessment team's arrival

The assessment team will normally enter your organisation together. Upon arrival, the assessors will meet with your organisation's delegated contact person. The assessment team will not delay the start of the assessment because this person or other staff are not available.

Your organisation's delegated contact person should be available at all times during the assessment to coordinate the process.

The assessment team will need an office to work in (with electrical power sockets for their laptops) which is large enough to interview staff. Please consider the requirements of the Health and Safety (Display Screen Equipment) Regulations 1992 and provide a suitable desk(s) or table(s) with adjustable chair(s). If the assessment team are unable to work safely in the office provided they may ask for alternative accommodation. If this cannot be found the assessment team may be unable to undertake the assessment.

On arrival the assessment team will need to transfer the organisation's evidence template folder to their laptops via a data stick. If there are likely to be any problems with this you should contact your assessor before the assessment.

### Opening meeting

The assessment team will hold a short opening meeting with your organisation. This meeting should be limited to a maximum of six representatives from the organisation (other than with the express permission of the assessor), which should ideally include an executive director.

The meeting will cover the following:

- An explanation of the purpose and scope of the assessment.
- An introduction to the assessment team, the general areas that each will be responsible for, and the various documents that they may request.
- Clarification of all areas and locations, departments, and patient care settings of your organisation that will be assessed.
- Information on the names, locations, and telephone numbers of key staff to whom questions should be addressed.
- The approximate time, location, and possible attendees of any meetings to be held during the assessment.
- Proposed times for meeting with senior staff from your organisation during day one and the closing meeting on day two.

### Meeting with risk manager or equivalent

Following the opening meeting the assessment team will meet with the organisation's risk manager or equivalent.

During this meeting the assessment team will review the following:

- The organisation's CQC profile – to confirm which sites the team will visit.
- The organisation's incident database – this will help to determine the organisation's risk profile and direct the assessment.
- A list of inpatients at the time of the assessment to allow a sample to be selected so that the assessor(s) can view open health records.

### Will the assessment team visit all sites?

For organisations with a number of in-patient hospitals the assessment team will visit at least two sites.

### The assessment

The objective of the assessment is to determine your organisation's compliance with the standards.

The outcome will be based on the evidence provided for review during the two day assessment period only, unless a clarification period is given.

### During the assessment

The assessment team will normally be accompanied by your organisation's staff as the assessment is conducted. However the team have discretion whether to allow, or refuse to allow, organisation staff to accompany them.

The assessment team will meet at least daily with senior staff to update them on:

- the status of the assessment;
- progress of completion of assigned activities;
- areas of concern; and
- to identify areas for additional investigations.

The meetings will include an update by each assessor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the assessment team and the organisation's staff will coordinate efforts to obtain additional information, if appropriate. Staff will have the opportunity to present additional information or to offer explanations concerning identified issues.

In instances where the evidence provided by you has not provided sufficient assurance, the assessment team may seek further documentary evidence. To enable the assessor(s) to determine an assessment

outcome, the organisation will be required to submit additional evidence well in advance of the closing meeting at the end of the assessment visit.

### What will be assessed?

#### Organisation's documentation

The assessors will review documentation at all assessment levels.

Documents reviewed by the assessment team during the assessment may be both paper and electronic and include:

- approved documents such as policies, procedure and guidelines;
- meeting minutes;
- patients' health records to validate information gained during interviews and review of approved documents;
  - assessors will use open patient health records rather than closed health records whenever possible;
- training records to determine if staff have completed the appropriate training;
- systems for checking pre-employment and registration requirements for staff; and
- maintenance and calibration records to determine if equipment is periodically checked and/or calibrated.

#### Health records

At Levels 2 and 3, the assessors will review a number of health records. A list of the criteria where this applies can be found in [Appendix D - Health record checks](#).

To ensure consistency in the assessment process, where health records are assessed, a sample size and minimum level of implementation have been set. In addition to the sample of records provided, assessors may select further health records to review at random.

The number of health records selected for review will typically be based on the

organisation's average daily inpatient admission rate. 10% of the average daily inpatient admission number is sufficient to determine compliance in most instances in a hospital with an average daily admission rate of 180 or more. For smaller hospitals the sample should not be fewer than 10 inpatient records, provided that the number of records is adequate to determine compliance with any given requirement.

Within the sample, the assessment team will select health records from across the clinical specialities. The sample size may be expanded as needed to assess the organisation's compliance with all applicable standards. It will not be possible for the assessors to view additional health records if the records selected are found to be non-compliant.

Whenever possible and appropriate, the assessment team will select records of patients who are in hospital during the time of the assessment (meaning open records). At no time should the review of health records compromise patient care in any way. There may be situations where closed records are needed to supplement the open records reviewed (for example too few open records available). Assessors will use their professional judgment in these situations.

### Training records

For some of the criteria the assessment team will review staff training records to determine the organisation's level of compliance. A list of the criteria where this applies can be found in the [Appendix A - Training Needs Analysis \(TNA\) Minimum Data Set](#).

### Observations

At Level 2 and 3, the assessment team will ask to visit areas of your organisation to review evidence in practice. Please note that at no time should the arrangements for the assessment compromise patient care in any way.

### Interviews

Interviews will take place at all assessment levels.

Interviews provide a method to collect information, and to check and confirm information obtained through review of documents and observations. Informal interviews will be conducted throughout the assessment. The assessors will use the information obtained from interviews to determine what additional observations, interviews, and document reviews are necessary.

When conducting interviews, the assessors will do the following:

- Interview staff to gather information about their knowledge of the organisation's approved documents and processes.
- Conduct telephone interviews if necessary, but the preference is for in-person interviews.
- Integrate the information from interviews with data gathered through observations and document reviews.

### Analysis of findings

Before the closing meeting, the assessment team will meet to review their findings. The objectives of this meeting are to integrate findings, review and analyse all information collected from observations, interviews, and documentation reviews, and to determine whether or not the organisation meets the requirements in the standards.

Decisions about any non-compliant criteria will be based on input from the assessment team members but the final decision shall always be the responsibility of the lead assessor.

### Closing meeting

A closing meeting is held at every assessment to enable the assessment team to present their findings. Normally the team will be able

to inform you of the outcome at the end of the assessment visit. On some occasions this may not be possible and it may be necessary for the assessment team to review their findings with colleagues to ensure consistency.

The lead assessor is responsible for the closing meeting and will determine who will present the findings.

The organisation should decide which staff will attend the closing meeting. This meeting should be limited to a maximum of six representatives from your organisation (other than with the express permission of the assessor), and should ideally include an executive director.

The identity of any individual patient or staff member will not be revealed in discussing assessment results.

The lead assessor will present the findings, highlighting areas of good performance in

relation to the standards and explaining why any findings have resulted in non-compliance.

It is DNV's policy to conduct a closing meeting at the conclusion of each assessment. However, there are some situations that justify refusal to continue or to conduct a closing meeting, for example, if your organisation creates an environment that is hostile or intimidating. Under such circumstances, the lead assessor will stop the closing meeting and call the DNV offices immediately for further direction.

Rare instances of inappropriate behaviour towards risk management assessors in performing their duties have made it necessary for DNV to introduce a *Procedure for Dealing with Abusive or Threatening Behaviour from External Sources*. A copy of this procedure can be obtained on request from [DNV](#).

# 7. After the assessment

*This section guides you through the post-assessment process.*

## Assessment report

Within 20 working days of the assessment date, or end of a clarification period if given, your organisation will receive a detailed report of the assessment outcome and a copy of the completed evidence template.

## Raising concerns

If you have any concerns about the assessment or report these should be raised with your named assessor or the [DNV Head of Resources](#) as soon as possible and no later than 20 working days after receipt of the report. Please note, however, that it will not be possible to make any additions to the report. If your concerns are not resolved or you feel that the assessment outcome is unjust, you may refer the matter to the NHSLA. An email or letter should be sent to the [NHSLA Risk Management Director](#) as soon as possible, and no later than 40 working days after receiving the assessment report.

Any allegations regarding the improper conduct of risk management assessments will be dealt with in accordance with the *NHSLA Complaints Policy*. A [leaflet](#) is available on the NHSLA website.

## Your feedback

DNV, as part of its commitment to the provision of a quality service to the NHSLA and its scheme members, aims to gather feedback on the services provided. All organisations that undergo assessment against the standards will be invited to complete a web based survey. Feedback from the survey will be used to inform the development of the standards and assessment process.

## Sharing your assessment results

The NHSLA will publish assessment results, on both an individual and aggregate basis, on its website at [www.nhsla.com](http://www.nhsla.com).

Assessment results can be found on Factsheet 4 which is updated monthly and provides details of the current levels achieved by organisations at assessment against the standards.

In addition, the NHSLA will also publish on its website the reports which are produced following assessments.

Further information about assessments may be disclosed under the Freedom of Information Act 2000.

Where the NHSLA has concerns about an organisation it will share them with regulators such as the Care Quality Commission and Monitor and with the local Strategic Health Authority cluster.

Additionally, the NHSLA may on occasion be invited to participate in meetings to review concerns that have been raised about organisations. These meetings are usually led by the Care Quality Commission and may involve a range of regulators, audit and risk management bodies working with the Strategic Health Authority cluster and other organisations to review plans and activity to:

- ensure the safety, quality and effective use of resources;
- target activity to be more effective and efficient; and
- jointly agree prospective, risk-based regulatory plans.

You may wish to publish information relating to your assessments on your own website. Such information might include assessment reports or minutes of meetings where assessments are discussed. The NHSLA

recognises this as good practice but would request that neither NHSLA nor DNV staff be named in such documents. In publishing assessment related information on your

website, you are reminded that you have a duty to ensure the accuracy of such information.



# 8. Support

*The NHSLA is committed to helping organisations achieve compliance with the standards. This section provides you with information on the support available.*

## General queries

The assessment team is always happy to answer questions by email or telephone on specific aspects of the standards. However, the assessors are unable to review in full documentation submitted to them outside of a formal assessment or informal visit. Prior to contacting your named assessor we would suggest that you review the support tools described below as you may find the answer in one of these.

It is always best to contact your named assessor, although other members of the DNV team will be able to provide some assistance. For example, any queries on the evidence template can be answered by the [DNV support team](#).

To make sure that the independence of the assessors is not compromised, and that all organisations are dealt with on a fair basis, general risk management advice cannot be given.

There is a contact list for the DNV and NHSLA risk management teams on the NHSLA website at [www.nhsla.com](http://www.nhsla.com).

## Advice within the standards

Within this manual you will find [Appendix G - Clarification of Terms](#), which defines the words and phrases used in this manual that have a specific meaning in the context of the standards. These terms appear in blue underlined text.

Every criterion within the standards includes references to documentation which provide the reasons for its inclusion within the standards. Documentation includes legislation, national guidance and

recommendations, and claims information and we would encourage all organisations to read these in their preparations for assessment.

The criteria also include links to template documents which are available for download at [www.nhsla.com/publications](http://www.nhsla.com/publications). These provide a framework within which to develop policies, procedures, etc. They support best practice, and include references to assist organisations in complying with the standards. Their use is entirely optional.

## Frequently asked questions

Frequently asked questions, which are updated quarterly, are available on the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications). These provide answers to common questions on the standards and assessment process.

## Informal visits

Informal visits are offered to all organisations to:

- provide advice and guidance on the standards;
- assist with preparations for assessment; and
- monitor progress against the organisation's action plan.

You may have one informal visit in each financial year, which may be booked at any time but cannot take place within the three months before an assessment. If you are due to be assessed between April and June you may have two informal visits during the previous financial year instead of one in the

year of assessment. Please contact either your named assessor or the support team to book a visit.

If an informal visit is cancelled without good reason and/or giving reasonable notice, the NHSLA reserves the right to recharge non-refundable accommodation and travel expenses incurred by the assessor(s).

To allow you to get the most benefit from the assessor's visit, we would ask you to develop an agenda for the day to include, as a minimum, time for the following:

- General update on the standards and assessment process - This will include an update on the manual, evidence template, template documents and frequently asked questions.
- Action plan - This may be from the previous NHSLA assessment, or alternatively the organisation may have completed its own action plan. This will form the basis for discussion and will be reviewed for progress and development.

Meetings with the organisation's leads on risk areas addressed by the NHSLA standards could also be arranged. These staff may have particular concerns regarding aspects of the standards and require advice on preparing for the next assessment.

It is also possible to ask for an education session from your assessor during the visit. The content of this should be agreed with the assessor before the visit. It will not be possible for the assessor to develop a custom made education session for the organisation. However the assessment team has a number of standard education packages which can be used and these can be discussed in further detail with the assessor.

## Networking

Networking and sharing between organisations is important. On request, your assessor may be able to provide you with information about organisations that have demonstrated clear and comprehensive

systems for achieving compliance with specific criteria.

The NHSLA has set up two Risk Forums to provide advice on the future development of the risk management standards, assessment process and educational support. One is for acute trusts and the other for community and mental health and learning disability trusts. Terms of reference and membership details, minutes of meetings, and information on how to apply to become a member, are available on the NHSLA website. Members of the forum have a responsibility to liaise with organisations within their Strategic Health Authority cluster in relation to the work of the forum.

DNV has established regional Network Forums to facilitate networking and sharing between organisations. For more information on this please contact [workshops@dnv.com](mailto:workshops@dnv.com).

## Education

The NHSLA provides an annual programme of education for scheme members. More information on this can be found at [www.nhsla.com/events](http://www.nhsla.com/events).

## Newsletter

*Risk E-News*, an NHSLA and DNV risk management newsletter, can be found on the NHSLA website at [www.nhsla.com](http://www.nhsla.com). This includes updates on the standards and important announcements.

## Support visits and training

For some organisations the annual informal visit is enough to help them maintain and move through the assessment levels. For others, further help is needed and for this reason, the NHSLA has agreed that organisations may purchase support visits from DNV.

Support visits are undertaken over a one day period and up to five visits per year can be requested per organisation. The visits are tailored to the specific needs of the

organisation and can cover topics such as how to:

- successfully monitor compliance;
- write policies; or
- prepare for assessment.

In addition, a mock assessment can be undertaken.

DNV also offer risk management training to NHSLA scheme members. This service assists in engaging relevant staff and spreading ownership of risk management through all levels of the organisation.

The training is flexible in its design. A two day training course is offered which combines information for staff who are new to the NHSLA standards with more in depth discussion for those who are familiar with the NHSLA and its risk management programme.

It is important to note that neither of these support packages guarantee success at assessment.

For further information about these support packages, please contact your assessor or email [nhsa@dnv.com](mailto:nhsa@dnv.com).

# 9. Detailed standards

**Standard 1: Governance**

**Standard 2: Learning from Experience**

**Standard 3: Competent & Capable Workforce**

**Standard 4: Safe Environment**

**Standard 5: Acute, Community and Non-NHS Providers**

**Standard 6: Mental Health & Learning Disability**

## Overview of risk areas

Standard ⇒	1	2	3	4	5	6
Criterion ↓	Governance	Learning from Experience	Competent & Capable Workforce	Safe Environment	Acute, Community and Non-NHS Providers	MH&LD
1	Risk Management Strategy	Clinical Audit	Corporate Induction	Secure Environment	Supervision of Medical Staff in Training	Clinical Supervision
2	Policy on Procedural Documents	Incident Reporting	Local Induction of Permanent Staff	Violence & Aggression	Patient Information & Consent	Patient Information
3	High Level Risk Committee(s)	Concerns & Complaints	Local Induction of Temporary Staff	Slips, Trips & Falls (Staff & Others)	Consent Training	Clinical Risk Assessment
4	Risk Management Process	Claims Management	Risk Management Training	Slips, Trips & Falls (Patients)	Maintenance of Medical Devices & Equipment	Physical Assessment & Examination of Patients
5	Risk Register	Investigations	Training Needs Analysis	Moving & Handling	Medical Devices Training	Observation & Engagement of Patients
6	Dealing with External Recommendations	Analysis & Improvement	Risk Awareness Training for Senior Management	Hand Hygiene Training	Screening Procedures	Dual Diagnosis
7	Health Records Management	Learning Lessons from Claims	Moving & Handling Training	Inoculation Incidents	Diagnostic Testing Procedures	Rapid Tranquilisation
8	Health Record-Keeping Standards	Best Practice - NICE	Harassment & Bullying	The Deteriorating Patient	Transfusion	Absent Without Leave (AWOL)
9	Professional Clinical Registration	Best Practice - National Confidential Enquiries & Inquiries	Supporting Staff Involved in an Incident, Complaint or Claim	Clinical Handover of Care	Venous Thromboembolism	Medicines Management Training
10	Employment Checks	Being Open	Stress	Discharge	Medicines Management	Medicines Management

**Changes to criteria numbers:** The criteria numbers from 2011-12 are mapped to the criteria numbers for 2012-13 listed at the beginning of each standard.

<b>Standard 1: Governance</b>	<b>2011-12 numbering</b>
<b>1.1 Risk Management Strategy</b>	<b>1.1</b>
<b>1.2 Policy on Procedural Documents</b>	<b>1.2</b>
<b>1.3 High Level Risk Committee(s)</b>	<b>1.3</b>
<b>1.4 Risk Management Process</b>	<b>1.5</b>
<b>1.5 Risk Register</b>	<b>1.6</b>
<b>1.6 Dealing with External Recommendations</b>	<b>1.7</b>
<b>1.7 Health Records Management</b>	<b>1.8</b>
<b>1.8 Health Record-Keeping Standards*</b>	<b>4.2</b>
<b>1.9 Professional Clinical Registration</b>	<b>1.9</b>
<b>1.10 Employment Checks</b>	<b>1.10</b>

\*Contains a training element

## 1.1 Risk Management Strategy

All organisations must have an approved risk management strategy.

### Level 1

Your documented process must include:

- a) the organisation's risk management structure, detailing all those committees and groups which have some responsibility for risk
- b) how the board or high level risk committee(s) review the organisation-wide risk register
- c) **how risk is managed [locally](#)**
- d) [duties](#) of the key individuals for risk management activities
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how risk is managed [locally](#).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how risk is managed [locally](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Implementation of risk management programmes can be viewed as a challenge for all managers. Success depends on effective leadership from the chief executive and senior management team. Critical to this process is the involvement of all support staff, clinicians, nursing, and allied healthcare professionals.

The overall aim of any risk management programme is to make the effective management of risk part of everyday practice. This can only be achieved if there is a comprehensive and cohesive risk management framework in place, underpinned by clear accountability arrangements across the organisation.

## Guidance

### Template document

A document checklist has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Department of Health (2002) *Assurance: The Board Agenda*
- Department of Health (2003) *Governing the NHS: A guide for NHS Boards*
- Department of Health (2006) *Integrated Governance Handbook. A handbook for executives and non-executives in healthcare organisations*
- Health and Safety Executive (HSE) (2010) *Leading Health and Safety at Work: Leadership Actions for Directors and Board Members*
- Monitor (2006) *NHS Foundation Trusts: Clinical Quality and Service Performance*
- Monitor (2006) *The NHS Foundation Trust Code of Governance*
- Monitor (2011) *Compliance Framework 2011-12*
- Steering Group on behalf of Dr Foster Intelligence (2006) *The Intelligent Board*
- Steering Group on behalf of Dr Foster Intelligence (2006) *The Intelligent Commissioning Board: Understanding the information needs of SHA and PCT boards*



## 1.2 Policy on Procedural Documents

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All organisations must have an approved documented process for developing organisation-wide procedural documents.

### Level 1

Your documented process must include:

- a) style and format
- b) an explanation of any terms used
- c) consultation process
- d) **ratification process**
- e) review arrangements
- f) **control, including archiving arrangements**
- g) associated documents
- h) supporting references
- i) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- the ratification process
- control of documents, including archiving arrangements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- the ratification process
- control of documents, including archiving arrangements.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

### Rationale

The development and ongoing management of procedural documents is important within any healthcare organisation. Making sure that daily practice is up to date in all areas, a standard approach to the development of documents will support the management of risk at all levels of the organisation.

The NHSLA solicitors risk management reports 2010-12 indicate that there can be differences between the process described in a policy or procedural document and what happens in practice, in both clinical and non-clinical areas, impacting on the level and cost of claims.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Legislation

- Human Rights Act 1998
- Health and Social Care Act 2001
- Equal Pay Act 1970 (Amendment) Regulations 2003
- Civil Partnership Act 2004
- Equality Act 2010
- Equality Act 2010 (Statutory Duties) Regulations 2011

The Equality and Human Rights Commission website provides further guidance, updates and resources in relation to equality impact assessments and the effect of the new legislation: [www.equalityhumanrights.com](http://www.equalityhumanrights.com)

#### Guidance from other organisations

- Department of Health, NHS Confederation and NHS Appointments Commission (2005)  
*Promoting equality and human rights in the NHS - a guide for non-executive directors of NHS boards*

## 1.3 High Level Risk Committee(s)

All organisations must have approved documented terms of reference for the high level committee(s) with overarching responsibility for risk.

### Level 1

Your terms of reference must include:

- a) [duties](#)
- b) who the members are, including nominated deputies where appropriate
- c) how often members must attend
- d) requirements for a quorum
- e) how often meetings take place
- f) **reporting arrangements into the high level risk committee(s)**
- g) **reporting arrangements into the board from the high level risk committee(s)**
- h) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of the terms of reference in relation to:

- reporting arrangements into the high level risk committee(s)
- reporting arrangements into the board from the high level risk committee(s).

### Level 3

You must evidence [monitoring](#) of the terms of reference in relation to:

- reporting arrangements into the high level risk committee(s)
- reporting arrangements into the board from the high level risk committee(s).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Committees with a responsibility for risk should work to approved terms of reference (TORs), which clearly describe areas of reporting and responsibility. This will provide a structure that is measurable at all levels of the organisation.

## Guidance

### Template document

A document checklist has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

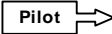
- Audit Commission (2009) *Taking it on Trust. A review of how NHS trusts and foundation trusts get their assurance*
- Department of Health (2006) *Integrated Governance Handbook. A handbook for executives and non-executives in healthcare organisations*
- Health and Safety Executive (HSE) (2010) *Leading Health and Safety at Work: Leadership Actions for Directors and Board Members*
- Vincent, Charles (ed.) (2001) *Clinical Risk Management: Enhancing Patient Safety (2nd edition)*

## 1.4 Risk Management Process

All organisations must have approved documentation which describes the organisation-wide systematic risk management process.

### Level 1

Your documented process must include:

- a) **how all risks are assessed**
- b) how risk assessments are conducted consistently
- c) authority levels for managing different levels of risk within the organisation
-  d) how risks are escalated through the organisation
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how all risks are assessed.

The assessor will select two risk categories, from those defined within the organisation's documentation, to assess compliance with this minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how all risks are assessed.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will select two risk categories, from those defined within the organisation's documentation, to assess compliance with this minimum requirement.

#### Rationale

All healthcare organisations should have systems for the continuous assessment of risk at all levels of the organisation. At corporate and directorate or business unit level, managers must aim to effectively manage risk appropriate to their level of authority. Continuous assessment can be used to question the effectiveness of organisational structure and processes, standards of conduct and control systems, including clinical governance and finance management.

## Guidance

### Template document

A document checklist has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Legislation

- Health and Safety at Work Act etc. 1974
- The Management of Health and Safety at Work Regulations SI 1999/3242

### Guidance from other organisations

- Audit Commission (2009) *Use of Resources Framework - Overall approach and key lines of enquiry*
- Department of Health (2002) *Assurance: The Board Agenda*
- Department of Health and NHS Appointments Commission (2003) *Governing the NHS: A guide for NHS Boards*
- Health and Safety Executive (HSE) (2010) *Leading Health and Safety at Work: Leadership Actions for Directors and Board Members*
- National Patient Safety Agency (2007) *Healthcare Risk Assessment made Easy*
- National Patient Safety Agency (2008) *A risk matrix for risk managers*
- National Patient Safety Agency (2009) *Seven Steps to Patient Safety in General Practice*

## 1.5 Risk Register

All organisations must have an approved organisation-wide risk register.

### Level 1

Your organisation-wide risk register must include:

- a) **source of the risk (including, but not limited to, incident reports, risk assessments, [local](#) risk registers, and external recommendations)**
- b) description of the risk
- c) risk score
- d) summary risk treatment plan
- e) date of review
- f) residual risk rating.

### Level 2

You must evidence that the organisation-wide risk register is populated with risks from the following sources:

- incident reports
- risk assessments
- [local](#) risk registers
- external recommendations.

The assessor will select two sources of risk, from the above list, to assess compliance with these minimum requirements.

### Level 3

You must evidence that the organisation-wide risk register is being monitored.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

A risk register keeps the organisation and senior management fully informed about the totality of the risk profile of the organisation. This will include dynamic risk management arrangements including unit level, directorate and the higher level organisation-wide risk registers.

## Guidance

### Template document

A document checklist has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Audit Commission (2009) *Taking it on Trust. A review of how NHS trusts and foundation trusts get their assurance*
- Audit Commission (2009) *Key Lines of Enquiry for Auditors: Local Evaluation Assessments*
- Department of Health and NHS Appointments Commission (2003) *Governing the NHS: A guide for NHS Boards*
- Department of Health (2002) *Assurance: The Board Agenda*
- Department of Health (2006) *Integrated Governance Handbook. A handbook for executives and non-executives in healthcare organisations*
- Health and Safety Executive (HSE) (2010) *Leading Health and Safety at Work: Leadership Actions for Directors and Board Members*
- Monitor (2006) *NHS Foundation Trusts: Clinical Quality and Service Performance*
- Monitor (2006) *The NHS Foundation Trust Code of Governance*
- Monitor (2011) *Compliance Framework 2011-12*
- Steering Group on behalf of Dr Foster Intelligence (2006) *The Intelligent Board*
- Steering Group on behalf of Dr Foster Intelligence (2006) *The Intelligent Commissioning Board: Understanding the information needs of SHA and PCT boards*



## 1.6 Dealing with External Recommendations Specific to the Organisation

All organisations must have an approved documented process for dealing with external recommendations specific to the organisation.

### Level 1

Your documented process must include:

- Pilot** → a) process for reviewing external recommendations specific to the organisation
- Pilot** → b) process for reporting on external recommendations specific to the organisation
- c) **how action plans are developed as a result of external recommendations**
- d) **how action plans are followed up**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how action plans are developed as a result of external recommendations
- how action plans are followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how action plans are developed as a result of external recommendations
- how action plans are followed up.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

All healthcare organisations are subject to recommendations following external agency visits, inspections, accreditations and inquest findings (Rule 43). They bring benefits to both the organisation and the review bodies, with increased organisational learning that supports patient and staff safety.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Audit Commission (2009) *Key Lines of Enquiry for Auditors: Local Evaluation Assessments*
- Care Quality Commission (CQC) (2011) *The state of health care and adult social care in England: An overview of key themes in care in 2010/11*
- Health and Safety Commission (HSC) (2004) *A Strategy for workplace health and safety in Great Britain to 2010 and beyond*
- Ministry of Justice (2008) *Guidance for coroners on changes to Rule 43: Coroner reports to prevent future deaths*
- Monitor (2010) *Code of Governance for NHS Foundation Trusts*

## 1.7 Health Records Management

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All organisations must have an approved documented process for managing the risks associated with paper and electronic health records.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) legal obligations that apply to records
- c) how a new record is created
- d) **how health records are [tracked](#) when in current use**
- e) how health records are retrieved from storage
- f) process for retention, [disposal](#) and [destruction](#) of records
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how health records are [tracked](#) when in current use.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how health records are [tracked](#) when in current use.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

## Rationale

All healthcare organisations are legally accountable for the processes, including information governance, that support health records management. Working to the *NHS Records Management: Code of Practice (2006)* will meet the requirements set out under the Data Protection Act 1998 and the Freedom of Information Act 2000.

The NHSLA solicitors risk management reports 2010-12 indicate that health record management can impact on the admission process for patients where previous medical history is documented, due to retrieval out of hours and tracking system failures.

## Guidance

### Legislation

- Access to Health Records Act 1990
- Access to Medical Reports Act 1988
- Data Protection Act 1998
- Freedom of Information Act 2000

### Guidance from other organisations

- Care Quality Commission (CQC) (2009) *The right information, in the right place, at the right time: A study of how healthcare organisations manage personal data*
- Department of Health website provides further information on health records management: [www.dh.gov.uk](http://www.dh.gov.uk)
  - *An Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS (2000)*
  - *Confidentiality: NHS Code of Practice (2003)*
  - *Records Management: NHS Code of Practice Part 1 and 2 (2006 and 2009)*
  - *NHS Information Governance: Guidance on Legal and Professional Obligations (2007)*
  - *Information Security Management: NHS Code of practice (2007)*
  - *A Question of Balance: Independent Assurance of Information Governance Returns. Summary of Guidance (2010)*
- Information Governance Toolkit website is an online system which allows NHS organisations and partners to assess themselves against Department of Health Information Governance policies and standards: [www.igt.connectingforhealth.nhs.uk](http://www.igt.connectingforhealth.nhs.uk)
- Nursing and Midwifery Council (2009) *Record Keeping: Guidance for Nurses and Midwives*

## 1.8 Health Record-Keeping Standards

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All organisations must have an approved documented process for health record-keeping.

### Level 1

Your documented process must include:

- a) [basic record-keeping standards](#), which must be used by all [staff](#)
- b) process for making sure a contemporaneous record of care is completed
- c) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- d) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- [basic record-keeping standards](#), which must be used by all [staff](#).

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- [basic record-keeping standards](#), which must be used by all [staff](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### Rationale

This criterion applies to any paper or electronic-based record which contains information or personal data pertaining to a person's care.

Good record-keeping is integral and essential to the provision of safe and effective care. Records that promote communication support healthcare staff to make effective clinical judgements and decisions, resulting in high quality care for patients. Standards should define good practice and address the requirements for a comprehensive, accurate, clear health record, free from unauthorised abbreviations. Poor record-keeping has a detrimental impact on patient care and increases the risk of harm when making decisions.

The quality of record-keeping has a significant impact on claims due to the failure of healthcare staff to keep accurate records of care or information provided to patients, and also due to the logistics of locating records to inform healthcare professionals at future care episodes and in the process of claims handling.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- Department of Health (2010) *Essence of Care. Benchmarking for Record Keeping*
- Nursing and Midwifery Council (NMC) (2009) *Record Keeping: Guidance for nurses and midwives*
- Royal College of Physicians (2008) *A Clinician's Guide to Record Standards Part 1: Why standardise the structure and content of medical records?*
- Royal College of Physicians (2008) *A Clinician's Guide to Record Standards - Part 2: Standards for the structure and content of medical records and communications when patients are admitted to hospital*
- Royal College of Physicians (2009) *Generic Medical Record Keeping Standards*

## 1.9 Professional Clinical Registration

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All organisations must have an approved documented process for making sure that all clinical staff are registered with the appropriate professional body.

### Level 1

Your documented process must include:

- a) [duties](#), both on initial appointment and on an ongoing basis
- b) ***how the organisation checks registration with the relevant professional body, in accordance with their recommendations, for all directly employed clinical [staff](#), both on initial appointment and on an ongoing basis***
- c) **how the organisation makes sure that registration checks are being carried out by all external agencies (such as NHS Professionals, recruitment agencies, etc.) used by the organisation in respect of all clinical [staff](#)**
- d) how the organisation follows up those directly employed clinical [staff](#) who do not satisfy the validation of registration process
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation checks registration with the relevant professional body, in accordance with their recommendations, for all directly employed clinical [staff](#).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation checks registration with the relevant professional body, in accordance with their recommendations, for all directly employed clinical [staff](#) both on initial appointment and on an ongoing basis
- how the organisation makes sure that registration checks are being carried out by all external agencies (such as NHS Professionals, recruitment agencies, etc.) used by the organisation in respect of all clinical [staff](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

**Rationale**

The professional regulation of all clinical staff is intended to protect the public, making sure that those who practice a health profession are doing so safely and working within their professional code of practice. All healthcare employers must check the registration of health professionals with the relevant regulatory body.

**Guidance****Guidance from other organisations**

- NHS Employers (2010) *NHS Employment Check Standards: Professional registration and qualification checks*



## 1.10 Employment Checks

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All organisations must have an approved documented process for making sure that all relevant employment checks are undertaken for all staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **types of check required**
- c) how checks are made
- d) how the organisation follows up those [staff](#) who do not satisfy the checking arrangements
- e) how the organisation makes sure that checks are being carried out by all external agencies (such as NHS Professionals, recruitment agencies, etc.) used by the organisation in respect of all [staff](#)
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- types of check required.

The assessor will select two elements of the [Employment Checks Minimum Data Set](#) at random to assess compliance with this minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- types of check required.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will select two elements of the [Employment Checks Minimum Data Set](#) at random to assess compliance with this minimum requirement.

### **Rationale**

The pre-employment checks undertaken by all healthcare organisations should be an integral part of the recruitment process. Robust checks support the organisation and the public.

Where the responsibility for pre-employment checks is undertaken by a third party, the employers must satisfy themselves that the required checks are being carried out to the same required standards.

The NHSLA solicitors risk management reports 2010-12 indicate that the failure to complete employment checks in line with the national requirements has been identified as a causal factor in a small minority of claims.

### **Guidance**

#### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### **Guidance from other organisations**

- Buying Solutions Health website offers further information on the use of temporary staff at: [www.buyingsolutions.gov.uk](http://www.buyingsolutions.gov.uk)
- Criminal Record Bureau website offers further information on criminal record checks at: [www.crb.gov.uk](http://www.crb.gov.uk)
- Health Professionals Council (2009) *Standards of Education & Training*
- NHS Employers website provides the full list of employment checks: [www.nhsemployers.org](http://www.nhsemployers.org)

<b>Standard 2: Learning from Experience</b>	<b>2011-12 numbering</b>
<b>2.1 Clinical Audit</b>	<b>5.1</b>
<b>2.2 Incident Reporting</b>	<b>5.2</b>
<b>2.3 Concerns &amp; Complaints</b>	<b>5.3</b>
<b>2.4 Claims Management</b>	<b>5.4</b>
<b>2.5 Investigations*</b>	<b>5.5</b>
<b>2.6 Analysis &amp; Improvement</b>	<b>5.6 and 5.7</b>
<b>2.7 Learning Lessons from Claims</b>	<b>NEW</b>
<b>2.8 Best Practice - NICE</b>	<b>5.8</b>
<b>2.9 Best Practice - National Confidential Enquiries &amp; Inquiries</b>	<b>5.9</b>
<b>2.10 Being Open</b>	<b>5.10</b>

\*Contains a training element

## 2.1 Clinical Audit

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All organisations must have an approved documented process for making sure that all clinical audits are undertaken, completed and reported on in a systematic manner.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation sets priorities for [audit](#), including local and national requirements
- c) **requirement that audits are conducted in line with the [approved](#) process for audit**
- d) how audit reports are shared
- e) format for all [audit](#) reports, including methodology, conclusions, action plans, etc.
- f) **how the organisation makes improvements**
- g) how the organisation [monitors](#) action plans and carries out re-audits
- h) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- requirement that audits are conducted in line with the [approved](#) process for audit
- how the organisation makes improvements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- requirement that audits are conducted in line with the [approved](#) process for audit
- how the organisation makes improvements.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

### Rationale

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Where indicated, changes are made at an individual team or service level and further monitoring is used to confirm improvement in healthcare delivery. Clinical audit is the quantitative assessment of the quality (principally the effectiveness) of care being provided compared with either agreed, documented, evidence-based criteria or the performance of other providers or commissioners. Its aim is both to stimulate quality improvement interventions and to assess their impact.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- Darzi, Professor the Lord (2008) *High Quality Care For All: NHS Next Stage Review Final Report*
- Department of Health (2006) *Good Doctors, Safer Patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. A report by the Chief Medical Officer*
- Healthcare Quality Improvement Partnership (HQIP) (2010) *Clinical Audit: A Simple Guide for NHS Boards and Partners*
- Healthcare Quality Improvement Partnership (HQIP) (2011) *New Principles for Best Practice in Clinical Audit*
- NHS Clinical Governance Support Team (2005) *A Practical Handbook for Clinical Audit. NHS Clinical Governance Team*

## 2.2 Incident Reporting

All organisations must have an approved documented process for internal and external reporting of all incidents and near misses.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how all incidents and near misses involving [staff](#), patients and others are reported**
- c) **how the organisation reports incidents to external agencies**
- d) how [staff](#) can raise concerns, for example, whistle blowing, open disclosure, etc.
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how all incidents and near misses involving [staff](#), patients and others are reported
- how the organisation reports to external agencies.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how all incidents and near misses involving [staff](#), patients and others are reported
- how the organisation reports to external agencies.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Incident reporting provides an opportunity for adverse events to be documented, analysed and used for learning and improvements in practice. Incident reporting is a key requirement for NHS organisations in efforts to improve patient safety, oversee performance and assure patients, staff and the public that systems for managing risk are robust and effective.

## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

- Department of Health (2006) *Safety First: A report for patients, clinicians and healthcare managers*
- General Medical Council (GMC) (2008) *Raising concerns about patient safety: Guidance for doctors*
- Health and Safety Executive (HSE) (2011) *Reporting injuries, diseases and dangerous occurrences in health and social care: Guidance for employers*
- National Patient Safety Agency (NPSA) (2009) *National Reporting and Learning Service (NRLS) Data Quality Standards: Guidance for Organisations Reporting to the Reporting and Learning System (RLS)*

## 2.3 Concerns & Complaints

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All organisations must have an approved documented process for listening, responding and improving when patients, their relatives and carers raise concerns and complaints.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation listens and responds to [concerns and complaints](#) from patients, their relatives and carers**
- c) how [joint complaints](#) are handled between organisations
- d) how the organisation makes sure that patients, their relatives and carers are not treated differently as a result of raising a [concern](#) or [complaint](#)
- e) **how the organisation makes improvements as a result of a [concern](#) or [complaint](#)**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation listens and responds to [concerns and complaints](#) from patients, their relatives and carers
- how the organisation makes improvements as a result of a [concern](#) or [complaint](#).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation listens and responds to [concerns and complaints](#) from patients, their relatives and carers
- how the organisation makes improvements as a result of a [concern](#) or [complaint](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.



### Rationale

Everyone has the right to expect a good service from public bodies and to have things put right if they go wrong. When things do go wrong, public bodies should manage concerns and complaints appropriately. Good complaint handling matters as an important way of ensuring that patients receive the service they are entitled to expect. Complaints are a valuable source of feedback for the public body; they provide an audit trail and an early warning of failures in service delivery. When handled well, complaints provide an opportunity for public bodies to improve their service and reputation. There is often a balance between responding appropriately to complaints and acting proportionately within available resources. However, prompt and efficient complaint handling can save the public body time and money by preventing a complaint from escalating unnecessarily. Learning from complaints can reduce the number of complaints in the future.

Parliamentary and Health Service Ombudsman (2009) *Principles of Good Complaint Handling*

### Guidance

#### Guidance from other organisations

- Department of Health (2009) *Listening, Responding, Improving – A guide to better customer care*
- Department of Health (2009) *Tackling Concerns Locally*
- National Audit Office (2008) *Feeding back? Learning from complaints handling in health and social care*
- Parliamentary and Health Service Ombudsman (2009) *Principles for Remedy*
- Parliamentary and Health Service Ombudsman (2009) *Principles of Good Complaint Handling*

## 2.4 Claims Management

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All organisations must have an approved documented process for managing all claims in accordance with NHSLA requirements.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) NHSLA schemes relevant to the organisation (CNST, LTPS and PES)
- c) **action to be taken, including timescales**
- d) **how the organisation communicates with relevant stakeholders, such as [staff](#), claimants, NHSLA, solicitors, HM Coroner, etc.**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- action to be taken, including timescales
- how the organisation communicates with relevant stakeholders, such as [staff](#), claimants, NHSLA, solicitors, HM Coroner, etc.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- action to be taken, including timescales
- how the organisation communicates with relevant stakeholders, such as [staff](#), claimants, NHSLA, solicitors, HM Coroner, etc.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

### Rationale

In complex, modern healthcare things can and do go wrong and unintentional harm can result in consequences that could be very serious for the patient, their family and carers. The individual who has suffered harm as a result of the healthcare they have received must get an apology, a clear explanation of what went wrong, treatment and care, and where appropriate, financial compensation. The NHS must also ensure that such bad experiences of individuals are learned from so that future NHS patients throughout the country benefit from reduced risks and safer care. The primary aim must be to reduce the number of medical errors that occur, preventing harm, reducing risks and enhancing safety. This must include a co-ordinated response to harm and injury: investigation, support, remedial treatment and care where needed; fair recompense and a system of redress that is affordable and reasonably predictable in the way it operates. The system for providing redress acts as an incentive for healthcare organisations and their staff to improve quality of care and patient safety.

Department of Health (2003) *Making Amends*

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- Department of Health (2003) *Making Amends*
- Department of Health (2005) *NHS Redress: Improving the response to patients*
- Department of Health (2005) *NHS Redress: Statement of Policy*
- Ministry of Justice (1998) *Pre-action Protocols for the Resolution of Clinical Disputes*
- Ministry of Justice (2009) *Civil Procedure Rules*

## 2.5 Investigations

All organisations must have an approved documented process for investigating all incidents, complaints and claims to enable learning.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- c) **different levels of investigation appropriate to the severity of the event**
- d) how the organisation shares safety lessons with internal and external stakeholders
- e) **how action plans are followed up**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- different levels of investigation appropriate to the severity of the event
- how action plans are followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- different levels of investigation appropriate to the severity of the event
- how action plans are followed up.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Organisations need to learn from adverse incidents, complaints and claims in order to improve safety. Organisations should make use of root cause analysis techniques to ensure there is a systematic investigation process that looks beyond the individuals concerned to discover underlying causes. Organisations should value the importance of identifying and learning from the causes of incidents, complaints and claims and implementation of solutions to prevent recurrence.

## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

- Department of Health (2004) *Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm: A protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive*
- National Patient Safety Agency (NPSA) (2008) *Root Cause Analysis Investigation Tools: A guide to aggregated and multi-incident RCA investigations*
- National Patient Safety Agency (NPSA) (2008) *Root Cause Analysis (RCA) Investigation Tools: Guide to investigation report writing following root cause analysis of patient safety incidents*
- National Patient Safety Agency (NPSA) (2009) *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*

## 2.6 Analysis & Improvement

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All organisations must have an approved documented process for the analysis of incidents, complaints and claims to enable learning and improvement.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how incidents, complaints and claims are analysed
- c) how this information is combined to provide a risk profile for the organisation
- d) **a report template which includes qualitative and quantitative analysis**
- e) how this information will be shared with relevant individuals or groups
- f) **how action plans are followed up**
- g) timescales for minimum requirements b) to f)
- h) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- reports, including qualitative and quantitative analysis
- how action plans are followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- reports, including qualitative and quantitative analysis
- how action plans are followed up.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

### Rationale

Assuring the safety of patients, staff and visitors should be a key priority within any healthcare organisation. This requires a collaborative approach to the analysis of incidents, complaints and claims and ensuring that lessons learned from this analysis are shared across the organisation as well as across the local health community. The reactive analysis of aggregated data can provide an opportunity for proactive risk management, learning from what has happened and implementing controls to prevent recurrence. Many serious events have occurred because organisations have ignored the warning signs of incidents, complaints or claims and failed to learn from the lessons of the past. Organisations need systematic processes in place that clearly determine when, how and by whom learning should be cascaded and acted upon. In most organisations the process for learning should use local and corporate risk registers, a grading matrix and managers' authority to treat risk. Organisations should develop ways to determine and share learning points and make improvements across the organisation and local health community.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhs.uk/publications](http://www.nhs.uk/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- Department of Health: National Quality Board (2010) *Review of early warning systems in the NHS*
- Dr Foster Intelligence (2010) *The Intelligent Board 2010: Patient Experience*
- Health Foundation (2010) *Snapshot Patient Safety: Transforming organisational approaches to deliver safer patient care*
- House of Commons (2009) *House of Commons Health Committee: Patient Safety: Sixth Report of Session 2008-09, Volume I*
- National Patient Safety Agency (NPSA) (2004) *Seven Steps to Patient Safety*
- National Patient Safety Agency (NPSA) (2010) *Never Events: Framework – Update for 2010/11: Process and action for Primary Care Trusts; Update for 2011: Never Events List*
- National Patient Safety Agency (NPSA) and NHS Confederation (2008) *Briefing 161: Act on reporting*
- National Patient Safety Agency (NPSA) and NHS Confederation (2009) *Questions are the answer! Seven questions every board member should ask about patient safety*
- Patient Safety First (2009) *The 'How to Guide' for Implementing Human Factors in Healthcare*

## 2.7 Learning Lessons from Claims

All organisations must evidence that action has been taken to learn lessons from claims.\*

\*With particular reference to the issues contained in the NHSLA Solicitors' Risk Management Reports on Claims where these have been received.

### Levels 1 - 3

You must evidence that action has been taken to improve safety in response to incidents giving rise to clinical negligence (CNST) claims. Where Solicitors' Risk Management Reports on Claims have been prepared, you must demonstrate that the risk issues identified have been considered and action taken (if any). If action has not been taken, the reasons why and how this decision was made must be clearly documented.

### Method of assessment

The assessor will select three Solicitors' Risk Management Reports on Claims to assess compliance with this criterion. Where fewer or no reports have been prepared, the assessment will be based on other CNST claims notified to the NHSLA. If fewer than three claims have been notified to the NHSLA, the assessment will be based on learning from Serious Untoward Incidents.

#### Rationale

NHS organisations have a responsibility to learn from their own incidents, complaints and claims in order to improve the safety of patients and staff and to reduce the number and severity of claims. As the body with responsibility for managing negligence claims made against NHS organisations, the NHSLA has a particular interest in making sure that organisations have systems and processes in place to learn lessons from claims. The Solicitors' Risk Management Reports on Claims will be used as a basis for assessing how well the organisation is learning these lessons.

#### Guidance

NHSLA (Feb 2010) *Letter to Organisations on Solicitors' Risk Management Reports on Claims*  
Available at: [www.nhsla.com](http://www.nhsla.com)



## 2.8 Best Practice - NICE

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All organisations must have an approved documented process for taking into account agreed best practice as defined in NICE clinical guidelines.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation identifies which NICE guidelines are relevant to its services
- c) **how a gap analysis is conducted to identify shortfalls**
- d) **how action plans are created to address any shortfalls, including recording decisions not to implement NICE guidelines**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how a gap analysis is conducted to identify shortfalls
- how action plans are created to address any shortfalls, including recording decisions not to implement NICE guidelines.

The assessor will select two guidelines from the [NICE Guidelines Minimum Data Set](#) to assess compliance with these minimum requirements.

Guidance specific support tools are available on the NICE website at [www.nice.org.uk/usingguidance](http://www.nice.org.uk/usingguidance).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how a gap analysis is conducted to identify shortfalls
- how action plans are created to address any shortfalls, including recording decisions not to implement NICE guidelines.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

Guidance specific support tools are available on the NICE website at [www.nice.org.uk/usingguidance](http://www.nice.org.uk/usingguidance).

## Rationale

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. They also provide guidance to help local authorities and other public organisations ensure services offered in each area improve the health and wellbeing of the local community. All NHS organisations in England and Wales are expected to take into account this guidance; this means wherever patients live they should get the same high quality care. NICE do not produce guidance on every health topic but are asked by the Department of Health to look at areas where there is confusion or uncertainty among healthcare professionals about the value of a drug, device or treatment. NICE also look at ways to promote and encourage good health in areas where there isn't already clear, nationally-agreed guidance. NICE quality standards, which are based on the best available guidance and evidence, can be used by commissioners and others to improve the standards of care.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Department of Health: National Quality Board (2010) *NICE Quality Standards*
- National Institute for Health and Clinical Excellence (NICE) (2004) *Legal Context of NICE guidance*
- National Institute for Health and Clinical Excellence (NICE) (2007) *How to change practice*
- National Institute for Health and Clinical Excellence (NICE) (2010) *How to put NICE guidance into practice: A guide to implementation for organisations*

## 2.9 Best Practice - National Confidential Enquiries & Inquiries

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All organisations must have an approved documented process for taking into account agreed best practice, as defined in National Confidential Enquiries and Inquiries, in the context of the clinical services provided by the organisation.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation responds to requests for data
- c) how the organisation identifies which National Confidential Enquiry/Inquiry recommendations are relevant to its services
- d) **how a gap analysis is conducted to identify shortfalls**
- e) **how action plans are developed to address any shortfalls, including recording decisions not to implement National Confidential Enquiry/Inquiry recommendations**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how a gap analysis is conducted to identify shortfalls
- how action plans are developed to address any shortfalls, including recording decisions not to implement National Confidential Enquiry/Inquiry recommendations.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how a gap analysis is conducted to identify shortfalls
- how action plans are developed to address any shortfalls, including recording decisions not to implement National Confidential Enquiry/Inquiry recommendations.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

## Rationale

National Confidential Enquiries and Inquiries are designed to help assess quality of healthcare and stimulate improvement in safety and effectiveness by systematically enabling clinicians, managers and policy makers to learn from adverse events and other relevant data. Organisations that learn from their incidents, complaints and claims learn about their own particular weaknesses and failings. Organisations that consider the guidance and recommendations of National Confidential Enquiries and Inquiries discover the weaknesses and failings of other organisations, and thereby learn lessons. Such organisations can undertake a gap analysis and ensure that measures are put into place to prevent the incidents experienced by others occurring within their organisation.

## Guidance

### Guidance from other organisations

- Reports from the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCI/NCISH) – University of Manchester are available at: [www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)
- Reports from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) are available at: [www.ncepod.org.uk](http://www.ncepod.org.uk)
- Reports from the Child Health Reviews Programme - Royal College of Paediatric and Child Health (RCPCH), (formerly led by the Centre for Maternal and Child Enquiries (CMACE)) are available at: [www.hqip.org.uk](http://www.hqip.org.uk)
- Reports from Maternal, Infant and Perinatal Programme (formerly Maternal and Newborn Programme, led by the Centre for Maternal and Child Enquiries (CMACE)) are available at: [www.hqip.org.uk](http://www.hqip.org.uk)

## 2.10 Being Open

**All organisations must have an approved documented process for open and honest communication following an incident, complaint or claim.**

### Level 1

Your documented process must include:

- a) how communication between healthcare organisations, healthcare teams, [staff](#), patients, their relatives and carers is encouraged
- b) **how [staff](#) acknowledge, apologise and explain when things go wrong**
- c) requirements for truthfulness, timeliness and clarity of communication
- d) how additional support is provided
- e) **how all communication is recorded**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how [staff](#) acknowledge, apologise and explain when things go wrong
- how all communication is recorded.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how [staff](#) acknowledge, apologise and explain when things go wrong
- how all communication is recorded.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Communicating honestly and sympathetically with patients and their families when things go wrong is a vital component in dealing effectively with errors or mistakes in their care. It is both natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives and to express sorrow or regret at the outcome. Such expressions of regret would not normally constitute an admission of liability. In being open, NHS organisations can mitigate the trauma suffered by patients and potentially reduce complaints and claims.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- National Health Service Litigation Authority (NHSLA) (2009 [2007]) *Apologies and Explanations*
- National Patient Safety Agency (NPSA) (2004) 'Incident decision tree' *Online tool*
- National Patient Safety Agency (NPSA) (2009) *Being open: Saying sorry when things go wrong*
- National Patient Safety Agency (NPSA) (2009) *Patient Safety Alert. Being open: Communicating with patients, their families and carers following a patient safety incident*
- Nursing & Midwifery Council (NMC) (2010 [2008]) *The Code: Standards of conduct, performance and ethics for nurses and midwives*
- National Patient Safety Agency (NPSA) (2010) *Medical Error: What to do if things go wrong: A guide for junior doctors*
- Royal College of Surgeons of England (RCS) (2010) *Openness and Transparency in Surgery*

## Standard 3: Competent & Capable Workforce

2011-12 numbering

<b>3.1 Corporate Induction*</b>	<b>2.1</b>
<b>3.2 Local Induction of Permanent Staff*</b>	<b>2.2</b>
<b>3.3 Local Induction of Temporary Staff*</b>	<b>2.3</b>
<b>3.4 Risk Management Training*</b>	<b>2.5</b>
<b>3.5 Training Needs Analysis*</b>	<b>2.6</b>
<b>3.6 Risk Awareness Training for Senior Management*</b>	<b>1.4</b>
<b>3.7 Moving &amp; Handling Training*</b>	<b>2.9</b>
<b>3.8 Harassment &amp; Bullying*</b>	<b>3.7</b>
<b>3.9 Supporting Staff Involved in an Incident, Complaint or Claim</b>	<b>3.9</b>
<b>3.10 Stress</b>	<b>3.10</b>

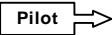
\*Contains a training element

## 3.1 Corporate Induction

All organisations must have an approved documented corporate induction process for all new permanent staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) minimum content of corporate induction
- c) process for booking all new [permanent staff](#) onto corporate induction
-  d) timescales for completion of corporate induction
- e) **how the organisation records that all new [permanent staff](#) complete corporate induction**
- f) **how the organisation follows up those who do not complete corporate induction**
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all new [permanent staff](#) complete corporate induction
- how the organisation follows up those who do not complete corporate induction.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all new [permanent staff](#) complete corporate induction
- how the organisation follows up those who do not complete corporate induction.

Where the [monitoring](#) has identified less than 95% completion of induction, you must evidence that changes have been made to address this.

#### Rationale

The purpose of a corporate induction is to ensure that all employees are given the key information they require that will help them to integrate into their role within the organisation quickly and effectively. Through the induction process, employees should have all of their necessary initial orientation, safety, training and information needs addressed.



## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

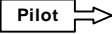
- Department of Health (2004) *Introduction to Today's NHS: NHS Corporate Induction Programme*
- Department of Health (2007) *Mental Health Policy Implementation Guide: A Learning and Development Toolkit for the whole of the mental health workforce across both health and social care*
- NHS Employers (2008) *Staff Induction Packs* (Available on request from: [www.nhsemployers.org](http://www.nhsemployers.org))
- NHS Employers and Department of Health (2004) *Guidelines for NHS Employers: Induction Programmes for Consultants and GPs Recruited From Abroad*

## 3.2 Local Induction of Permanent Staff

All organisations must have an approved documented local induction process for all new permanent staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) minimum content of [local](#) induction
-  c) timescales for completion of [local](#) induction
- d) **how the organisation records that all new [permanent staff](#) complete [local](#) induction**
- e) **how the organisation follows up those who do not complete [local](#) induction**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all new [permanent staff](#) complete [local](#) induction
- how the organisation follows up those who do not complete [local](#) induction.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all new [permanent staff](#) complete [local](#) induction
- how the organisation follows up those who do not complete [local](#) induction.

Where the [monitoring](#) has identified less than 95% completion of induction, you must evidence that changes have been made to address this.

#### Rationale

Local induction is an essential feature of starting a job in a new organisation at any grade. There may be different policies and procedures in place within the organisation, and a lack of understanding of how things work locally may lead to mistakes and omissions. Organisations should therefore have a comprehensive induction process to make sure staff are orientated to the organisation and confident and competent to undertake their role.

## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

- Department of Health and H.M. Prison Service (2003) *Prison Health Induction Framework*
- Department of Health (2003) *Good Medical Practice for Doctors providing Primary Care Services in Prisons*
- Department of Health (2004) *Introduction to Today's NHS: NHS Corporate Induction Programme*
- Department of Health (2007) *Mental Health Policy Implementation Guide: A Learning and Development Toolkit for the whole of the mental health workforce across both health and social care*
- NHS Employers (2008) *Staff Induction Packs* (Available at on request from [www.nhsemployers.org](http://www.nhsemployers.org))
- NHS Employers and Department of Health (2004) *Guidelines for NHS Employers: Induction Programmes for Consultants and GPs Recruited From Abroad*

### 3.3 Local Induction of Temporary Staff

All organisations must have an approved documented local induction process for all temporary staff.

#### Level 1

Your documented process must include:

- a) [duties](#)
- b) minimum content of [local](#) induction
- c) timescales for completion of [local](#) induction
- d) **how the organisation records that all [temporary staff](#) complete [local](#) induction**
- e) **how the organisation follows up those who do not complete [local](#) induction**
- f) how the organisation [monitors](#) compliance with all of the above.

Pilot

#### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all [temporary staff](#) complete [local](#) induction
- how the organisation follows up those who do not complete [local](#) induction.

#### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all [temporary staff](#) complete [local](#) induction
- how the organisation follows up those who do not complete [local](#) induction.

Where the [monitoring](#) has identified less than 95% completion of induction, you must evidence that changes have been made to address this.

#### Rationale

Local induction is important for temporary staff as it acts as a vital guide to ensure that staff are appropriately orientated to the area they are working within. This should involve explaining the policies and practices of the organisation, clarifying any queries or potential problems and setting 'boundaries' or 'ground rules' to encourage them to work to a set of principles. Any lack of understanding of how things work locally may lead to mistakes or omissions and it is the responsibility of the organisation to ensure that temporary staff are confident and competent to undertake their role.

### **Guidance**

#### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### **Guidance from other organisations**

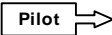
- NHS Executive (1997) *Code of Practice in the Appointment and Employment of HCHS Locum Doctors*

## 3.4 Risk Management Training

All organisations must have an approved documented risk management training process for all permanent staff.

### Level 1

Your documented process must include:

- a) process for developing a [training needs analysis](#), which must include all those topics referred to in the [TNA Minimum Data Set](#)
- b) how action plans are developed to deliver the training identified within the [training needs analysis](#)
- c) how an annual training prospectus is developed which reflects the [training needs analysis](#)
- d) how the organisation records that all [permanent staff](#) complete relevant training, in line with the [training needs analysis](#)
- e) how the organisation follows up those who do not complete relevant training programmes
-  f) action to be taken in the event of persistent non-attendance
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete relevant training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete relevant training programmes.

The assessor will randomly select two elements of risk management training from the [TNA Minimum Data Set](#) to assess the organisation's compliance with the above minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete relevant training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete relevant training programmes.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

The assessor will randomly select two elements of risk management training from the [TNA Minimum Data Set](#) to assess the organisation's compliance with the above minimum requirements.

### Rationale

The overall aim of this criterion is to ensure organisations have a systematic approach to ensuring that all staff receive relevant and timely risk management education. Training and development helps an employee to achieve the organisational goals as well as their individual goals. Training is also an essential control measure when managing risks associated with the provision of healthcare. A lack of training can be a contributory factor in incidents, therefore if staff have been trained appropriately to undertake their duties the risks of an error or omission occurring can be reduced.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- Boorman, Dr S (2009) *NHS Health and Well-Being Review – Final Report*
- Boorman, Dr S (2009) *NHS Health and Well-Being Review – Interim Report*
- Chartered Institute for Professional Development (CIPD) (2008) 'What's new from CIPD research?' *CIPD website page*
- Chartered Institute of Personnel and Development (CIPD) (2003) *Focus on the learner: The Change Agenda*
- Department of Health (2000) *An Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS*
- McNamara. C (1997) 'Systematic Approaches to Training and Development' *Free management library website* (Available at: [www.managementhelp.org](http://www.managementhelp.org))
- NHS Employers (2010) 'Health and safety essential guide' *NHS Employers website pages*
- Sloman. M (2005) *Change Agenda: Training to Learning* (Available at: [www.cipd.co.uk](http://www.cipd.co.uk))
- Trulove. S (2006) *Training in Practice*

## 3.5 Training Needs Analysis

All organisations must have a documented training needs analysis to identify the risk management training requirements for all permanent staff.

### Level 1

The [training needs analysis](#) for all [permanent staff](#) must include:

- a) a list of topics defined as risk management training by the organisation, which must include all those topics referred to in the [TNA Minimum Data Set](#)
- b) which [staff groups](#) are required to attend each type of training
- c) frequency of updates required for each type of training.

### Level 2

You must evidence the provision of the risk management training for all [permanent staff](#) by:

- producing an annual training prospectus which reflects the [training needs analysis](#).

### Level 3

You must evidence [monitoring](#) of the risk management [training needs analysis](#) for all [permanent staff](#) by:

- producing an annual training report covering all the topics identified within the [TNA Minimum Data Set](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Training is a learning process that involves the acquisition of knowledge, enhancement of skills, and sometimes a changing of attitudes and behaviour leading to improved practice. There are many approaches that organisations may take to the analysis of training needs. The aim should be to objectively identify the training needs of all staff groups and the frequency of attendance. This will enable the organisation to build a plan to deliver essential training opportunities. A lack of training can be a contributory factor in incidents, therefore the organisation must ensure that staff have been trained appropriately to undertake their duties to reduce the risks of an error or omission occurring.



## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Legislation

- Health and Safety at Work etc. Act 1974

### Guidance from other organisations

- Boorman, Dr S (2009) *NHS Health and Well-Being Review – Final Report*
- Boorman, Dr S (2009) *NHS Health and Well-Being Review – Interim Report*
- Department of Health (2000) *An Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS*
- Elaine Sauvé Associates for the Department of Health (2005) *An Education and training Framework for Staff providing Healthcare in Prisons* (Available at: [www.dh.gov.uk](http://www.dh.gov.uk))
- Health Professions Council (2004) *Standards of Education and Training*
- Health Professions Council (2009) *Your duties as an education provider: Standards of education and training*
- NHS Employers (2010) 'Health and safety essential guide' *NHS Employers website pages*

## 3.6 Risk Awareness Training for Senior Management

All organisations must have an approved documented process for delivering risk management awareness training to all board members and senior managers.

### Level 1

Your documented process must include:

- a) **how risk management awareness training is delivered to board members and senior managers, in line with the [training needs analysis](#)**
- b) how attendance is recorded
- c) **how non-attendance is followed up**
- d) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how risk management awareness training is delivered to all board members and senior managers, in line with the [training needs analysis](#)
- how non-attendance is followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how risk management awareness training is delivered to all board members and senior managers, in line with the [training needs analysis](#)
- how non-attendance is followed up.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

#### Rationale

Senior members of management, including non-executive directors, should have a clear understanding of risk. This will support the organisation to review, identify and adequately manage principle risks and operational risk, helping to achieve strategic objectives.

## Guidance

### Guidance from other organisations

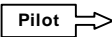
- Audit Commission (2009) *Key Lines of Enquiry for Auditors: Local Evaluation Assessments*
- Audit Commission (2009) *Use of Resources Framework - Overall approach and key lines of enquiry*
- Department of Health (2002) *Assurance: The Board Agenda*
- Health and Safety Executive (HSE) (2010) *Leading Health and Safety at Work: Leadership Actions for Directors and Board Members*
- Monitor (2010) *The role of boards in improving patient safety*
- Patient Safety First 'How to Support Leaders to Build a Safety Culture' *Patient Safety First website page*

## 3.7 Moving & Handling Training

All organisations must have an approved documented process which sets out the moving and handling training requirements for all permanent staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation records that all [permanent staff](#) complete moving and handling training, in line with the [training needs analysis](#)
- c) how the organisation follows up those who do not complete moving and handling training
-  d) action to be taken in the event of persistent non-attendance
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all [permanent staff](#), as listed in the [training needs analysis](#), complete moving and handling training
- how the organisation follows up those who do not complete moving and handling training.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all [permanent staff](#), as listed in the [training needs analysis](#), complete moving and handling training
- how the organisation follows up those who do not complete moving and handling training.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

### Rationale

In accordance with health and safety legislation employers are required to take reasonable steps to safeguard the health and safety of all employees. This should include increasing awareness of hazards in relation to moving and handling to minimise risk. The most up to date figures show that Musculoskeletal Disorders (MSD) cost society £5.7 billion and in healthcare services manual handling injuries account for 40% of absence from work through sickness. There are over 5000 manual handling injuries reported each year which occur in healthcare services. The costs to both the individuals and organisations involved are significant. Damage to an employee's back may render them incapable of work and if procedures are carried out incorrectly may also put patients at risk of significant harm. It is therefore essential that all staff receive appropriate moving and handling training to enable them to carry out their duties safely and effectively.

HSE 'Moving and handling in health and social care'

### Guidance

#### Legislation

- Health and Safety at Work etc Act 1974
- Manual Handling Operations Regulations 1992 SI 1992/2793

#### Guidance from other organisations

- Health and Safety Executive (HSE) 'Moving and handling in health and social care' *HSE website page*
- Healthy Working Lives provides further information on manual handling: [www.healthyworkinglives.com](http://www.healthyworkinglives.com)
- National Back Exchange website offers further information on the management of back pain: [www.nationalbackexchange.org](http://www.nationalbackexchange.org)
- NHS Employers (2010) 'Health and safety essential guide' *NHS Employers website pages*
- Royal College of Nursing (RCN) (2003) *Manual Handling Assessments in Hospitals and the Community*
- Smith, J. and P.Lloyd (2005) *The Guide to the Handling of People (5th edition)*

## 3.8 Harassment & Bullying

All organisations must have an approved documented process for dealing with the harassment or bullying of staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) statement by the organisation that harassment and bullying are not acceptable
- c) **how concerns about harassment or bullying can be raised**
- d) **what should be done once a concern has been raised**
- e) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how concerns about harassment or bullying can be raised
- what should be done once a concern has been raised.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how concerns about harassment or bullying can be raised
- what should be done once a concern has been raised.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

All employees have the right to be treated with consideration, dignity and respect which NHS organisations should enforce. Organisations should aim to provide a happy and fulfilling environment in which to work.

## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

- British Medical Association (BMA) (2006) *Bullying and Harassment of Doctors in the Workplace*
- Chartered Institute of Personnel and Development (CIPD) (2005) *Bullying at Work: Beyond Policies to a Culture of Respect*
- Department of Health (2000) *Improving Working Lives Standard*
- Department of Health (2010) *The NHS Constitution: The NHS belongs to us all*
- Department of Health. (2002) *Code of Conduct for NHS Managers*
- NHS Employers (2010) 'Health and safety essential guide' *NHS Employers website*
- NHS Employers website provides further information and resources on bullying and harassment: [www.nhsemployers.org](http://www.nhsemployers.org)
- Royal College of Nursing (2005) *Bullying & Harassment at Work: A Good Practice Guide for RCN Negotiators and Healthcare Managers*

## 3.9 Supporting Staff Involved in an Incident, Complaint or Claim

All organisations must have an approved documented process for making sure that all staff involved in traumatic or stressful incidents, complaints or claims are adequately supported.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) immediate support offered to [staff](#) (internally and, if necessary, externally)
- c) ongoing support offered to [staff](#) (internally and, if necessary, externally)
- d) advice available to [staff](#) (internally and, if necessary, externally) in the event of their being called as a witness
- e) **action for managers or individuals to take if the [staff](#) member is experiencing difficulties associated with the event**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- action for managers or individuals to take if the [staff](#) member is experiencing difficulties associated with the event.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- action for managers or individuals to take if the [staff](#) member is experiencing difficulties associated with the event.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Organisations have a duty of care to look after the psychological as well as the physical well-being of staff who have been exposed to a traumatic incident. When a traumatic event occurs, staff need to know exactly what support is available to them in the short and longer term, internally and externally, and should be provided with details of how to access that support. Organisations must therefore make sure that adequate support systems are in place for staff that have been involved with, or directly affected by, incidents, complaints or claims, regardless of the extent and nature of their involvement.



## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Department of Health (2005) *The management of health, safety and welfare issues for NHS staff*
- Health and Safety Executive (HSE) website provides further information and resources in relation to stress: <http://www.hse.gov.uk/healthservices/>
  - 'Line Manager Competency Indicator Tool' *HSE online tool*
  - *How to tackle work-related stress: A guide for employers on making the Management Standards work* (2009)
  - *Stress Competency Indicator Tools - How Effective Are You at Preventing and Reducing Stress in Your Staff?* (2009)
- National Patient Safety Agency (NPSA) website provides further information and resources in relation to managing patient safety incidents: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)
  - *Being open: Saying sorry when things go wrong* (2009)
  - *Being open: Supporting information* (2009)
  - *Patient Safety Alert. Being Open: Communicating with patients, their families and carers following a patient safety incident* (2009)
- Royal College Nursing (RCN) (2005) *Managing Your Stress: A guide for nurses*

## 3.10 Stress

All organisations must have an approved documented process for managing the risks associated with work-related stress.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how [staff](#) can access information on the management of work-related stress
- c) how [workplace stressors](#) are identified
- d) how the organisation carries out risk assessments for the prevention and management of work-related stress
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how [workplace stressors](#) are identified
- how the organisation carries out risk assessments for the prevention and management of work-related stress.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how [workplace stressors](#) are identified
- how the organisation carries out risk assessments for the prevention and management of work-related stress.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Work-related stress is a major cause of occupational ill health and could mean sickness absence, high staff turnover and poor performance in an organisation. Managing stress effectively could help organisations, their employees and their representatives proactively and reactively manage the issue of stress sensibly, and minimise the impact of work-related stress within the NHS. Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows approximately 100 claims with a total expected value of £5 million.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

- Health and Safety Executive (HSE) and Chartered Institute of Personnel and Development (CIPD) (2008) *Managing Stress at Work: A Refined Framework for Line Managers*
- Health and Safety Executive (HSE) website provides further information and resources in relation to stress: <http://www.hse.gov.uk/healthservices/>
  - 'Work-related stress' *HSE website page*
  - 'Work-related stress: Resources' *HSE website page*
  - 'Board Director/Chief Executive Officer: Your role in the management standards' *HSE website page*
  - 'Line Manager Competency Indicator Tool' *HSE online tool*
  - *Interventions to Control Stress at Work in Hospital Staff, Contract Research Report* (2002)
  - *How to tackle work-related stress: A guide for employers on making the Management Standards work* (2009)
  - *How to tackle work-related stress: A guide for employers on making the Management Standards work* (2009)
  - *Managing the causes of work-related stress: A step-by-step approach using the Management Standards* (2009)
- International Stress Management Association (2008) *Working Together to Reduce Stress at Work. A Guide for Employees*
- Royal College Nursing (RCN) website provides further information and resources in relation to stress for nurses: [www.rcn.org.uk](http://www.rcn.org.uk)
  - *Managing Your Stress: A guide for nurses* (2005)
  - *RCN Working Well Initiative Guidance on traumatic stress management in the health care sector* (2007)
  - *Work-related stress: A good practice guide for RCN representatives* (2009)

<b>Standard 4: Safe Environment</b>	<b>2011-12 numbering</b>
<b>4.1 Secure Environment</b>	<b>3.1</b>
<b>4.2 Violence &amp; Aggression*</b>	<b>3.8</b>
<b>4.3 Slips, Trips &amp; Falls (Staff &amp; Others)*</b>	<b>3.2</b>
<b>4.4 Slips, Trips &amp; Falls (Patients)*</b>	<b>3.3</b>
<b>4.5 Moving &amp; Handling</b>	<b>3.4</b>
<b>4.6 Hand Hygiene Training*</b>	<b>2.8</b>
<b>4.7 Inoculation Incidents*</b>	<b>3.5</b>
<b>4.8 The Deteriorating Patient</b>	<b>4.7</b>
<b>4.9 Clinical Handover of Care</b>	<b>4.9</b>
<b>4.10 Discharge</b>	<b>4.10</b>

\*Contains a training element

## 4.1 Secure Environment

**All organisations must have an approved documented process for managing the risks associated with the physical security of premises and assets.**

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation risk assesses the [physical security](#) of [premises and assets](#)**
- c) **how action plans are developed as a result of risk assessments**
- d) **how action plans are followed up**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation risk assesses the [physical security](#) of [premises and assets](#)
- how action plans are developed as a result of risk assessments
- how action plans are followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation risk assesses the [physical security](#) of [premises and assets](#)
- how action plans are developed as a result of risk assessments
- how action plans are followed up.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

NHS organisations should ensure that the delivery of healthcare takes place in a safe and secure environment. Organisations should develop a clear framework by which they can protect their property and assets, in line with the requirements and guidance of NHS Protect.

Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows that fire, floods, storm damage, vandalism and theft are expected to cost the NHS in the region of £21 million.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates (Restricted access to Local Security Management Specialists).

### Guidance from other organisations


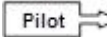
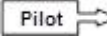
- NHS Protect website provides further information on managing security:  
<http://www.nhsbsa.nhs.uk/Protect.aspx>
  - *A Professional Approach to Managing Security in the NHS* (2003)
  - *Foundation Level Training for Local Security Management Specialists* (2008)
  - *NHS security management service security of prescription form guidance* (2008)
  - *NHS Security Management Manual* (2008) (Restricted access to Local Security Management Specialists)

## 4.2 Violence & Aggression

All organisations must have an approved documented process for the prevention and management of violence and aggression.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation carries out risk assessments for the prevention and management of violence and aggression**
-  c) timescales for review of risk assessments
-  d) how action plans are developed as a result of risk assessments
-  e) how action plans are followed up
- f) **arrangements for making sure lone workers are safe**
- g) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- h) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation carries out risk assessments for the prevention and management of violence and aggression
- arrangements for making sure lone workers are safe.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation carries out risk assessments for the prevention and management of violence and aggression
- arrangements for making sure lone workers are safe.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

NHS staff and other healthcare workers have a right to expect a safe and secure workplace. Measures to reduce violence need to be based on sound risk assessment and risk management underpinned by effective strategies and locally developed policies (NAO 2003). Organisations should develop a clear framework by which they can manage violence and aggression, in line with the requirements and guidance of the NHS Protect. Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows approximately 2,000 assaults, which are expected to cost in the region of £40 million.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates (Restricted access to Local Security Management Specialists).

### Guidance from other organisations

- Department of Health (2008) *A Code of Practice for the Use of Powers to Counter NHS Fraud and Security Incidents*
- Health and Safety Executive (HSE) website provides further information and resources: <http://www.hse.gov.uk/healthservices/>
  - 'Risk Assessment for Work Related Violence' *HSE website page*.
  - 'Work Related Violence' *HSE website page*.
  - *Violence at Work: A Guide for Employers (2006)*
  - *Working alone: Health and safety guidance on the risks of lone working (2009)*
  - *Preventing workplace harassment and violence: Joint guidance implementing a European social partner agreement (2009)*
- Ipsos MORI (2010) *Violence against frontline NHS staff: Research study conducted for COI on behalf of the NHS Security Management Service*
- National Audit Office (NAO) (2003) *A Safer Place to Work - Protecting NHS Hospital and Ambulance Staff from Violence & Aggression*
- NHS Protect website provides further information and resources: [www.nhsbsa.nhs.uk](http://www.nhsbsa.nhs.uk)
  - *Conflict Resolution Training. Implementing the National Syllabus (2004)*
  - *Non Physical Assault Explanatory Notes. A framework for Reporting and Dealing with Non-physical Assaults against NHS Staff and Professionals (2004)*
  - *Offensive Weapons. NHS Security Management Service Guidance (2006)*
  - *Prevention and Management of Violence Where the Withdrawal of Treatment is not an Option (2007)*
  - *NHS Security Management Manual (2008) (Restricted access to Local Security Management Specialists)*
  - *Tackling Violence against Staff: Explanatory Notes for Reporting Procedures Introduced by Secretary of State Directions (2009 [2003])*
  - *Not Alone: A Guide for the better protection of lone workers in the NHS. (2009)*
- UNISON *Violence at Work: A Guide to Risk Prevention*



## 4.3 Slips, Trips & Falls (Staff & Others)

All organisations must have an approved documented process for managing the risk of slips, trips and falls involving staff and others.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation assesses the risk of slips, trips and falls involving [staff](#) and others (including falls from height)**
- c) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- d) how the organisation raises awareness about preventing and reducing the number of slips, trips and falls involving [staff](#) and others
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation assesses the risk of slips, trips and falls involving [staff](#) and others (including falls from height).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation assesses the risk of slips, trips and falls involving [staff](#) and others (including falls from height).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

The management of the risk of slips and trips is especially important in healthcare as injuries to healthcare workers and members of the public are frequent; trips account for almost 62% of major injuries and are believed to cause 8% of fatalities to members of the public in the healthcare industry (HSE 2003). Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows that slips, trips and falls are a high cause of litigation, with approximately 6000 claims recorded with a total expected value of £90 million. In response to these statistics the NHSLA Standards split this risk area into two criteria; patient falls and staff and other falls.

## Guidance

### Guidance from other organisations

- Health and Safety Executive (HSE) website provides further information on managing the risks associated with slips, trips and falls: <http://www.hse.gov.uk/healthservices/>
  - 'Falls from Height' *HSE website page*
  - 'Slips Resources' *HSE website page*
  - 'Watch Your Step Campaign' *HSE website page*
  - 'Slips Assessment Tool' *Online tool*
  - *Slips and Trips in the Health Services Health Services Sheet Number 2 (2003)*

## 4.4 Slips, Trips & Falls (Patients)

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All organisations must have an approved documented process for managing the risk of slips, trips and falls involving patients.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation assesses the risk of slips, trips and falls involving patients (including falls from height)**
- c) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- d) how the organisation raises awareness about preventing and reducing the number of slips, trips and falls involving patients
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation assesses the risk of slips, trips and falls involving patients (including falls from height).

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation assesses the risk of slips, trips and falls involving patients (including falls from height).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

## Rationale

A patient falling is the most common patient safety incident reported to the National Reporting and Learning Service (NRLS) from inpatient services. Over 200,000 falls were reported to the NRLS in the 12 months from September 2005 to August 2006, with reports of falls coming from 98% of organisations that provide inpatient services. The National Patient Safety Agency (NPSA) recommends that each patient at risk of falling should receive multifaceted clinical and environmental interventions that could reduce the risk (NPSA 2007).

Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows that slips, trips and falls are a high cause of litigation, with approximately 6,000 claims recorded with a total expected value of £90 million. In response to these statistics the NHSLA Standards split this risk area into two criteria; patient falls and staff and other falls.

## Guidance

### Guidance from other organisations

- Department of Health website provides further information on managing the risks associated with slips, trips and falls: [www.dh.gov.uk](http://www.dh.gov.uk)
  - National Service Framework for Older People. (2001)
  - Implementing the NSF for Older People Falls Standard - Support for Commissioning Good Services. (2003)
  - Making the Case for Investing in Falls and Fractures Prevention. A Workbook of Ideas. (2004)
  - Developing Integrated Falls Services - A Web-based Resource. (2005)
- Health and Safety Executive (HSE) website provides further information on managing the risks associated with slips, trips and falls: <http://www.hse.gov.uk/healthservices/>
  - 'Falls from Height' *HSE website page*
  - 'Slips Resources' *HSE website page*
  - 'Watch Your Step Campaign' *HSE website page*
  - 'Slips Assessment Tool' *Online tool*
- Help the Aged (2002) *Preventing Falls: Reducing Falls Risks Amongst Older People: Examples of Falls Services across England*
- National Institute of Clinical Excellence (NICE) (2004) *Clinical practice guideline for the assessment and prevention of falls in older people*
- National Institute of Clinical Excellence (NICE) (2004) *Falls: The assessment and prevention of falls in older people - Quick reference guide*
- National Patient Safety Agency (NPSA) (2007) *The Third Report from the Patient Safety Observatory - Slips, Trips and Falls in Hospital*
- NHS Employers. (2010) 'Health and safety essential guide' *NHS Employers website pages*

## 4.5 Moving & Handling

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**All organisations must have an approved documented process for managing the risks associated with moving and handling.**

### Level 1

Your documented process must include:

- a) [duties](#)
- b) techniques to be used in the moving and handling of patients and objects, including the use of appropriate equipment
- c) arrangements for access to appropriate specialist advice
- d) **how the organisation risk assesses the moving and handling of patients and objects**
- e) **how action plans are developed as a result of risk assessments**
- f) **how action plans are followed up**
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation risk assesses the moving and handling of patients and objects
- how action plans are developed as a result of risk assessments
- how action plans are followed up.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation risk assesses the moving and handling of patients and objects
- how action plans are developed as a result of risk assessments
- how action plans are followed up.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

## Rationale

Musculoskeletal disorders (MSDs) are the most common occupational illness in Great Britain, affecting 1 million people a year. They include problems such as low back pain, joint injuries and repetitive strain injuries of various sorts. Figures show that MSDs cost society £5.7 billion and in healthcare services manual handling injuries account for 40% of absence from work through sickness. There are over 5,000 manual handling injuries reported each year which occur in healthcare services. Approximately half of these happen during the handling of patients (HSE 'Moving and handling in health and social care').

Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows 2,500 manual handling claims with a total expected value of around £43 million.

## Guidance

### Guidance from other organisations

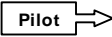
- Health and Safety Executive (HSE) website provides further information and resources for managing the risks associated with manual handling:  
<http://www.hse.gov.uk/healthservices/>
  - 'Moving and handling in health and social care' *HSE website page*
  - 'Manual Handling Assessment Chart Tool' *HSE online tool*
  - 'Musculoskeletal disorders in health and social care' *HSE website page*
  - 'Risk assessment and process planning for bariatric patient handling pathways' (2007)
  - 'Getting to grips with hoisting people' (2011)
- National Back Exchange website offers further information on the management of back pain: [www.nationalbackexchange.org](http://www.nationalbackexchange.org)
- The Healthy Working Lives provides further information on manual handling: [www.healthyworkinglives.com](http://www.healthyworkinglives.com)
- NHS Employers (2010) 'Health and safety essential guide' *NHS Employers website pages*
- Royal College Nursing (RCN) (2003) *Manual Handling Assessments in Hospitals and the Community: An RCN Guide*
- Smith, J. (Editor) (2005) *The Guide to the Handling of People (5th edition)*

## 4.6 Hand Hygiene Training

All organisations must have an approved documented process which sets out the hand hygiene training requirements for all permanent staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation records that all [permanent staff](#) complete hand hygiene training, in line with the [training needs analysis](#)
- c) how the organisation follows up those who do not complete hand hygiene training
-  d) action to be taken in the event of persistent non-attendance
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete hand hygiene training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete hand hygiene training.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete hand hygiene training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete hand hygiene training.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

#### Rationale

Healthcare related infections are costly in both human and financial terms. Bodily secretions and skin surfaces can carry bacteria and viruses that are potentially infectious to patients, relatives or staff. Effective hand hygiene is the single most important procedure for significantly reducing and preventing infection. Hand hygiene is a simple, but effective way to tackle infections in hospitals. All organisations have a responsibility to ensure their staff are trained to comply with guidance and procedures relating to hand hygiene.

## Guidance

### Guidance from other organisations

- Department of Health (2002) *Getting Ahead of the Curve: Strategy for Combating Infectious Diseases*
- Department of Health (2003) *Winning Ways: Working Together to Reduce Healthcare Associated Infection in England*
- Department of Health (2007) 'Towards Cleaner Hospitals and Lower Rates of Infection' *DH website*
- Department of Health (2010) *The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance*
- Department of Health 'Delivering Clean and Safe Care' *DH website*
- National Audit Office (NAO) (2000) *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England*
- National Audit Office (NAO) (2004) *Improving Patient Care by Reducing the Risk of Hospital Acquired Infection: A Progress Report*
- National Patient Safety Agency (NPSA) (2004) *The Full Economic Case - Implementing Near Patient Alcohol Hand Rub in Your Trust*
- National Patient Safety Agency (NPSA) (2008) *Patient Safety Alert 2008/02. Clean Hands Save Lives. (2nd edition)*
- NHS Estates and Department of Health (2004) *A Matron's Charter: An Action Plan for Cleaner Hospitals*
- The House of Commons Committee of Public Accounts (2005) *Improving Patient Care by Reducing the Risk of Hospital Acquired Infection: A Progress Report*



## 4.7 Inoculation Incidents

All organisations must have an approved documented process for managing the risks associated with inoculation incidents.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how [inoculation incidents](#) are reported
- c) process for the management of an [inoculation incident](#) (including prophylaxis)
- d) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- process for the management of an [inoculation incident](#) (including prophylaxis).

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- process for the management of an [inoculation incident](#) (including prophylaxis).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

The main risk posed by a needle stick injury to NHS employees is exposure of the worker to blood-borne viruses (BBV). The main viruses concerned are: Hepatitis B (HBV), Hepatitis C (HCV) and Human immunodeficiency virus (HIV). The prevalence of BBVs in the UK population is generally low and the risk of infection from needle stick injuries remains low. Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows 1,000 claims with a total expected value of £7 million.

NHS employees may acquire a BBV infection if they are exposed to infected blood or body fluids; this could be either via the mucous membranes (eyes, inside of the mouth and nose), through broken skin or through an inoculation injury route, where the skin is punctured or scratched by a needle or sharp device that has been used in a medical procedure, (HSE 'Needle-stick injuries').

## Guidance

### Legislation

- Directive 2010/32/EU - Prevention from Sharp Injuries in the Hospital and Healthcare Sector

### Guidance from other organisations

- Department of Health (1998) *Guidance for Clinical Health Care Workers - Protection against Infection with Blood-borne Viruses*
- European Biosafety Network website provides further information on implementing the EU Directive: <http://www.europeanbiosafetynetwork.eu/>
- Health Protection Agency (HPA) (2008) *Eye of the Needle - United Kingdom Surveillance of Significant Occupational Exposures to Bloodborne Viruses in Healthcare Workers*
- Health Protection Agency (HPA) (2010) 'Examples of good and bad practice to avoid sharps injuries' *HPA website page*
- Health and Safety Executive (HSE) website provides further information on managing the risks associated with inoculation incidents:  
<http://www.hse.gov.uk/healthservices/>
  - 'Needlestick Injuries' *HSE website page*
  - 'Management and Prevention of Sharps Injuries: Inspection of NHS Trusts 2010/2011 by Occupational Health Inspectors' *HSE website page*
  - Working with substances hazardous to health: What you need to know about COSHH (2009) *HSE website page*
- National Audit Office (NAO) (2003) *A Safer Place to Work: Improving the management of health and safety risks to staff in NHS trusts*
- Royal College of Nursing (RCN) (2001) *Sharps safety: RCN guidance to support implementation of the EU Directive 2010/32/EU on the prevention of sharps injuries in the healthcare sector*

## 4.8 The Deteriorating Patient

All organisations must have an approved documented process for managing the risks associated with the deteriorating patient.

### Level 1

Your documented process must include:

- Pilot** →
- a) requirement for a documented plan for vital signs monitoring that identifies which variables need to be measured, including the frequency of measurement
  - b) **use of an early warning system within the organisation to recognise patients at risk of deterioration**
  - c) actions to be taken to minimise or prevent further [deterioration in patients](#)
  - d) **do not attempt resuscitation orders (DNAR)**
  - e) how the organisation documents that resuscitation equipment is checked, stocked and fit for use
  - f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- use of an early warning system within the organisation to recognise patients at risk of [deterioration](#)
- do not attempt resuscitation orders (DNAR).

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- use of an early warning system within the organisation to recognise patients at risk of [deterioration](#)
- do not attempt resuscitation orders (DNAR).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

## Rationale

Patients who are admitted to hospital believe that they are entering a place of safety in which they will receive the best possible care. Unfortunately some will become acutely unwell and where a patient's clinical condition deteriorates, this should be recognised and acted on.

However the recognition of deteriorating health by staff is can be delayed or managed inappropriately resulting in late treatment, avoidable admissions to intensive care and unnecessary deaths.

A large proportion of patients who suffer cardio-respiratory arrest in hospital have recognisable changes in routine observations during the preceding twenty-four hours including changes in vital signs, level of consciousness and oxygenation. Action taken during these early stages can prevent deterioration progressing to cardiac arrest. It is essential that healthcare staff are equipped to recognise and manage deterioration confidently and competently.

## Guidance

### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### Guidance from other organisations

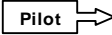
- Department of Health (2009) *Competencies for Recognising and Responding to Acutely Ill Patients in Hospital*
- National Institute for Health and Clinical Excellence (NICE) (2007) *CG50. Acutely Ill Patients in Hospital*
- National Patient Safety Agency (NPSA) (2007) *Recognising and responding appropriately to early signs of deterioration in hospitalised patients*
- Patient Safety First (2008) *How to Guide Reducing Harm from Deterioration*
- Resuscitation Council (UK) (2010) *Resuscitation Guidelines*

## 4.9 Clinical Handover of Care

All organisations must have an approved documented process for the handover of care of patients.

### Level 1

Your documented process must include:

- a) [handover](#) requirements between all care settings, to include both giving and receiving of information
-  b) how [handover](#) is recorded
- c) **out of hours [handover](#) process**
- d) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- out of hours [handover](#) process.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- out of hours [handover](#) process.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

## Rationale

Clinical handover has been described as “the transfer of professional responsibility and accountability for some or all aspects of care for a patient on a temporary or permanent basis” (NPSA). It is considered a high risk step in the patient pathway wherever it occurs. Good communication between all members of the healthcare team, including those with the patient and their family, improves handover helps to identify unstable and unwell patients, so that their management remains optimal, clear and unambiguous.

Lapses in information handover can lead to mistakes being made, including delayed decisions, repeated investigations, incorrect diagnoses and incorrect treatment. How the information is transmitted and recorded in the handover process has a major impact on the way it is retained and therefore acted on subsequently. Given the differing factors and environments that handover occurs in, there should be flexible requirements that incorporate a minimum content that must be recorded and transferred in an individual patient handover.

## Guidance

### Guidance from other organisations

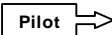
- Association of Anaesthetists of Great Britain and Ireland (2009) *Interhospital Transfer*
- Australian Commission on Safety and Quality in Health Care (2010) *The OSSIE Guide to Clinical Handover Improvement*
- BMA (2004) *Safe handover: safe patients*
- Royal College of Nursing (2008) *Improving the safe transfer of care: A quality improvement initiative*
- Royal College of Physicians (2011) *Acute care toolkit. Handover*
- Royal Pharmaceutical Society (2011) *Keeping patients safe when they transfer between care providers –getting the medicines right*

## 4.10 Discharge

All organisations must have an approved documented process for the discharge of patients.

### Level 1

Your documented process must include:

- a) [discharge](#) requirements for all patients
- b) **information to be given to the receiving healthcare professional**
- c) **information to be given to the patient when they are [discharged](#)**
-  d) how a patient's medicines are managed on [discharge](#)
- e) **how the organisation records the information given in minimum requirements b) and c)**
- f) out of hours [discharge](#) process
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- information to be given to the receiving healthcare professional
- information to be given to the patient when they are [discharged](#).

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- information to be given to the receiving healthcare professional
- information to be given to the patient when they are [discharged](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### Rationale

The risks associated with the discharge or 'transfer of care' for patients leaving hospital can be as a result of poor planning and communication with on-going care providers or patients themselves. Identifying and reducing these risks will assist in maintaining and supporting the safety of the patient and provide continuity of the right care in the right place. Poor planning, communication and documentation can result in patients being unprepared for home. This could result in a protracted length of stay in hospital or readmission, resulting in the inappropriate use of hospital resources.

### Guidance

#### Guidance from other organisations

- Department of Health (2010) *Ready to go? Planning the discharge and transfer of patients from hospital and intermediate care*
- Royal Pharmaceutical Society (2011) *Keeping patients safe when they transfer between care providers – getting the medicines right*
- Pharmaceutical Services Negotiating Committee (2008) *Moving patients, Moving medicines, Moving safely: Guidance on Discharge and Transfer Planning*



## Standard 5: Acute and Community Services and Non-NHS Providers

2011-12 numbering

5.1	Supervision of Medical Staff in Training*	2.4
5.2	Patient Information & Consent	4.1
5.3	Consent Training*	2.10
5.4	Maintenance of Medical Devices & Equipment	3.6
5.5	Medical Devices Training*	2.7
5.6	Screening Procedures	4.3
5.7	Diagnostic Testing Procedures	4.4
5.8	Transfusion*	4.6
5.9	Venous Thromboembolism*	4.8
5.10	Medicines Management*	4.5

\*Contains a training element

## 5.1 Supervision of Medical Staff in Training

### Organisations providing acute services must have met the GMC minimum requirements for supervision.

To assess part of this criterion the NHSLA takes assurance from the organisation's compliance with the General Medical Council's (GMC) minimum requirements for clinical supervision set out in Domain 6 of the GMC Generic Standards for Training.

#### Level 1

Your organisation has GMC approval, but there are minor concerns about supervision of medical staff in training identified through GMC's evidence.

#### Level 2

Your organisation has GMC approval and no concerns about supervision of medical staff in training have been identified through GMC's evidence.

**Pilot** → In addition, you must evidence that issues relating to the supervision of medical staff in training are reported to, and discussed, at least quarterly at a committee.

#### Level 3

Your organisation has GMC approval and has demonstrated notable practice in some areas of the supervision of medical staff in training.

**Pilot** → In addition you must evidence that shortfalls identified within the quarterly reports on issues relating to the supervision of medical staff in training are being addressed.

#### Rationale

It is essential that medical staff in training receive appropriate supervision whilst working within an organisation. A lack of appropriate supervision can lead to acts or omissions which result in unintentional harm to patients. The NHSLA, GMC and COPMeD agree that the review of systems to ensure appropriate supervision of medical staff in training should be undertaken by GMC and COPMeD and direct assurance is taken from these bodies by the NHSLA within its assessment process.

## **Guidance**

### **Guidance from other organisations**

- General Medical Council (2010) *Generic standards for specialty including GP training*
- General Medical Council (2010) *Quality Framework for specialty including GP training*
- General Medical Council (2010) *Quality framework operational guide*
- General Medical Council 'National Summary Reports' *GMC website page*

## 5.1 Supervision of Medical Staff in Training (Community and Non-NHS Providers)

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Organisations providing community services and non-NHS providers will not be assessed against this criterion and will receive a positive score.

### Level 1

The organisation will not be assessed against the requirements of this criterion and will receive a positive score.

### Level 2

The organisation will not be assessed against the requirements of this criterion and will receive a positive score.

### Level 3

The organisation will not be assessed against the requirements of this criterion and will receive a positive score.

## 5.2 Patient Information & Consent

Organisations providing acute and community services and non-NHS providers must have an approved documented process for obtaining consent.

### Level 1

Your documented process must include:

- a) process for obtaining consent
- b) how information is provided to patients to support their decision making, including risks, benefits and alternatives where appropriate
- c) **how the discussion and provision of information to patients is recorded**
- d) process for recording that consent has been given
- e) **archiving arrangements for any information given to patients to support their decision making**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the discussion and provision of information to patients is recorded
- archiving arrangements for any information given to patients to support their decision making.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the discussion and provision of information to patients is recorded
- archiving arrangements for any information given to patients to support their decision making.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### Rationale

A principle of consent is that it is given voluntarily and that sufficient information has been imparted to allow the consent to be valid. It is a legal and ethical principle that valid consent is obtained for every person.

When deciding on the approach for consent, organisations are reminded of the need not only to consider legal requirements but the standards expected of healthcare professionals by their regulatory bodies. All practical and appropriate steps must be taken to enable a person to make the decision themselves. Information should be communicated in an appropriate way, include the nature and purpose of procedures, and the provision of any other relevant information.

If there is a failure to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may give rise to a valid negligence claim.

Analysis of the NHSLA claims database shows a significant number of claims where consent is an issue. The majority of these are in relation to surgical procedures or treatments. A major factor is the apparent lack of adequate, clear information for patients, due to issues with verbal or written communication, or competence contributing to these failures.

### Guidance

#### Guidance from other organisations

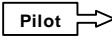
- Department of Health (2009) *Reference Guide to Consent for Examination or Treatment (2nd edition)*
- Department of Health (2010) *The NHS Constitution: The NHS belongs to us all*
- General Medical Council (2008) *Consent: Patients and Doctors Making Decisions Together*
- Human Tissue Authority (2009) *Codes of Practice. Code 1 Consent*

## 5.3 Consent Training

Organisations providing acute and community services and non-NHS providers must have an approved documented process which sets out the consent training requirements for all relevant staff.

### Level 1

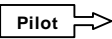
Your documented process must include:

- a) how the organisation trains clinical [staff](#) on the consent process, in line with the [training needs analysis](#)
- b) how the organisation identifies clinical [staff](#) who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure
- c) **how the organisation provides procedure-specific training on consent for clinical [staff](#) who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure**
- d) **how the organisation follows up where an individual has obtained consent without the authorisation to do so**
-  e) **how the organisation notifies the GMC via the [required form](#), of any individual who has obtained consent without the authorisation to do so**
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation provides procedure-specific training on consent for [staff](#) who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure
- how the organisation follows up where an individual has obtained consent without the authorisation to do so

-  — how the organisation notifies the GMC via the [required form](#), of any individual who has obtained consent without the authorisation to do so.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation provides procedure-specific training on consent for [staff](#) who are not capable of performing the procedure, but who are authorised to obtain consent for that procedure
- how the organisation follows up where an individual has obtained consent without the authorisation to do so

-  — how the organisation notifies the GMC via the [required form](#), of any individual who has obtained consent without the authorisation to do so.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

## Rationale

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Analysis of data of the NHSLA database shows a significant number of claims involving the inappropriate or incorrect taking of consent. It is therefore essential that organisations have in place robust and overarching consent training programmes for all staff that are required to obtain or validate the taking of informed consent from patients.

## Guidance

### Legislation

- The Mental Health Act 1983 (as amended by the Mental Health Act 2007)
- The Human Tissue Act 2004
- The Mental Capacity Act 2005

### Guidance from other organisations

- Department of Health website provides a number of documents relating to consent: [www.dh.gov.uk](http://www.dh.gov.uk)
  - *Consent - What You Have a Right to Expect: A Guide for Children and Young People* (2001)
  - *Consent - What You Have a Right to Expect: A Guide for Adults* (2001)
  - *Consent - What You Have a Right to Expect: A Guide for Parents* (2001)
  - *Consent - What You Have a Right to Expect: A Guide for Relatives and Carers* (2001)
  - *Good Practice in Consent Implementation Guide: Consent to examination or treatment* (2001)
  - *Seeking Consent: Working with Children* (2001)
  - *Seeking Consent: Working with Older People* (2001)
  - *Consent: What You Have a Right to Expect - Taking Blood Specimens* (2002)
  - *Information to Assist in Amending Consent Form.* (2009)
  - *Reference Guide to Consent for Examination or Treatment (2nd edition)* (2009)
- General Medical Council (2008) *Consent: Patients and Doctors Making Decisions Together*
- Human Tissue Authority (2009) *Codes of Practice. Code 1 Consent.* London: Department of Health

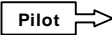


## 5.4 Maintenance of Medical Devices & Equipment

Organisations providing acute and community services and non-NHS providers must have an approved documented process for managing the maintenance of reusable diagnostic and therapeutic equipment.

### Level 1

Your documented process must include:

- a) [duties](#)
-  b) how the organisation includes all items of diagnostic and therapeutic equipment on an inventory
- c) **how reusable diagnostic and therapeutic equipment is maintained**
- d) **how reusable diagnostic and therapeutic equipment is repaired**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how reusable diagnostic and therapeutic equipment is maintained
- how reusable diagnostic and therapeutic equipment is repaired.

The assessor will review the organisation's incident database and select two items to assess the organisation's compliance with the above minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how reusable diagnostic and therapeutic equipment is maintained
- how reusable diagnostic and therapeutic equipment is repaired.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will review the organisation's incident database and select two items to assess the organisation's compliance with the above minimum requirements.

### Rationale

The development of an approved document which covers the maintenance and repair of all medical devices will help ensure a systematic approach to the management of equipment within NHS organisations. Arrangements must be in place to access appropriate servicing facilities to maintain and repair devices, and to ensure that manufacturers' recalls, updates and modifications are carried out. Analysis of claims on the NHSLA database with an incident date between 1 April 2005 and 31 March 2010 shows nearly 2,000 claims, with a total expected value of £33 million.

### Guidance

#### Guidance from other organisations




- Medicines Healthcare Regulatory Agency (MHRA) website provides further information, safety warnings, alerts and recalls at: [www.mhra.gov.uk](http://www.mhra.gov.uk).
  - *Devices in Practice: A Guide for Professionals in Health and Social Care* (2008)
  - *Device Bulletin: Managing Medical Devices* (2006)
  - *Device Bulletin: Reporting Adverse Incidents and Disseminating Medical Device Alert* (2010)
- National Audit Office (NAO) (1999) *The Management of Medical Equipment in NHS Acute Trusts in England*
- NHS Estates (2004) *Best practice advice: Establishing and Managing Backlog*

## 5.5 Medical Devices Training

Organisations providing acute and community services and non-NHS providers must have an approved document which sets out the training requirements of all permanent staff in relation to the use of diagnostic and therapeutic equipment.

### Level 1

Your documented process must include:

- a) [duties](#)
-  b) how the organisation includes all items of diagnostic and therapeutic equipment on an inventory
- c) **how the organisation identifies which [permanent staff](#) are authorised to use the equipment listed on the inventory**
- d) **how the organisation decides the training required**
- e) **how the organisation decides the frequency of updates required**
- f) **how the organisation records that all [permanent staff](#) complete training**
-  g) how the organisation follows up those who do not complete training
-  h) action to be taken in the event of persistent non-attendance
- i) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation identifies which [permanent staff](#) are authorised to use the equipment listed on the inventory
- how the organisation decides the training required
- how the organisation decides the frequency of updates required
- how the organisation records that all [permanent staff](#) complete training.

The assessor will review the organisation's incident database and select two items to assess the organisation's compliance with the above minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation identifies which [permanent staff](#) are authorised to use the equipment listed on the inventory
- how the organisation decides the training required
- how the organisation decides the frequency of updates required
- how the organisation records that all [permanent staff](#) complete training.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

The assessor will review the organisation's incident database and select two items to assess the organisation's compliance with the above minimum requirements.

### **Rationale**

Diagnostic and therapeutic equipment is used every day by most healthcare professionals in the course of their work to support the treatment and care of patients. It is the responsibility of each organisation to ensure that healthcare professionals are using equipment safely and for the purpose it was intended. The delivery of safe and effective treatment in healthcare settings is dependent on the correct use of medical devices in a range of applications. These interventions can optimise treatment, reduce length of stay and improve the patient experience of care. However, when used inappropriately medical devices carry the associated risk of causing harm to patients that can, if unchecked be serious. It is therefore essential that all organisations have overarching medical devices training programmes to minimise the risk of errors occurring.

### **Guidance**

#### **Guidance from other organisations**



- Medicines Healthcare Regulatory Agency (MHRA) website provides further information, safety warnings, alerts and recalls at: [www.mhra.gov.uk](http://www.mhra.gov.uk)
  - *Devices in Practice: A Guide for Professionals in Health and Social Care* (2008)
  - *Device Bulletin: Managing Medical Devices* (2006)
  - *Device Bulletin: Reporting Adverse Incidents and Disseminating Medical Device Alerts* (2010)

## 5.6 Screening Procedures



Organisations providing acute and community services and non-NHS providers must have a documented process for managing the risks associated with screening procedures.

### Level 1

Your documented process must include:

-  a) a list of the [screening](#) procedures carried out on the organisation's own patients
-  b) how the organisation risk assesses [screening](#) procedures

For each of the [screening](#) procedures listed, your documented process must include:

-  c) how the [screening](#) procedure is requested
- d) **how the clinician treating the patient is informed of the result, including timescales**
- e) **how the patient is informed of the result, including timescales**
-  f) how the patient is followed-up or referred, including timescales
- g) **how minimum requirements c) to f) are recorded**
- h) how the organisation [monitors](#) compliance with all of the above.

Where the organisation has developed an overarching document, this will be assessed along with one screening-specific procedure. Where the organisation has not developed an overarching document, two screening-specific procedures will be assessed.

For the purpose of the assessment, you should provide evidence for those screening procedures you have assessed as being highest risk.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the clinician treating the patient is informed of the result, including timescales
- how the patient is informed of the result, including timescales.

The assessor will select two screening-specific procedures, from the organisation's list, to assess compliance with these minimum requirements.

For the purpose of the assessment, you should provide evidence for those screening procedures you have assessed as being highest risk.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the clinician treating the patient is informed of the result, including timescales
- how the patient is informed of the result, including timescales.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will select two screening-specific procedures, from the organisation's list, to assess compliance with these minimum requirements.

For the purpose of the assessment, you should provide evidence for those screening procedures you have assessed as being highest risk.

### Rationale

Screening is the process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk or any complications arising from the disease or condition.

There should be clear information to enable people to make an informed choice as to whether to participate in a screening test and there should be appropriate follow-up of positive screen results. Organisations should describe clear levels of responsibility for the different aspects of screening, have rigorous systems in place to ensure the effective tracking of individuals, and robust processes to ensure that results can be acted upon in a timely way.

Analysis of claims on the NHSLA database shows that a failure or delay in interpreting or acting on test results is one of the most common factors in relation to claims.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

- National Cancer Screening Programmes 'NHS Cancer Screening Programmes' *Website page*
- National Cancer Screening Programmes (2009) *Consent in Cancer Screening*
- UK National Screening Committee website lists guidance and policies on whether specific screening programmes are recommended or not, plus supporting evidence: [www.screening.nhs.uk](http://www.screening.nhs.uk)
  - *Managing Serious Incidents in the English NHS National Screening Programmes* (2010)

## 5.7 Diagnostic Testing Procedures

Organisations providing acute and community services and non-NHS providers must have an approved documented process for managing the risks associated with diagnostic testing procedures.

### Level 1

Your documented process must include:

- Pilot → a) a list of the [diagnostic tests](#) carried out on the organisation's own patients
- Pilot → b) how the organisation risk assesses [diagnostic testing](#) procedures

For each of the diagnostic tests listed, your documented process must include:

- c) how the [diagnostic test](#) is requested
- d) **how the clinician treating the patient is informed of the result, including timescales**
- e) **how the patient is informed of the result, including timescales**
- Pilot → f) actions to be taken by the clinician, including timescales
- g) **how minimum requirements c) to f) are recorded**
- h) how the organisation [monitors](#) compliance with all of the above.

Where organisations have developed an overarching document, this will be assessed along with one diagnostic test-specific document. Where the organisation has not developed an overarching document, two diagnostic test-specific documents will be assessed.

For the purpose of the assessment, you should provide evidence for those diagnostic tests you have assessed as being highest risk.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the clinician treating the patient is informed of the result, including timescales
- how the patient is informed of the result, including timescales.

The assessor will select two diagnostic test-specific documents, from the organisation's list, to assess compliance with these minimum requirements.

For the purpose of the assessment, you should provide evidence for those diagnostic tests you have assessed as being highest risk.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the clinician treating the patient is informed of the result, including timescales
- how the patient is informed of the result, including timescales.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will select two diagnostic test-specific documents, from the organisation's list, to assess compliance with these minimum requirements.

For the purpose of the assessment, you should provide evidence for those diagnostic tests you have assessed as being highest risk.

### **Rationale**

The failure to access, acknowledge and act upon the results of diagnostic tests may result in an inappropriate delay and lack of timely treatment resulting in harm to patients. Organisations should have in place clear clinical risk management systems that identify guidance to reduce this risk. These should include the ability to record timely and accurate data; ensure that staff are trained in the use of software systems that support diagnostic functions; enable communication channels that are consistent across the organisation; provide known pathways that assist in the tracking of patients; and advise patients on how their test results will be communicated to them.

Analysis of claims on the NHSLA database shows that a failure or delay in interpreting or acting on test results is one of the most common factors in relation to claims.

### **Guidance**

#### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### **Guidance from other organisations**

- British Medical Association (2010) *Acting upon test results in an electronic world*
- National Patient Safety Agency (NPSA) (2004) *Right Patient Right Care*



## 5.8 Transfusion

**Organisations providing acute and community services and non-NHS providers must have an approved documented process for transfusion.**

### Level 1

Your documented process must include:

- a) how blood samples are requested for pre-transfusion compatibility testing
- b) **how [transfusions](#) are administered, including patient identification**
- c) **care of patients receiving a [transfusion](#)**
- d) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- e) how the organisation assesses the competency of all [staff](#) involved in the [transfusion](#) process
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how [transfusions](#) are administered, including patient identification
- care of patients receiving a [transfusion](#).

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how [transfusions](#) are administered, including patient identification
- care of patients receiving a [transfusion](#).

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### Rationale

Administering the wrong blood type (ABO incompatibility) is the most serious outcome of error during transfusions, which can result in death. Most of these incidents are due to the failure of the final identity checks carried out between the patient and the product to be transfused.

To ensure the right patient receives the right blood, every organisation must have in place clear, strict checking procedures and processes which should be followed during the pre-transfusion and administration stages of any blood product. It is paramount that all staff involved in these processes receive training in line with their roles and are competent in performing these processes.

### Guidance

#### Guidance from other organisations

- British Committee for Standards in Haematology (2009) *Guideline on the Administration of Blood Components*
- National Patient Safety Agency (2006) *SPN 14. Right patient, Right blood*
- Royal College of Nursing (2005) *Right blood, right patient, right time: RCN guidance for improving transfusion practice*
- UK Blood Transfusion and Tissue Transplantation Service (2007) *Handbook of Transfusion Medicine, 4th Edition*

## 5.9 Venous Thromboembolism

Organisations providing acute and community services and non-NHS providers must have an approved documented process for the prevention and management of venous thromboembolism (VTE).

### Level 1

Your documented process must include:

- a) **how patients are assessed for their risk of developing venous thromboembolism (VTE), including timescales**
- b) prophylactic treatment regime for high risk patients
- c) **procedure to be followed if VTE is suspected**
- d) management of the patient once a positive diagnosis has been made
- e) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how patients are assessed for their risk of developing venous thromboembolism (VTE), including timescales
- procedure to be followed if VTE is suspected.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how patients are assessed for their risk of developing venous thromboembolism (VTE), including timescales
- procedure to be followed if VTE is suspected.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

## Rationale

The House of Commons Health Committee reported in 2005 that 25,000 people in the UK die from preventable hospital-acquired venous thromboembolism (VTE) every year. The assessment of the risk of developing a VTE is a key element in reducing avoidable death, disability and chronic ill health.

Once the risk has been identified there should be a recognised procedure that involves considering all forms of prophylaxis for use in the prevention of VTE. However a UK survey suggested that 71% of patients assessed to be at medium or high risk of developing deep vein thrombosis did not receive any form of mechanical or pharmacological VTE prophylaxis (Rashid 2005). In addition the risk should be reassessed at recommended intervals to identify increased risk through bleeding or further VTE.

## Guidance

### Guidance from other organisations

- Department of Health (2010) *Venous Thromboembolism (VTE) Risk Assessment*
- House of Commons Health Committee (2005) *The Prevention of Venous Thromboembolism in Hospitalised Patients*
- National Institute for Health and Clinical Excellence (NICE) (2010) *CG92. Venous Thromboembolism: Reducing the Risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in in-patients*
- National Institute for Health and Clinical Excellence (NICE) (2010) *VTE Prevention Quality Standard*
- National Patient Safety Authority (2011) *The 'How to Guide' for Venous Thromboembolism Risk Assessment*
- Rashid ST, Thursz MR, Razvi NA et al. (2005) 'Venous thromboprophylaxis in UK medical inpatients' *Journal of the Royal Society of Medicine* 98 (11): 507–12.

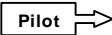
## 5.10 Medicines Management

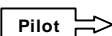
Organisations providing acute and community services and non-NHS providers must have an approved documented process for learning from medication errors.

### Level 1

Your documented process must include:

- a) how medicines are prescribed
- b) **how the organisation makes sure that all prescription charts are accurate**
- c) **how medication errors are reported**

 d) how the organisation learns from medication errors

 e) how a patient's medicines are managed on handover between care settings

- f) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- g) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation makes sure that all prescription charts are accurate
- how medication errors are reported.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation makes sure that all prescription charts are accurate
- how medication errors are reported.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### Rationale

A prescribed medicine is the most frequent treatment provided for patients in the NHS. Medication errors (particularly prescribing errors) are common, can be serious and sometimes result in death.

There needs to be clear lines of responsibility and accountability for managing risk and clear systems that ensure the prescribing, procurement, production, acquisition, storage, distribution, dispensing, preparation, administration and the safe handling and disposal of medicines occurs.

### Guidance

#### Guidance from other organisations

- General Pharmaceutical Council (2010) *Guidance for Responsible Pharmacists*
- National Institute for Health and Clinical Excellence, National Patient Safety Agency (2007) *Technical patient safety solutions for medicines reconciliation on admission of adults to hospital*
- Nursing and Midwifery Council (2007) *Standards for Medicines Management*
- Patient Safety First 'How to Reduce Harm from High Risk Medicines' *Patient Safety First website page*
- Royal Pharmaceutical Society (2011) *Keeping patients safe when they transfer between care providers – getting the medicines right*

**Standard 6: Mental Health & Learning Disability Services**

2011-12 numbering

<b>6.1 Clinical Supervision*</b>	<b>2.4</b>
<b>6.2 Patient Information</b>	<b>4.1</b>
<b>6.3 Clinical Risk Assessment*</b>	<b>2.7</b>
<b>6.4 Physical Assessment &amp; Examination of Patients*</b>	<b>4.4</b>
<b>6.5 Observation &amp; Engagement of Patients*</b>	<b>4.6</b>
<b>6.6 Dual Diagnosis*</b>	<b>4.3</b>
<b>6.7 Rapid Tranquilisation*</b>	<b>4.8</b>
<b>6.8 Absent Without Leave (AWOL)</b>	<b>3.6</b>
<b>6.9 Medicines Management Training*</b>	<b>2.10</b>
<b>6.10 Medicines Management</b>	<b>4.5</b>

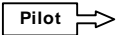
\*Contains a training element

## 6.1 Clinical Supervision

Organisations providing MH&LD services must have an approved documented process for making sure that all clinical staff receive appropriate supervision.

### Level 1

Your documented process must include:

- a) [duties](#)
-  b) how clinical supervision is provided
- c) **how the organisation makes sure that all clinical [staff](#) receive appropriate clinical supervision**
- d) how the organisation makes sure that all clinical [staff](#) receive management supervision
- e) how the organisation trains staff, in line with the [training needs analysis](#)
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation makes sure that all clinical [staff](#) receive appropriate clinical supervision.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation makes sure that all clinical [staff](#) receive appropriate clinical supervision.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Clinical supervision is an essential component in ensuring the provision of safe and accountable practice. It is an activity that brings skilled supervisors and practitioners together in order to reflect upon their practice. Supervision aims to identify solutions to problems, improve practice and increase understanding of professional issues. It contributes significantly to reduce emotional exhaustion among clinical staff. There are various models or approaches to clinical supervision: one-to-one supervision, group supervision, peer group supervision.



## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Guidance from other organisations**

- HM Government (2011) *No health without mental health: a cross-government mental health outcomes strategy for people of all ages*
- Nursing and Midwifery Council (2008) *Clinical Supervision for registered nurses*
- Patient Safety First 'How to Reduce Harm from Deterioration' *Patient Safety First website page*
- Royal College of Psychiatrists (2010) *Self-harm, suicide and risk: a summary. Position statement*
- Sloan, G (2006) *Clinical Supervision in Mental Health Nursing*

## 6.2 Patient Information

Organisations providing MH&LD services must have an approved documented process for managing the risks associated with patient information.

### Level 1

Your documented process must include:

- a) how information is provided to patients to support their decision making, including risks, benefits and alternatives
- b) **how the discussion and provision of information to patients is recorded**
- c) **archiving arrangements for any information given to patients to support their decision making**
- d) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the discussion and provision of information to patients is recorded
- archiving arrangements for any information given to patients to support their decision making.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the discussion and provision of information to patients is recorded
- archiving arrangements for any information given to patients to support their decision making.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### **Rationale**

Patient in all client groups need information and support to help them to make informed choices in relation to the care and treatment they receive. Communicating clear and accessible information to all groups of patients is crucial to facilitating choice and working in partnership to achieve the best outcome. Among the core principles for promoting choice is acknowledging that people have the right to choose their treatment, and that choice applies across the spectrum of care.

Information given to patients should include choices in medication, talking therapies, and access to alternative self-management programmes as well as information on daily care planning.

### **Guidance**

#### **Legislation**

- The Mental Health Act 1983 (as amended by the Mental Health Act 2007)
- The Mental Capacity Act 2005
- Health and Social Care Act 2008

#### **Guidance from other organisations**


- Department of Health (2010) *The NHS Constitution: The NHS belongs to us all*
- General Medical Council (2008) *Consent: Patients and Doctors Making Decisions Together*
- HM Government (2011) *No health without mental health: a cross-government mental health outcomes strategy for people of all ages New Horizons. A shared vision for mental health*
- Human Tissue Authority (2009) *Codes of Practice. Code 1 Consent*

## 6.3 Clinical Risk Assessment

Organisations providing MH&LD services must have an approved documented process for making sure that all clinical staff who undertake assessments of patients are competent in the assessment and management of clinical risk.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- c) tools and processes authorised for use within the organisation, including timescales for use
-  d) how clinical risk assessments are reviewed, including timescales
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation trains [staff](#), in line with the [training needs analysis](#)
- tools and processes authorised for use within the organisation, including timescales for use.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation trains [staff](#), in line with the [training needs analysis](#)
- tools and processes authorised for use within the organisation, including timescales for use.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.

### Rationale

Clinical risk assessment is the process used to determine risk management priorities for patient care by evaluating and comparing the level of risk against organisational standards, predetermined target risk levels or other criteria. The focus should always be on patient safety.

Clinical risk assessment and management are key skills when promoting safety and positive risk taking. It is also important to empower patients to decide the level of risk they are prepared to take with health and safety. This includes working with the tension between promoting safety and positive risk taking, including assessing and dealing with possible risks for patients, carers, family members and the wider public.

### Guidance

#### Template document

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### Guidance from other organisations

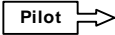
- Department of Health (2007) *Best Practice in Managing Risks: principles and guidance for best practice in the assessment and management of risk to self and others in mental health services*
- HM Government (2011) *No health without mental health: a cross-government mental health outcomes strategy for people of all ages New Horizons. A shared vision for mental health*
- University of Manchester website lists all the National Confidential Inquiries into Suicide and Homicide by People with Mental Illness (NCI/NCISH): [www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)

## 6.4 Physical Assessment & Examination of Patients

Organisations providing MH&LD services must have an approved documented process for managing the risks associated with the physical assessment and examination of patients.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **physical assessment of patients when they are admitted to a service, including timeframes**
- c) how appropriate follow-up of physical symptoms takes place
- d) **ongoing assessment of physical needs for all patients, including timeframes**
-  e) how the organisation assesses the competency of all [staff](#) involved in the physical assessment and examination of patients
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- physical assessment of patients when they are admitted to a service, including timeframes
- ongoing assessment of physical needs for all patients, including timeframes.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- physical assessment of patients when they are admitted to a service, including timeframes
- ongoing assessment of physical needs for all patients, including timeframes.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

It is recognised that poor mental health does not exist in isolation: good mental health is linked to good physical health. People with mental illness have significantly higher rates of mortality and morbidity from physical illnesses such as cardiovascular disease, diabetes and obesity. Despite this, they frequently do not receive the health interventions they need, including screening.

A holistic approach to providing care to services users should be adopted to ensure that the care delivered covers both mental and physical well-being.

## **Guidance**

### **Guidance from other organisations**

- Department of Health (2006) *Choosing Health: Supporting the physical health needs of people with severe mental illness - commissioning framework*
- HM Government (2011) *No health without mental health: a cross-government mental health outcomes strategy for people of all ages New Horizons. A shared vision for mental health*
- Royal College of Psychiatrists (2008) *Linking Physical and Mental Health - Fair Deal For Mental Health*

## 6.5 Observation & Engagement of Patients

Organisations providing MH&LD services must have an approved documented process for the observation and engagement of patients.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **observation at differing levels**
- c) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- d) **how observation is recorded**
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- recording observation at differing levels.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- recording observation at differing levels.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.



### **Rationale**

The key purpose of observation is to provide a period of safety for people during temporary periods of distress when they are at risk of harm to themselves or others. Observation is a therapeutic intervention and includes the assessment of a patient's mental state.

It is important for all mental health professionals, especially staff working in inpatient units, to be trained in the skills and competencies required to practice observation, and be supervised in their practice of therapeutic activity as they would with any other form of treatment.

### **Guidance**

#### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

#### **Guidance from other organisations**

- Department of Health (2006) *Mental health observation, including constant observation: Good practice guidelines for staff working in prisons*
- Patient Safety First 'How to Reduce Harm from Deterioration' *Patient Safety First website page*
- Standard Nursing and Midwifery Advisory Committee (1999) *Practice Guidance. Safe and Supportive Observation of Patients at Risk*
- University of Manchester website lists all the National Confidential Inquiries into Suicide and Homicide by People with Mental Illness (NCI/NCISH): [www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)

## 6.6 Dual Diagnosis

Organisations providing MH&LD services must have an approved documented process for addressing the needs of patients who present with a dual diagnosis of mental health problems and substance misuse.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **how the organisation addresses the needs of this group of patients**
- c) **details of internal and external joint working arrangements**
- d) procedure to be followed where there is a difference of opinion between professionals
- e) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- f) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation addresses the needs of this group of patients
- details of internal and external joint working arrangements.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation addresses the needs of this group of patients
- details of internal and external joint working arrangements.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### **Rationale**

Supporting someone with a mental health illness and substance misuse problems - alcohol and or drug problems is one of the biggest challenges facing frontline mental health services. The complexity of issues makes diagnosis, care and treatment more difficult. One of the main difficulties is that there are a number of agencies involved in a person's care, for example, mental health services, specialist rehabilitation services, organisations in the statutory and voluntary sector. As a result care can be fragmented and aspects of care can be overlooked.

A framework within which staff can work to strengthen services should be developed. Additionally staff must have the skills and knowledge necessary to tackle this demanding area of work. Mental health services must work closely with specialist substance misuse services to ensure that care is well coordinated to maintain high standards of service delivery.

### **Guidance**

#### **Guidance from other organisations**

- Department of Health (2002) *Mental Health Policy Implementation Guide: Dual Diagnosis Good Practice Guide*
- HM Government (2011) *No health without mental health: a cross-government mental health outcomes strategy for people of all ages New Horizons. A shared vision for mental health*
- University of Manchester website lists all the National Confidential Inquiries into Suicide and Homicide by People with Mental Illness (NCI/NCISH):  
[www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)

## 6.7 Rapid Tranquilisation

Organisations providing MH&LD services must have an approved documented process for rapid tranquilisation.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **prescribing guidelines for rapid tranquilisation**
- c) **how observations are recorded, including timeframes when patients have received rapid tranquilisation**
- d) how the organisation trains [staff](#), in line with the [training needs analysis](#)
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- prescribing guidelines for rapid tranquilisation
- how observations are recorded, including timeframes when patients have received rapid tranquilisation.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet all of the above relevant minimum requirements.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- prescribing guidelines for rapid tranquilisation
- how observations are recorded, including timeframes when patients have received rapid tranquilisation.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will be typically equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### **Rationale**

Aggression and violence sometimes occur in mental health settings, and staff need to know how to de-escalate these situations. If de-escalation techniques are unsuccessful, the service user may need to be physically restrained or placed in seclusion. It may also be necessary to administer medication to calm the individual and this may involve rapid tranquillisation.

Rapid tranquillisation should be used to calm or lightly sedate the patient, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place and allowing a robust assessment of the service user's needs.

All staff involved in the intervention should have the appropriate skills and knowledge to carry out all aspects of the process.

### **Guidance**

#### **Legislation**

- The Mental Health Act 1983 (as amended by the Mental Health Act 2007)
- The Mental Capacity Act 2005

#### **Guidance from other organisations**

- Department of Health (2004) *Mental Health Policy Implementation Guide: Developing Positive Practice To Support The Safe And Therapeutic Management Of Aggression And Violence In Mental Health In-Patient Settings*
- National Institute for Clinical Excellence (NICE) (2005) *CG25. Violence: The Short-Term Management Of Disturbed/Violent Behaviour In In-Patient Psychiatric Settings And Emergency Departments*

## 6.8 Absent Without Leave (AWOL)

Organisations providing MH&LD services must have an approved documented process for managing the risks associated with patients who are absent without leave (AWOL).

### Level 1

Your documented process must include:

- a) [duties](#)
- b) **what should be done when a patient absents themselves from an inpatient setting**
- c) **what should be done when a patient fails to return from a period of leave of absence**
- d) how the organisation learns from AWOL incidents
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- what should be done when a patient absents themselves from an inpatient setting
- what should be done when a patient fails to return from a period of leave of absence.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- what should be done when a patient absents themselves from an inpatient setting
- what should be done when a patient fails to return from a period of leave of absence.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

#### Rationale

Organisations have a clear responsibility to ensure that patients who suffer from mental health problems receive high quality care and treatment in the least restrictive environments, including inpatient and secure settings, in their own homes and in alternative settings such as care homes. A balance has to be struck between the patient autonomy and the patient safety; this can be difficult at times. Therefore if the situation arises where a patient who has been admitted for their own protection leaves the clinical environment swift action should take place to return them as soon as possible. Organisations must develop robust documentation to address this issue.

## **Guidance**

### **Template document**

A template document has been created to assist organisations in complying with the criterion, but its use is entirely optional. It is available for downloading from the NHSLA website at [www.nhsla.com/publications](http://www.nhsla.com/publications), under Risk Management Publications followed by Document Templates.

### **Legislation**

- Mental Health Act 1983 (as amended by the Mental Health Act 2007)
- Code of Practice to the Mental Health Act 1983
- Mental Capacity Act 2005
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

### **Guidance from other organisations**

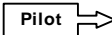
- University of Manchester website lists all the National Confidential Inquiries into Suicide and Homicide by People with Mental Illness (NCI/NCISH):  
[www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)

## 6.9 Medicines Management Training

Organisations providing MH&LD services must have an approved documented process which sets out the medicines management training requirements for all permanent staff.

### Level 1

Your documented process must include:

- a) [duties](#)
- b) how the organisation records that all [permanent staff](#) complete relevant medicines management training, in line with the [training needs analysis](#)
- c) how the organisation follows up those who do not complete relevant medicines management training
-  d) action to be taken in the event of persistent non-attendance
- e) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete relevant medicines management training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete relevant medicines management training.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation records that all [permanent staff](#) complete relevant medicines management training, in line with the [training needs analysis](#)
- how the organisation follows up those who do not complete relevant medicines management training.

Where the [monitoring](#) has identified less than 95% completion of training, you must evidence that changes have been made to address this.



### **Rationale**

It is important that staff who work with medicines are educated in best practice, and to ensure that guidelines are followed and patient safety maintained. The training provided should cover all aspects of medicines management to ensure that staff are competent to carry out their role. It is imperative to ensure that systems are in place to check the ongoing competency of staff.

Organisations should have a policy on how they will review the medicines of patients in their care which covers the training and competency requirements for undertaking reviews and the triggers for undertaking a comprehensive review.

### **Guidance**

#### **Legislation**

- Health Act 2006
- The Controlled Drugs (Supervision of Management and Use) Regulations 2006. SI 2006/3148
- The Misuse of Drugs Regulations 2001. SI 2001/3998
- The Misuse of Drugs (Safe Custody) Regulations 1973, amended 2007

#### **Guidance from other organisations**

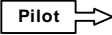
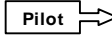
- Care Quality Commission website provides further information and resources: [www.cpc.org.uk](http://www.cpc.org.uk)
- Department of Health website provides further information on medicines management: [www.dh.gov.uk](http://www.dh.gov.uk)
- National Prescribing Centre website provides further information and resources: [www.npci.org.uk](http://www.npci.org.uk) and [www.npc.org.uk](http://www.npc.org.uk)
- University of Manchester website lists all the National Confidential Inquiries into Suicide and Homicide by People with Mental Illness (NCI/NCISH): [www.medicine.manchester.ac.uk](http://www.medicine.manchester.ac.uk)

## 6.10 Medicines Management

Organisations providing MH&LD services must have an approved documented process for medicines management in all care settings.

### Level 1

Your documented process must include:

- a) how medicines are prescribed
- b) **how the organisation makes sure that all prescription charts are accurate**
- c) how the side effects of prescribed medication are monitored
-  d) how the organisation learns from medication errors
- e) how medication is administered, including patient identification
- f) patient self-administration
-  g) how a patient's medicines are managed on handover between care settings
- h) how drugs are disposed of safely
- i) how the organisation [monitors](#) compliance with all of the above.

### Level 2

You must evidence implementation of your documented process in relation to:

- how the organisation makes sure that all prescription charts are accurate.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

### Level 3

You must evidence [monitoring](#) of your documented process in relation to:

- how the organisation makes sure that all prescription charts are accurate.

Where your [monitoring](#) has identified shortfalls, you must evidence that changes have been made to address them.

The assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for this criterion.

### **Rationale**

Managing medicines safely, efficiently and effectively is a key component for the delivery of high quality patient centred care. Medicines play a significant role in the care of users of mental health and learning disability services and as a consequence medicines management must be a priority for this type of organisation. Policies and procedures should support good practice in medicines management, creating an effective system designed to assist patients using mental health and learning disability services to have positive outcomes rather than leaving practice to chance.

### **Guidance**

#### **Legislation**

- Health Act 2006
- The Controlled Drugs (Supervision of Management and Use) Regulations 2006. SI 2006/3148
- The Misuse of Drugs Regulations 2001 2001/3998
- The Misuse of Drugs (Safe Custody) Regulations 1973, amended 2007

# 10. Appendices

- A. Training Needs Analysis Minimum Data Set
- B. Employment Checks Minimum Data Set
- C. Nice Guidelines Minimum Data Set
- D. Health record checks
- E. Changes to the standards since previous version
- F. Overview of proposed changes to the standards
- G. Clarification of terms used in the standards

## A. Training Needs Analysis (TNA) Minimum Data Set

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Within the NHSLA risk management standards there are key subject areas in relation to risk which incorporate aspects of training. The organisation must therefore ensure it includes the following areas of risk management training within the training needs analysis at 1.3.5. Please note this list is not exhaustive and if any additional risk management training specific to the organisation is provided this could be included within the evidence.

The list below applies to all NHS trusts providing acute, community or mental health & learning disability services and non-NHS providers of NHS care, except where otherwise indicated.

As a minimum the following must be included:

### Standard 1

- Health Record-Keeping Training (criterion 1.8)

### Standard 2

- Investigation of Incidents, Complaints & Claims Training (criterion 2.6)

### Standard 3

- Risk Awareness Training for Senior Management (3.6)
- Moving & Handling Training (criterion 3.7)
- Harassment & Bullying Training (criterion 3.8)

### Standard 4

- Violence & Aggression Training (criterion 4.2)
- Slips, Trips & Falls Training (Staff & Others) (criterion 4.3)
- Slips, Trips & Falls Training (Patients) (criterion 4.4)
- Hand Hygiene Training (criterion 4.6)
- Inoculation Incident Training (criterion 4.7)

### Standard 5 - Organisations providing acute and community services and non-NHS providers of NHS care

- Consent Training (criterion 5.3)
- Transfusion Process Training (criterion 5.8)
- Venous Thromboembolism Training (criterion 5.9)
- Medicines Management Training (criterion 5.10)

**Standard 6 - Organisations providing MH&LD services**

- Clinical Supervision Training (criterion 6.1)
- Clinical Risk Assessment Training (criterion 6.3)
- Observation of Patients Training (criterion 6.5)
- Dual Diagnosis (Mental Health & Substance Misuse) Training (criterion 6.6)
- Rapid Tranquilisation Training (criterion 6.7)
- Medicines Management Training (criterion 6.9)

## B. Employment Checks Minimum Data Set

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NHS Employers have published a set of six employment standards in conjunction with the Department of Health and employers in the NHS. These documents make up the [NHS Employment Check Standards \(2010\)](#).

The NHS Employment Check Standards outline the mandated requirements that NHS organisations and non-NHS providers of NHS care must carry out on all prospective employees before they take up appointment in the NHS, regardless to their term of contract. Where organisations appoint temporary staff they will need to ensure that their providers comply with these standards.

As a minimum the following must be considered:

- Verification of identity checks
- Right to work checks
- Employment history and reference checks
- Professional registration and qualification checks
- Occupational health checks
- Criminal record checks

These standards replace previous NHS Employers guidance on safer recruitment and outline the employment checks NHS organisations and non-NHS providers of NHS care must carry out.

## C. NICE Guidelines Minimum Data Set

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At a Level 2 assessment, the assessor will select two guidelines from the list below to assess compliance with the minimum requirements for criterion 2.8 Best Practice - NICE.

Guidance specific support tools are available on the NICE website at [www.nice.org.uk/usingguidance](http://www.nice.org.uk/usingguidance).

### NICE guidelines relevant to acute and community services

- CG3 [Preoperative tests](#)
- CG7 [Pressure relieving devices](#)
- CG29 [Pressure ulcer management](#)
- CG43 [Obesity](#)
- CG50 [Acutely ill patients in hospital](#)
- CG76 [Medicines adherence](#)
- CG75 [Metastatic spinal cord compression](#)
- CG85 [Glaucoma](#)
- CG88 [Low back pain](#)
- CG89 [When to suspect child maltreatment](#)
- CG91 [Depression with a chronic physical health problem](#)
- CG92 [Venous thromboembolism - reducing the risk](#)
- CG95 [Chest pain of recent origin](#)
- CG97 [Lower urinary tract symptoms](#)
- CG101 [Chronic obstructive pulmonary disease](#)
- CG103 [Delirium](#)
- CG104 [Metastatic malignant disease of unknown primary origin](#)
- CG108 [Chronic heart failure](#)
- CG124 [Hip fracture](#)



**NICE guidelines relevant to paediatric care**

- CG54 [Urinary tract infection in children](#)
- CG84 [Diarrhoea and vomiting in children](#)
- CG89 [When to suspect child maltreatment](#)
- CG99 [Constipation in children and young people](#)
- CG102 [Bacterial meningitis and meningococcal septicaemia](#)
- CG112 [Sedation in children and young people](#)
- CG115 [Alcohol-use disorders](#)

**NICE guidelines relevant to mental health & learning disability services**

- CG25 [Violence](#)
- CG26 [Post traumatic stress disorder](#)
- CG38 [Bipolar disorder](#)
- CG42 [Dementia](#)
- CG78 [Borderline personality disorder](#)
- CG82 [Schizophrenia](#)
- CG90 [Depression in adults \(update\)](#)
- CG91 [Depression with a chronic physical health problem](#) (should be linked with CG90)
- CG120 [Psychosis and substance misuse](#)

## D. Health record checks

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### Level 2

At a Level 2 assessment, for the following criteria the assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#).

To award a score the assessors will need to be assured that 75% of the records presented for each criterion meet all of the relevant minimum requirements.

### Level 3

At a Level 3 assessment, for the following criteria the assessor will look at between 10 and 30 health records in current use in order to spot check the organisation's [monitoring](#) results. This will typically be equivalent to 10% of all [daily admission numbers](#).

If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being awarded for that criterion.

### Standard 1

- Health Records Management (criterion 1.7)
- Health Record-Keeping Standards (criterion 1.8)

### Standard 4

- Slips, Trips & Falls (Patients) (criterion 4.4)
- The Deteriorating Patient (criterion 4.8)
- Clinical Handover of Care (criterion 4.9)
- Discharge (criterion 4.10)

### Standard 5

- Patient Information & Consent (criterion 5.2)
- Transfusion (criterion 5.8)
- Venous Thromboembolism (criterion 5.9)
- Medicines Management (criterion 5.10)

### Standard 6

- Patient Information (criterion 6.2)
- Observation & Engagement of Patients (criterion 6.5)
- Dual Diagnosis (criterion 6.6)

- Rapid Tranquilisation (criterion 6.7)
- Medicines Management (criterion 6.10)

## E. Changes to the standards since previous version

### Key changes

Information on the changes to the standards for 2012-13 is set out below.

In a number of the criteria the wording of the statement relating to the process for documentation has been changed to ensure consistency, or to simplify the language used but this has not changed what is required.

We have changed the order and headings in the introduction to the manual to make it easier to understand and find the information that you need. The language throughout the manual has been made simpler and clearer so that it is easier to understand.

### Introduction to the standards

The changes or additions that have been made to the introduction to the standards are:

- The objectives of the standards have been updated (p.6).
- The information for non-NHS providers on being assessed has been updated (p.10).
- We have changed the way that assessors are allocated (p.22).
- There are now 60 criteria in total, incorporating the mental health & learning disability criteria; please refer to the introduction for how these will apply to your organisation (p.13).
- Criteria that are removed from the standards will be included in the manual as an appendix (p.12).
- We will now be randomly selecting ten documents at all levels to check use and availability (p.15).
- At Level 2 and 3 a number of criteria are now being assessed through a review of health records, and a minimum of 75% implementation must be achieved (p.24).
- Pilot criteria will no longer be included in the manual and will be tested outside of the assessment process (p.12).
- Changes to the manual are now included as an appendix rather than as part of the introduction.
- The rationale and references from the handbook are now included in the standards manual.

### Changes to the names of criteria

2012-13	2011-12
1.3 High Level Risk Committee(s)	1.3 Risk Management Committee(s)
1.6 Dealing with External Recommendations Specific to the Organisation	1.7 Responding to External Recommendations Specific to the Organisation

2012-13	2011-12
4.8 The Deteriorating Patient	4.7 Resuscitation
4.9 Clinical Handover of Care	4.9 Transfer of Patients
2.4 Claims Management	5.4 Claims
2.6 Analysis & Improvement	5.6 Analysis AND 5.7 Improvement
6.5 Observation & Engagement of Patients	4.6 Observation of Patients

### Pilot minimum requirements

Pilot minimum requirements are listed in the table below. These will be assessed on a pilot basis only in 2012-13 and failure to meet them will not result in the organisation failing the relevant criterion.

Criterion	Pilot minimum requirement
1.4 Risk Management Process	d. how risks are escalated through the organisation
1.6 Dealing with External Recommendations Specific to the Organisation	a. process for reviewing external recommendations specific to the organisation b. process for reporting on external recommendations specific to the organisation
3.1 Corporate Induction	d. timescales for completion of corporate induction
3.2 Local Induction of Permanent Staff	c. timescales for completion of local induction
3.3 Local Induction of Temporary Staff	c. timescales for completion of local induction
3.4 Risk Management Training	f. action to be taken in the event of persistent non-attendance
3.7 Moving & Handling Training	d. action to be taken in the event of persistent non-attendance
4.2 Violence & Aggression	c. timescales for review of risk assessments d. how action plans are developed as a result of risk assessments e. how action plans are followed up
4.6 Hand Hygiene Training	d. action to be taken in the event of persistent non-attendance
4.8 The Deteriorating Patient	a. requirement for a documented plan for vital signs monitoring that identifies which variables need to be measured, including the frequency of measurement
4.9 Clinical Handover	b. how handover is recorded
4.10 Discharge	d. how a patient's medicines are managed on discharge
5.1 Supervision of Medical Staff in Training	Level 2 In addition, you must evidence that issues relating to the supervision of medical staff are reported to, and discussed,

Criterion	Pilot minimum requirement
	at least quarterly at a committee. Level 3 In addition you must evidence that shortfalls identified within the quarterly reports are being addressed.
5.3 Consent Training	e. <b>how the organisation notifies the GMC via the required form, of any individual who has obtained consent without the authorisation to do so</b>
5.4 Maintenance of Medical Devices & Equipment	b. how the organisation includes all items of diagnostic and therapeutic equipment on an inventory
5.5 Medical Devices Training	b. how the organisation includes all items of diagnostic and therapeutic equipment on an inventory g. how the organisation follows up those who do not complete training h. action to be taken in the event of persistent non-attendance
5.6 Screening Procedures	a. a list of screening procedures carried out on the organisation's own patients b. how the organisation risk assesses the screening procedures c. how the screening procedure is requested f. how the patient is followed-up or referred, including timescales
5.7 Diagnostic Testing Procedures	a. a list of the diagnostic tests carried out within the organisation b. how the organisation risk assesses the diagnostic testing procedures f. actions to be taken by the clinician, including timescales
5.10 Medicines Management	d. how the organisation learns from medication errors e. how a patient's medicines are managed on handover between care settings
6.1 Clinical Supervision	b. how clinical supervision is provided
6.3 Clinical Risk Assessment	d. how clinical risk assessments are reviewed, including timescales
6.4 Physical Assessment & Examination of Patients	e. how the organisation assesses the competency of all staff involved in the physical assessment and examination of patients
6.9 Medicines Management Training	d. action to be taken in the event of persistent non-attendance
6.10 Medicines Management	d. how the organisation learns from medication errors g. how a patient's medicines are managed on handover between care settings

## Changes to minimum requirements (not piloted)

### Standard 1

- 1.1.1c (previously 1.1.1d) - removal of reference to organisation-wide strategy
- 1.1.3 – change in order of minimum requirements
- 1.1.3g (previously 1.1.3b) - clarification that reporting to board is from high level risk committee(s)
- 1.1.4a (previously 1.1.5a) - *all* risks rather than all ‘types’ of risk to be assessed
- 1.1.4c (previously 1.1.5c) – authority levels rather than management levels
- 1.1.4c (previously 1.1.1e) – minimum requirement moved from Risk Management Strategy to Risk Management Process
- 1.5 (previously 1.6) – sources of risk for higher levels now includes external recommendations
- 1.1.5a (previously 1.1.6a) – *local* risk registers
- 1.6 (previously 1.7) – action plan process broken down; adding to risk register moved to 1.5
- 1.7 (previously 1.8) – change in order of minimum requirements; change in minimum requirements carried forward for assessment at higher levels
- 1.1.7d (previously 1.1.8c) – tracking records *when in current use*
- 1.8 (previously 4.2) – removal of minimum requirement a) ‘duties’
- 1.1.8b (previously 1.4.2b) – healthcare professionals changed to *all staff*
- 1.1.9b and c – all clinical staff – both temporary and permanent
- 1.1.9d - directly employed clinical staff rather than permanent clinical staff (included temporary directly employed clinical staff)
- 1.1.10e – all staff not just temporary

### Standard 2

- 1.2.1c (previously 1.5.1c) – clarified that audits need to follow the audit process approved within the organisation
- 2.5 (previously 5.5) – emphasis in overarching text that investigations should *enable learning*
- 2.6 (previously 5.6 and 5.7) – this is now a combination of elements from 5.6 (Analysis) and 5.7 (Improvement)
- 2.6 (previously 5.6) – change in minimum requirements carried forward
- 1.2.6b, c and g (previously 1.5.6b and c) – clarification that incidents, complaints and claims need to be analysed together in order to provide a risk profile for the organisation
- 1.2.6d (previously 1.5.6d) – clarification that easiest way to describe the minimum content of the analysis report is to provide a report template containing the required information
- 1.2.6f (previously 1.5.7) – the requirement for action plans in this criterion replaces the minimum requirements of 1.5.7 for 2011-12 which required sharing of lessons, ensuring learning and implementing risk reduction measures
- 2.7 – Learning from Claims – an additional criterion has been added which is not being piloted as it is looking at work that organisations have already been requested to undertake by the NHSLA
- 2.8 (previously 5.8) – removal of requirement to ‘disseminate relevant documents’

- 1.2.8a (previously 1.5.8a) – removal of ‘leadership for all stages of the process’ as the organisation can choose how it wants to describe duties
- 1.2.8b (previously 1.5.8b) – clarification it is NICE guidelines that need identifying as relevant
- 1.2.8d (previously 1.5.8e and f) – action plan will include acting on recommendations, and also record decisions not to implement NICE guidance
- 2.9 (previously 5.9) – removal of requirement to ‘disseminate relevant documents’
- 1.2.9b (previously 1.5.9b) – clarification it is National Confidential Enquiry/Inquiry recommendations that need identifying as relevant
- 1.2.9d (previously 1.5.9f and g) – action plan will include acting on recommendations, and also record decisions not to implement recommendations

#### Standard 4

- 4.1 (previously 3.1) – removal of minimum requirement b) on producing a lockdown risk profile; action plan process broken down
- 4.5 (previously 3.4) – action plan process broken down
- 4.8 (previously 4.7) – change from resuscitation to ‘the deteriorating patient’
- 1.4.8c (previously 1.4.7c) – ‘post-resuscitation care’ changed to specify actions taken to minimise further deterioration
- 1.4.8e (previously 1.4.7e) – clarification availability of resuscitation equipment means it needs to have been documented as ‘checked, stocked and fit for use’
- 1.4.8 (previously 1.4.7) – training requirement removed
- 4.9 – removal of requirement to define patient groups
- 1.4.9a – change from transfer to handover, applies to *all care settings*, and now need to describe giving and receiving of information
- 4.10 – removal of requirement to define patient groups
- 1.4.10b and e (previously 1.4.10d) – documentation to accompany patient clarified to mean information to be given to the receiving healthcare professional, plus how this is recorded
- 1.4.10c (previously 1.4.10e) – now carried forward for assessment at the higher levels
- 1.4.10e – need to describe how information given is recorded

#### Standard 5

- 1.5.3a (previously 1.2.10a) – reworded to identify that we would expect the organisation to cover all generic and procedure specific training within the approved document
- 1.5.5e and f (previously 1.2.7d) – previous minimum requirement split to add clarity to the criterion so that frequency of update and recording of training are addressed separately
- 1.5.6 d, e and f (previously 1.4.3a, b and c) – wording changed to clarify that the actions to be taken are patient referral and follow-up, and that it is the clinician and patient who need to be informed of the results
- 1.5.7 d, e, f and g (previously 1.4.4b, c and d) – wording changed to clarify that the actions to be taken are by the clinician, and that it is the clinician and the patient who need to be informed of the results
- 5.9 (previously 4.8) – change of carried forward minimum requirement



- 1.5.9a (previously 1.4.8a) – timescales need to be included
- 5.10 (previously 4.5) – removal of minimum requirements c) and d) regarding administration; and removal of minimum requirement e) on safe disposal of drugs
- 1.5.10c (previously 4.5) – addition of requirement c) ‘how medication errors are reported’ – not piloted as would have been part of incident reporting

### Standard 6

- 1.6.3c (previously 1.2.7c MH) – timescales need to be included
- 6.5 (previously 4.6 MH) – inclusion of ‘engagement’ in overarching text
- 6.6 (previously 4.3 MH) – shift of focus in the overarching text from managing the risks to addressing the needs of patients
- 1.6.7c (previously 1.4.8c MH) – timescales need to be included

### Changes to the training criteria and criterion 3.5 (previously 2.6) Training Needs Analysis

- All criteria containing training requirements that are contained within the TNA Minimum Data Set are marked with an asterisk at the beginning of each standard.
- Where training requirements are carried forward to the higher levels, at Level 1 a pilot requirement to address persistent non-attendance has been added, and at Level 3 95% attendance must be shown or evidence provided of how this is being addressed; this includes the induction criteria in Standard 3.
- Training criteria (marked with \* in the list of criteria at the beginning of each standard) ask for the organisation to describe how they *record* completion of training - this is a change in emphasis from ‘checking’ that training is completed – checking is covered at higher levels.
- All training requirements ask for recording *completion* of training, rather than only attendance.
- Risk Awareness Training for Senior Management added to TNA.
- Resuscitation Training has been removed from the TNA.

### Changes to method of assessment

- For all those criteria listed in [Appendix D - Health record checks](#) the assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all [daily admission numbers](#). To award a score the assessors will need to be assured that the 75% of the records presented for each criterion meet all of the relevant minimum requirements.
- The random selection of ten documents at Level 1 to check use and availability has been extended to Levels 2 and 3. If the organisation is unable to evidence that a document is approved and in use then it will fail the relevant criterion rather than the whole assessment.
- 1.4 – Risk Management Process – drop down list at higher levels ‘two risk categories, from those defined within the organisation’s documentation’.
- 1.5 – Risk Management Register – drop down list at higher levels ‘two sources of risk, from the above list’.
- 2.8 – Best Practice – NICE – drop down list at higher levels to select NICE guidelines – removal of interventional procedures, and specified list of guidelines to choose from.

- 2.8 – Best Practice – NICE – at Level 3, the assessor will be looking at the gap analysis process for all NICE guidance and then will spot check from the list of NICE guidelines.
- 5.1 – Supervision of Medical Staff in Training – as well as taking assurance from GMC, a pilot requirement has been added to provide evidence of discussion of any issues around supervision.
- 5.5 – Medical Devices Training – incident database to be reviewed and two medical devices selected.
- 5.6 – Screening Procedures – assessors will look at documented processes for individual screening procedures that the organisation has assessed as high risk rather than just the overarching document.
- 5.7 – Diagnostic Testing Procedures – assessor will look at documented processes for individual diagnostic testing procedures that the organisation has assessed as high risk rather than just the overarching document.

## F. Overview of proposed changes to the standards

During 2012/13 the NHSLA will continue to explore proposals to further develop its risk management standards and assessments, including:

- Proportional assessments
- Assessment frequency
- Assessment dates

Updates on progress with the proposals will be provided in the NHSLA's e-newsletter *Risk E-News*.

The NHSLA will also continue its review of the discounts from schemes contributions given to organisations for demonstrating compliance with the risk management standards at assessment. Any changes are likely to favour organisations achieving the higher levels.

The standards manual has recently been revised to simplify the language. This process will be ongoing in an aim to use a more plain English approach.

### Detailed standards

The standards and assessment process are reviewed annually to ensure that they continue to meet their objectives. The review process is continuous with a key aim being to ensure that each year the standards are published on time, allowing organisations time to prepare for assessment.

Throughout the year a DNV and NHSLA project group reviews national guidance, consults with stakeholders and reviews feedback on the standards and assessment process. Feedback from organisations and the assessment team has the most significant impact on the standard review process. In addition assessment data is reviewed to identify trends.

This review process often highlights the need for new criteria to cover new or emerging risk areas. When new criteria are to be introduced they are piloted for one year to enable them to be tested and allow organisations preparation time before being formally assessed against them.

In future, pilot criteria will no longer be included in the standards manual but published in a separate document on the NHSLA website at the beginning of the financial year. Organisations and other stakeholders will have the opportunity to comment on them and influence their development. More information on this will be provided when the pilot criteria for 2012/13 are published.

Pilot criteria will be tested in a small number of organisations. The NHSLA plans to ask those organisations that are members of the NHSLA Risk Management Forum to participate in the pilot process but other volunteers would be welcomed.

When criteria are removed in their entirety they will be included in an appendix. Organisations are advised to continue managing these risk areas as they may be reintroduced to the assessment process at any time without the need to be piloted.

### Assessment process

The NHSLA may change the Level 1 requirements carried forward for assessment at Levels 2 and 3 wholly or in part at any time in the future. These and other minor changes to individual criteria or minimum requirements will not be piloted.

The NHSLA may also increase or decrease the health and training records sample size required at Levels 2 and 3 at any time in the future.

The need for organisations to demonstrate that processes to manage risks have been implemented in at least 75% of cases to achieve compliance at Level 2 and 3 may be introduced in the future.

The NHSLA may also introduce an appropriate standard of compliance for the training criteria whereby organisations will have to demonstrate that 75% of all staff groups have been trained against the risk management training included in the Training Needs Analysis - Minimum Data Set over a full 12 month period at Levels 2 and 3.

In addition to this in future years there may be a requirement for organisations to show improvements in the level of compliance within each criterion at subsequent higher level assessments. For example where previously 75% of relevant staff have attended training this should have increased to at least 80% at the next assessment.

The NHSLA is exploring the possibility of changing the assessment process to allow organisations to present evidence at Level 1, 2 or 3, within a single assessment depending on the maturity of that particular risk area. This new process would take away the need for organisations to declare ahead of the assessment which level they want to be assessed at and the outcome of the assessment would be determined by the evidence presented.

#### **Risk areas identified for possible inclusion in future standards:**

- Burns and scalds
- X-ray
- Tissue viability
- Cannulation tissue viability
- Staff welfare (by amalgamating the stress, bullying and harassment and supporting staff criteria)
- Surgery check list
- Nutrition
- Staffing levels
- Leadership
- Suicide (for mental health organisations)

#### **Criteria which may be changed next year:**

1.7 Healthcare Records Management – where the assessors see loose documentation in the health records, compliance will not be awarded for this criterion

1.5 Risk Register – assessment process may be changed to include the use of a drop down list at Levels 2 and 3 to allow assessors to focus in more depth on a certain areas

4.9 Clinical Handover – may focus on shift changes

#### **Criteria considered for removal in 2013/14:**

- Stress
- Bullying and Harassment
- Supporting Staff
- Transfusion

- Secure Environment
- Being open
- Hand hygiene

## G. Clarification of terms used in the standards

- **Approved**

Approved documentation is that which has been ratified by the relevant body within the organisation as set out in its policy on procedural documents.

- **Basic record-keeping standards**

Good record-keeping is essential in supporting safe and effective care. Basic standards should be defined, and be evident in all forms of the health record; these may be set in accordance with recommendations from regulatory or professional bodies, for example NMC, GMC, RCoP

- **Clinical audit**

Clinical audit provides a method for systematically reflecting on and reviewing practice.

- **A local clinical audit** is one an organisation chooses to undertake based on its own requirements; funding will be arranged by the organisation.
- **National clinical audit:**
  - seeks to assess and drive improvements in clinical practice at a national level (England);
  - the focus is the quality of clinical practice;
  - evaluates practice against agreed clinical criteria/guidelines including collection of outcomes data;
  - supports the complete audit cycle conducted at local trust level and monitors clinical/patient outcomes data in an ongoing way;
  - includes patients in their governance and takes data from patients themselves.

National clinical audit is designed to improve patient outcomes across a wide range of medical, surgical and mental health conditions. Its purpose is to engage all healthcare professionals across England and Wales in systematic evaluation of their clinical practice against standards and to support and encourage improvement in the quality of treatment and care.

Most national clinical audits have been developed because they are in an area of medicine that is highly important and where it is felt that national results are essential to improve practice and standards. In all cases they form part of a broader approach to improve quality, and fit into the information strategy of the condition involved, especially in areas like cancer or diabetes which have national information strategies.

Such audits are backed by the relevant Royal College and the national clinical director concerned, and usually have the support and engagement of the relevant national voluntary organisation which represents patient interests.

For more information please go to [www.hqip.org.uk](http://www.hqip.org.uk).

- **Concerns and complaints**

All NHS bodies (and local authorities) must provide information that explains very clearly how people can give their views and complain. When a person has made their concern or complaint known, organisations must act upon that.

- **Daily admission numbers**

This is the number patients that are admitted to the organisation on a daily basis for emergency or elective care. The organisation should review these numbers over a two week period and provide the assessor with an average daily rate at the opening meeting on which to base the sample of health records required to be viewed during the assessment.

- **Deteriorating patient**

The identification and recognition of sudden physiological deterioration in acutely ill patients, which must include all patient groups, to prevent increasing deterioration and subsequent cardio respiratory arrest.

- **Diagnostic test**

A test or measurement that can be used to determine what conditions, diseases or syndromes a patient may currently have or is likely to develop.

- **Discharge**

The formal release of a patient at the conclusion of a hospital stay or series of treatments. This may incorporate the transfer of care to another provider.

- **Disposal and destruction (as applied to health records)**

- **Disposal** as applied to health records may include one or more of the following: the transfer of selected records to an archive facility which may be off site; transfer from one application to another, paper to scanned electronic record or Microfiche.
- **Destruction** is the process of eliminating or deleting records beyond any possible reconstruction.

- **Duties**

This encompasses both strategic and operational roles, and can be an individual, for example, the Finance Director, or a committee, for example, the Risk Management Group.

- **GMC form**

The form to use to notify the GMC of any individual who has obtained consent without the authorisation to do so is available at: <http://www.gmc-uk.org/education>

- **Handover**

The efficient transfer of high quality clinical documented information used by all healthcare professionals to ensure that continuity of care and safety for patients is maintained.

- **Inoculation incident**

This includes any incident where there is a risk of acquiring infection due to occupational exposure to blood-borne viruses through contact with blood or body fluids, by inoculation, absorption or

inhalation. Examples include needle or other sharp instrument injuries; the contamination of damaged skin or mucous membranes by infected body fluids.

- **Joint complaints**

This relates to complaints that are made about care delivered by more than one organisation. It is important to provide a single point of contact and a single response to the complainant.

- **Local**

A subdivision of the organisation, for example, division, directorate, speciality or business unit.

- **Medical device**

The term 'medical device' encompasses medical devices as legally defined in the Medical Devices Regulations. This refers to an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or physical impairment;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception.

A medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. This definition includes devices intended to administer a medicinal product, such as a syringe driver, or which incorporate a substance defined as a medicinal product, such as a drug-eluting stent.

MHRA (2006) *Device Bulletin: Managing Medical Devices: Guidance for healthcare and social services organisations*

- **Monitor/monitoring**

Organisations should measure, monitor and evaluate compliance with the minimum requirements within the NHSLA risk management standards. This should include the use of audits and data related to the minimum requirements. The organisation should define the frequency and detail of the measurement, monitoring and evaluation processes.

Monitoring demonstrates whether or not the process for managing risk, as described in the approved documentation, is working across the entire organisation. Where failings have been identified, action plans must have been drawn up and changes made to reduce the risks. Monitoring is normally proactive - designed to highlight issues before an incident occurs - and should consider both positive and negative aspects of a process.

- **Physical security**

This term relates to buildings and objects.

- **Premises and assets**

- **Premises are** the physical buildings in which NHS staff and professionals work, where patients are treated and from which the business of the NHS is delivered.



- **Assets**, irrespective of their value, can be defined as the materials and equipment used to deliver NHS healthcare. In respect of staff, professionals and patients it can also mean the personal possessions they retain whilst working in or providing services to the NHS.

- **Screening**

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition.

The risk assessment of screening procedures is a way for you to identify the risks associated with those procedures, and then prioritise actions.

- **Staff**

People working within any healthcare organisation, supporting the daily activities required for diagnostic, therapeutic, interventional care and treatments.

- **All staff** includes all staff directly employed under a contract of employment with the organisation. Staff will range from the chief executive to the portering staff. Staff have different responsibilities and areas of capability. Each member of staff will have individual requirements for training and competency development which can be linked the Training Needs Analysis.
- **Permanent staff** includes medical, clinical staff including allied healthcare professionals and medical staff in training
- **Temporary staff** are workers supplied by one organisation (locum or staffing agency, for example, NHS Professionals) for the temporary use of another organisation. Temporary staff are the employees of the supplying organisation.

- **Tracked**

This is the process whereby once the health record is created or re-assigned to a patient its location can be determined at any point in time. The process of tracking supports clinical care and information governance.

- **Transfusion**

The transfusion of blood or blood components. Safe transfusion practice is aimed at all staff groups involved in the administration of blood or blood components, including medical and nursing staff, operating department practitioners, clinical support workers and porters.

- **Training needs analysis**

A breakdown, usually presented in the form of a spreadsheet or table, which contains as a minimum: all staff groups; all training required by each group; and the frequency of training required by each group. The training needs analysis (TNA) may also include further details such as who will provide the training, the specific training package to be used, etc.

Refer to the [Training Needs Analysis \(TNA\) Minimum Data Set](#) for the items which need to be included in relation to risk management training in order to achieve compliance with the NHSLA Risk Management Standards.

- **Workplace stressors**

Organisational factors identified by undertaking a systematic risk assessment. For the HSE definition see the Management Standards at [www.hse.gov.uk](http://www.hse.gov.uk).