# Review of compliance

Basildon and Thurrock University Hospitals NHS Foundation Trust  
**Basildon Hospital**

<table>
<thead>
<tr>
<th>Region:</th>
<th>East</th>
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</table>
| **Location address:** | Basildon Hospital  
Nethermayne  
Basildon  
Essex  
SS16 5NL |
| **Type of service:** | ACS Acute services |
| **Regulated activities provided:** | Treatment of disease, disorder or injury  
Surgical procedures  
Diagnostic and screening procedures  
Maternity and midwifery services  
Termination of pregnancies  
Management of supply of blood and blood-derived products |
| **Type of review:** | Responsive review |
Review of compliance

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<tr>
<th>Date of site visit (where applicable):</th>
<th>28/09/2010</th>
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<tr>
<td>Name of site(s) visited (where applicable):</td>
<td>Basildon hospital</td>
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<td>Date of publication:</td>
<td>14/12/2010</td>
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## Information for the reader

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<th>Document purpose</th>
<th>Review of compliance report</th>
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<tr>
<td>Author</td>
<td>Care Quality Commission</td>
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## Care Quality Commission

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## Introduction to our review of compliance

By law, providers of certain adult social care and health care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards that everyone should be able to expect when they receive care.

The Care Quality Commission (CQC) has written guidance about what people who use services should experience when providers are meeting essential standards. This is called *Guidance about compliance: Essential standards of quality and safety*.

CQC licenses services if they meet essential standards and we will constantly monitor whether they continue to do so. We formally review a service when we receive information that is of concern and, as a result, decide we need to check whether it is still meeting one or more of the essential standards. We also formally review services at least every two years to check whether they are meeting all of the essential standards in each of their locations. Our reviews include checking all the available information and intelligence we hold about a provider. We may seek more information by contacting people who use services, public representative groups and organisations such as other regulators. We may also ask for more information from the provider, and carry out a site visit with direct observations of care.

When we make our judgements about whether services are meeting essential standards, we will decide whether we need to take further regulatory action. This might include discussions with the provider about how they could improve. We only use this approach where issues can be resolved quickly, easily and where there is no immediate risk of serious harm to people.

Where we have concerns that providers are not meeting essential standards, or where we judge that they are not going to keep meeting them, we may also set improvement actions, compliance actions or take enforcement action:

<table>
<thead>
<tr>
<th><strong>Improvement actions</strong></th>
<th>These are actions a provider should take so that they maintain continuous compliance with essential standards. Where a provider is complying with essential standards, but we are concerned that they will not be able to maintain this, we ask them to send us a report describing the improvements they will make to enable them to do so.</th>
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<tr>
<td><strong>Compliance actions</strong></td>
<td>These are actions a provider must take so that they achieve compliance with the essential standards. Where a provider is not meeting the essential standards, but people are not at immediate risk of serious harm, we ask them to send us a report that says what they will do to make sure they comply. We monitor the implementation of action plans in these reports and, if necessary, take further action to make sure that essential standards are met.</td>
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<tr>
<td><strong>Enforcement actions</strong></td>
<td>These are actions we take using the criminal and/or civil procedures in the Health and Adult Social Care Act 2008 and relevant regulations. These enforcement powers are set out in the law and mean that we can take swift, targeted action where services are failing people.</td>
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How this report is presented

On page 5 below, there is a summary that shows whether the essential standards about quality and safety that were checked during this review of compliance are being met. The section on each outcome is set out in this way:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>XX: The outcome number and title</td>
<td>Whether the service provider is compliant, or whether we have minor, moderate or major concerns about their compliance</td>
</tr>
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</table>

Following the summary, there is a detailed section on the outcomes for each of the essential standards that we looked at. The evidence that we used when making our judgements for each one is set out in the following way:

**Outcome XX (number):**

**Outcome title**

Details of the outcome, taken from our *Guidance about compliance: Essential standards of quality and safety.*

**What we found for the Outcome**

**Our judgement**

Our judgement about whether the <service/provider> meets the outcome described in the *Guidance about compliance: Essential standards of quality and safety*, or whether there are minor, moderate, or major concerns in relation to compliance.

**Our findings**

A summary of the evidence and findings used to reach our judgement, related to regulated activities as appropriate.

At the end of the report you will find details of:

- Any improvement and/or compliance action(s) that the service provider should make to maintain or achieve compliance with the essential standards of quality and safety.
- Any formal enforcement action that we are taking against the service provider.
Summary of findings for the essential standards of quality and safety

The table below shows the judgement that we reached for each of the essential standard outcomes that we reviewed.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Judgement</th>
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<tr>
<td>4: Care and welfare of people who use services</td>
<td>Major concern</td>
</tr>
<tr>
<td>10: Safety and suitability of premises</td>
<td>Compliant</td>
</tr>
<tr>
<td>11: Safety, availability and suitability of equipment</td>
<td>Compliant</td>
</tr>
<tr>
<td>16: Assessing and monitoring the quality of service provision</td>
<td>Major concern</td>
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Summary of key findings:

This report covers an unannounced responsive review of Basildon and Thurrock University Hospitals NHS Foundation Trust ("the trust") which was undertaken on 28 September 2010 in response to concerns raised around the trust’s management and assurance practices of serious untoward incidents.

The Strategic Health Authority had raised concerns with the Care Quality Commission (CQC) in August 2010 regarding two serious incidents reported within seven months of each other (December 2009 and July 2010) regarding the reporting of suspicious histopathology results at the trust. The first incident related to an error in 2004 which only came to light when the patient re-presented in 2009. The second incident occurred in January 2010 and came to light in July 2010. The majority of the visit time was spent talking to staff and senior managers about the current practices in relation to reporting and investigating serious incidents. We looked at how the processes are being managed with regard to actions taken, lessons learnt and practice changes to prevent reoccurrences of serious incidents to protect patients and staff. Evidence was also requested about how the Board of Directors assures itself that the management of serious incidents is robust.
Background:
In November 2009, Monitor found the trust to be in significant breach of its terms of authorisation and intervened under Section 52 of the National Health Service Act 2006. The concerns raised by Monitor were around the governance arrangements within the trust to assess and monitor the quality of service provision. The Care Quality Commission also raised concerns regarding the care and welfare of people who use the services and issues around staffing, recruitment and support. The reporting by the trust on quality, risk and improvement planning demonstrated ongoing improvements, however, concerns remained particularly around the care and welfare of patients, staff competencies, and professional development and appraisal practices.

Five compliance conditions were imposed on the trust at the time of registration on 01 April 2010 to ensure that people who use care services are kept safe and their welfare is promoted, and to ensure the trust met the requirements of the law. Since this time, two responsive reviews have been carried out; one in May 2010 and the second in July 2010. These resulted in four conditions of registration being removed as evidence had been provided, by the trust, to show that appropriate actions had been taken to meet these. We placed an improvement action around information given to people on discharge and a compliance action regarding training in violence and aggression. These are monitored through ongoing planned reviews.

Key Findings:
There are major concerns around the management of and learning from incidents and or near misses that resulted in or had the potential to result in harm including those defined as Serious Untoward Incidents (SUIs), in order to protect patients and others who may be at risk of inappropriate or unsafe care and treatment.

There are concerns that the trust is not always following the NHS East of England SI Requiring Investigation Policy 2010 or its own policy as to what constitutes a serious incident, as there were three recent incidents which fit the criteria that were reported to the National Patient Safety Agency but not raised as serious incidents by the trust. The Board of Directors is ultimately accountable for governance within the Trust. It was apparent from talking to staff and looking in detail at relevant documentation that board members were not always receiving separate agenda reports relating solely to the management of serious incidents within the Trust, although the Board were receiving regular updates within individual performance reports.

Following scrutiny of the reports and minutes submitted, there is a disparity between the number of SUIs shown as being reported to, and reviewed by, the Board of Directors and those listed on the SUI update spreadsheet maintained by the trust. The SUI update spreadsheet also contains incidents that, on the evidence provided, have not been reviewed by the Board of Directors and therefore there is no clear evidence of action planning, monitoring of improvements or lessons learnt by the Board of Directors. Therefore the trust cannot provide assurance that action plans are developed, and acted upon to avoid reoccurrence, reduce risks to patients and improve the service by learning from adverse events and or near misses.

There was a lack of evidence to show the effective operation of systems designed to enable the trust to identify, analyse and review incidents which had harmed or may harm patients. There was not a robust mechanism in place across the trust for staff to learn lessons from these incidents. Staff said they sometimes had updates in department meetings but only regarding their area of work and these were not always minuted. No evidence was
provided, despite requests from us, of monitoring or follow up audit practices being initiated
to measure improved outcomes for patients following a serious incident.

We examined two incidents relating to follow up practices of cancer patients reported as
SUIs in December 2009, and July 2010, which involved delays in the treatment of patients.
A number of staff interviewed reported that there was no consistent system for reporting
histopathology results to doctors. In the absence of any reliable process, some staff have
made efforts to introduce their own failsafe systems and have taken on additional
responsibility which has put them under significant pressure. There is evidence through an
incident involving cancer reporting practices in April 2010 and July 2010 that these
inconsistent practices are putting patients at risk and that people are experiencing delays in
receiving care that is for serious or significant needs because lessons are not learnt from
incidents.

The majority of serious incidents looked at by us were poorly recorded. In several
instances, including two cases regarding children, they were not reported appropriately or
investigated in accordance with the trust’s policy or the Care Quality Commission Essential
Standards of Quality and Safety December 2009. Of incidents reported to the National
Patient Safety Agency since 01 April 2010, the average delay in reporting is 39 days. One
of these incidents raises a child safeguarding concern. Whilst there is evidence that the
Children’s Safeguarding Lead reviewed this incident and there are quality improvement
actions outlined, there is no evidence that it was raised for the attention of the clinical
governance leads or Board of Directors, which again indicates there was no evidence of
shared learning, which is a major concern.

Five selected serious incidents, reported through the National Patient Safety Agency, since
April 2010 were examined and only one had been investigated appropriately. One had been
partially actioned and three of the incident reports were poorly documented, with no witness
statements, no evidence of solutions being developed to reduce risk, or implementation of
practice changes to avoid reoccurrence. We found no evidence of these specific incidents
being reported to, reviewed by or monitored by the Medical and/or Nursing Director, nor
evidence that they were considered by the wider Board of Directors to ensure practice
improvement and sustainability. The trust must ensure that it protects patients and others
against the risks of inappropriate or unsafe care and treatment by implementing robust
incident reporting procedures and ensuring lessons learnt are cascaded to and
implemented by staff.

During this review, the review of the safe management of legionella (water testing) was also
inspected as the trust had applied for this last and fifth condition of registration to be
removed.

The trust received confirmation from the Health and Safety Executive (HSE) on 15
September 2010 that the trust had met their improvement notice in relation to legionella.
The trust could demonstrate that they have fully complied with the actions required. This is
an improvement on the review carried out by the Care Quality Commission prior to
registration in April 2010. This review of compliance confirmed that the Trust had complied
with the fifth and final condition imposed at the time of registration.
What we found for each essential standard of quality and safety

The section below details the findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

Further detail about each of the outcomes described below can be found in the Guidance about compliance: Essential standards of quality and safety.
**Outcome 4:**  
**Care and welfare of people who use services**

**People who use services:**
- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

**This is because providers who comply with the regulations will:**
- Reduce the risk of people receiving unsafe or inappropriate care treatment and support by:
  - assessing the needs of people who use services
  - planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
  - taking account of published research and guidance
  - making reasonable adjustments to reflect people’s needs, values and diversity
  - having arrangements for dealing with foreseeable emergencies.
What we found for Outcome 4

Our judgement

There are major concerns with Outcome 4: Care and welfare of people who use services

Our findings

We looked at the process for reporting suspicious and unexpected pathology results from histopathology to the gynaecology medical teams as there have been two serious untoward incidents relating to gynaecology patients and one incident of a missed diagnosis of a large soft tissue mass from a medical patient reported since September 2009, which have resulted in a delay in the diagnosis of cancer and the beginning of treatment.

Referrals are received from GP referrals through the two week wait route and through the general gynaecology clinic. Most referrals are generic although some are directed to specific consultants. Patients referred through the two week wait route are seen by a consultant at the trust in the general gynaecology clinic in the first instance. The cancer team are responsible for tracking all cancer patients from the time of the GP referral onwards. Members of the cancer team also act as Multi Disciplinary Team (MDT) coordinators, monitoring the patient pathway and ensuring full communication between the team regarding the patients treatment. Patient notes are prepared by the clinic team; all pathology results are printed and put in patient notes. Clinic lists indicate which patients have had diagnostic tests. Pathology results can only be accessed electronically within the pathology department or by the cancer tracking team at present. (Three additional licenses have been requested by the gynaecology department to allow access to histopathology results in gynaecology outpatients and by the gynaecology medical secretaries.)

All histopathology results are forwarded to the gynaecology Cancer Clinical Nurse Specialist (CNS) for logging and review. This constitutes a significant workload and a considerable amount of responsibility. The CNS then forwards them to the most appropriate place. Results are in paper format and are sequentially numbered. It was reported that the envelopes that results arrive in are also sequentially numbered to facilitate easier identification of missing results however this was not backed up by the pathology department. Inadequate specimens should trigger a discussion with the Lead Gynaecology Oncologist. It was reported that histopathologists call the lead gynaecology oncologist direct with suspicious and unexpected results; however this was not backed up by all staff. In addition a number of different processes appear to be in place to inform consultants of unexpected results i.e. through the CNS, through the medical secretary, through a direct call from histopathology (the consultant or office staff) and through pigeon holes.

All inadequate or ‘suspicious’ results are “red lined / starred” and are delivered personally by the CNS to the relevant medical secretary. In the absence of the CNS the Colposcopy Nurse or Manager takes responsibility for reviewing pathology results. The majority of patients requiring a Multi Disciplinary Team discussion are listed for discussion through the CNS. The CNS also has clinic responsibilities and tries to be present for all discussions where “bad” news is given.
A number of staff interviewed reported that there was no consistent system for reporting histopathology and the reliance on a paper system increases the risk of error. In the absence of any reliable process, some staff have made considerable efforts to introduce failsafe systems and have taken on additional responsibility which has put them under significant pressure.

We were informed that a trust wide histopathology review is being led by the Associate Medical Director for Patient Safety and a Histopathology Reporting Policy is being developed.

If a patient does not attend (DNA) an out patient clinic appointment their notes are passed to the relevant consultant’s secretary following the clinic. This is for a review by the consultant. The consultant looks at notes and results, decides on any action to be taken and writes a plan in the notes. The process is understood by staff at all levels and is included in Junior Doctors training.

The gynaecology MDT meets weekly, by way of a videoconferencing link with Southend Hospital, on Wednesday morning. A new lead Gynaecology Oncologist has recently been appointed and is demonstrating clear leadership. Staff reported a clearer understanding of their own role.

The new policy of consultant vetting and letter writing to GPs following patients who do not attend now appears robust and understood by all members of staff interviewed. However, there is still confusion over the histopathology process by gynaecological staff even though the histopathology department seems to have a clear written policy and pathway for informing clinical staff of cancer diagnoses and unexpected diagnoses. Consequently several different mechanisms appear to be in place within the gynaecology department to act as a failsafe following the recent serious untoward incident which is a concern.
Outcome 10: Safety and suitability of premises

People who use services:
- Are in safe, accessible surroundings that promote their wellbeing.

This is because providers who comply with the regulations will:
- Make sure that people who use services, staff and others know they are protected against the risks of unsafe or unsuitable premises by:
  - the design and layout of the premises being suitable for carrying out the regulated activity
  - appropriate measures being in place to ensure the security of the premises
  - the premises and any grounds being adequately maintained
  - compliance with any legal requirements relating to the premises
- Take account of any relevant design, technical and operational standards and manage all risks in relation to the premises.
What we found for Outcome 10

Our judgement

The provider is compliant with Outcome 10: Safety and suitability of premises

Our findings

The Trust was prosecuted in 2004 for a Legionella related death. The death occurred in 2002 when limited control measures were in place. The Health and Safety Executive (HSE) conducted an in-depth investigation into another Legionella outbreak in June 2007 and found a significant number of shortcomings in the trust's arrangements for Legionella control. An investigation was started at Basildon University Hospital after two patients were confirmed as having contracted Legionaires disease in two separate parts of the Trust in December 2009. There were concerns about reoccurrences. The HSE issued an improvement notice in respect of Legionella with a completion date of 15th September 2010. We reinforced this action by imposing a condition of registration on the trust.

The trust received confirmation from the Health and Safety Executive (HSE) on the 15 September 2010 that the trust had met the notice as the trust could demonstrate that they have fully complied with the actions required. Through minutes of the legionella management group meetings evidence of the following was noted:

- The percentage of planned maintenance jobs related to water systems had been completed. In July the target of 95% of all water related jobs was exceeded with a completion rate of 97% achieved.
- Temperature monitoring of hot and cold outlets. In July 38.2% and in August 34.4% of cold outlets tested were found to be at temperature in excess of 20 degrees. Forty six cold outlets were tested in July and 68 outlets in August. All the cold water temperatures that were above 20 degrees were due to the high ambient temperatures affecting the supply water to the site apart from one which related to the Breast Care Unit.
- No hot outlets were found to have a temperature of less than 50 degrees.
- Monitoring of Chlorine Dioxide (ClO2) at a representative number of outlets. In July the ClO2 samples showed a range of between 0.2 and 1.17 parts per million (ppm). In August the range was between 0.14 and 3.32 ppm. Samples taken in the week commencing 03 September showed only one sample below 1 ppm at 0.88 ppm.
- A new water dosing plant has been installed and became operational in late June.

The trust have taken sufficient action in order that the compliance condition imposed at the time of registration can be removed.
Outcome 11: Safety, availability and suitability of equipment

People who use services:
- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

This is because providers who comply with the regulations will:
- Make sure that equipment:
  - is suitable for its purpose
  - is available
  - is properly maintained
  - is used correctly and safely in line with manufacturers' instructions
  - promotes independence
  - is comfortable.
- Follow published guidance about how to use medical devices safely.
What we found for Outcome 11

Our judgement

The provider is compliant with Outcome 11: Safety, availability and suitability of equipment

Our findings

The safety, availability and suitability of medical devices was reviewed by us in response to a recent serious untoward incident which raised concerns around staff training and the management of medical devices.

The Central Alert System (CAS) replaces the Safety Alert Broadcast System (SABS). It is now a combination of both the Public Health Link (PHL) and the Safety Alert Broadcast System. It therefore includes safety alerts, emergency alerts, drug alerts, 'Dear Doctor' letters and medical device alerts. Basildon University Hospital was assessed by the Trust’s Internal Auditors using specialists regarding the central alert system and the audit opinion noted a generally sound system of internal control designed and operating in a way that gives a reasonable likelihood that the system’s objectives will be met. The key issues found were regarding the lack of a detailed written organisational strategy for central alert reporting and no annual sample audits of current alert practices being undertaken to ensure implementation which needs to be addressed by the trust.

One member of staff spoken to confirmed that when staff are new their competence to use the necessary equipment is checked. Nine staff spoken to confirmed they were provided with training for new equipment/medical devices and were advised not to use a piece of equipment until they were confident in its use. Several examples of training records across the trust were submitted to support this. These noted who has had training and is competent and also who is not currently competent to use the equipment. One member of staff said that there is some refresher training but this is ad hoc, whilst another said there isn’t a formal system of updating staff. Another confirmed that they are advised of any changes to equipment.

There is a medical equipment services and maintenance procedure for staff to refer to. This includes hazard management and safety notices practices. The management of medical devices and equipment procedure clearly states :-

- medical devices must be suitable for their intended purpose
- be properly understood by the professional user
- maintained in a safe and reliable condition
- the professional using them must be fully trained and competent in their use.

A recent incident (NPSA 685 2010) of 10 August 2010 involving the use of a infusion pump had resulted in practice changes such as additional training checks for relevant staff, laminated instruction manuals being attached to medical devices and posters highlighting key operating practices and safety checks to reduce the risk of reoccurrence. Urgent e-mails were sent to staff alerting heads of departments as to the actions being taken, although some clinical staff spoken to were not fully aware of the recent changes. The trust was able to show that there are clear processes in place for the safety, availability and
suitability of equipment
Outcome 16:
Assessing and monitoring the quality of service provision

People who use services:
- Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

This is because providers who comply with the regulations will:
- Monitor the quality of service that people receive.
- Identify, monitor and manage risks to people who use, work in or visit the service.
- Get professional advice about how to run the service safely, where they do not have the knowledge themselves.
- Take account of:
  - comments and complaints
  - investigations into poor practice
  - records held by the service
  - advice from and reports by the Care Quality Commission.
- Improve the service by learning from adverse events, incidents, errors and near misses that happen, the outcome from comments and complaints, and the advice of other expert bodies where this information shows the service is not fully compliant.
- Have arrangements that say who can make decisions that affect the health, welfare and safety of people who use the service.
### What we found for Outcome 16

#### Our judgement

There are major concerns with Outcome 16: Assessing and monitoring the quality of service provision

#### Our findings

The serious untoward incident process was reviewed by us, as concerns had been raised about the management and timeliness of the trust in response to two recent serious untoward incidents.

The trust have a management of Serious Untoward Incident (SI) policy which was updated in July 2010 to reflect the National Framework for reporting and learning from serious incidents requiring investigation. The policy outlines the reporting practices and accountability levels. If an SI occurs the following people **must** be informed – the General Manager and the Clinical Director of the relevant areas, the Medical Director, Director of Nursing and the Chief Executive. The Director of Nursing (DON) is responsible for ensuring that SIs are reported to the Board of Directors, or next appropriate committee following the incident, i.e. Board of Clinical Directors, Clinical Governance Committee or Health and Safety Committee. They will, on behalf of the Board of Directors, have ultimate responsibility for monitoring and implementing the action plan. A monthly SI report will be sent to the Clinical Governance Management Group and Clinical Governance Committee to update and advise of the progress of investigations. Action plans and lessons learnt will be shared with these groups. The Executive Team and Board of Directors are advised at the next available meeting once a SI has occurred. The interim Director of Nursing confirmed that this is the current practice.

There are concerns that the trust is not following the NHS East of England serious incident requiring investigation policy or the Trusts own policy as to what constitutes a serious untoward incident as there were three recent incidents fitting the criteria which were reported to the National Patient Safety Agency but not raised or investigated as a serious incident. Close scrutiny of the Clinical Governance and Board of Directors open and closed meeting minutes and quality reports submitted by the trust, after our visit, as evidence of Board assurance does show that the Board receive regular updates within individual performance reports. However, it does not demonstrate a robust system to continuously identify, analyse and review risks, adverse events, incidents, errors and near misses. There is a disparity between the number of SUIs shown as being reported to, and reviewed by the Board of Directors and those listed on the SUI update spreadsheet maintained by the trust. The SUI update spreadsheet also contains incidents that, on the evidence provided, have not been reviewed by the Board of Directors and therefore there is no clear evidence of action planning, monitoring of improvements or lessons learnt by the Board of Directors. The Board of Directors is ultimately accountable for governance within the trust and from the evidence submitted cannot provide assurance that action plans are developed, monitored and, where necessary, reviewed and changed to avoid reoccurrence and improve the service by learning from adverse events. There was no evidence provided, despite our request, of any analysis of serious untoward incidents that resulted in or had the potential to result in harm to a patient. No evidence was provided of
monitoring or follow up audit practices being initiated to measure improved outcomes for patients following a serious incident. When asked a member of staff said they were not aware of auditing of any practice changes following an SUI although they thought they might be within an existing auditing arrangement.

It was noted that document control may be an issue in the trust as different versions of the policy were found in some of the work areas. Staff spoken with were aware of where to locate the serious untoward incident policy. All of the members of frontline staff spoken to were aware of the process for reporting a serious untoward incident but five of nine staff members had minimal knowledge or experience of examples of lessons learnt and practice changes implemented to improve standards and avoid reoccurrence of a serious incident. One person spoken with said some serious untoward incidents may lead to a change in policy of which they may be informed by e-mail. There is no system in place for checking all staff read any such e-mail communications. From discussions with staff and through reading minutes of meetings it was clear that there was not a robust trust wide mechanism for cascading practice changes from incidents to staff of lessons learnt to improve practice. Some staff said they had updates in department meetings but only regarding their area of work and these were not always minuted.

Five serious incidents that were reported in the last six months, from April to September 2010, through the National Patient Safety Agency (NPSA) were randomly selected by us for more detailed inspection. This we did with the interim Director of Nursing. It was noted that three of the five incidents had not been recorded on the trust's Serious Incident updated spreadsheet despite fitting the criteria of the NHS East Of England SI requiring investigation policy and the trusts policy as these incidents contribute to a pattern of sustained reduction in standards of care that the provider or commissioner identifies as being below agreed minimum safe standards. There was no evidence in the Clinical Governance meeting, Quality report or Board of Directors minutes that they had been discussed, which is a concern. This spreadsheet or record is kept by the trust as a record of serious untoward incidents.

One recent incident (SHA SI ref 685 2010), had been investigated appropriately, incorporating timely reviews. The report for this was in its initial draft stage. This investigation was detailed including an executive summary, investigation methodology, root cause analysis, lessons learned, recommendations and practice changes. There was also evidence of the incident being discussed with the patient’s family. (see outcome 11 inspection notes)

Both Incident 113893 and 6151131 were poorly documented, with no witness statements, no evidence of action planning or implementation of practice changes to reduce the risk of reoccurrence, despite one being regarding a delay in cancer diagnosis resulting in the patient being readmitted when a diagnosis of cancer with metastasis was confirmed. This would be an SI under the trusts policy in relation to actual or possible failure of screening services. There was no evidence of it being reported to the Board for audit or for monitoring for improvements and sustainability. There was no evidence of the incident being discussed with the patient or family as required by the trust's policy.

There was some evidence of an investigation in to one incident (NPSA 6338682) but it did not follow the trust's policy or time lines. The staff member asked to investigate the incident in the first instance delegated this to another member of staff who focused purely on the nursing care on one ward; the investigation did not take a broader view of the care provided. There was no evidence of challenge of the member of staff being asked to undertake the investigation as to why they had then delegated this to somebody else.

There was no evidence of the incident being discussed at the Clinical Governance Committee meeting or at Board level for audit/monitoring for improvements and
sustainability. There was no evidence of the incident being discussed with the family. The report had to be found as it was not attached to the incident form on inspection.

The region's Strategic Health Authority had spoken to the governance team at the trust regarding another incident (NPSA 6356590). The governance team have advised that the delayed recall of the patient to attend hospital had resulted in a delay in further treatment for the patient concerned. This case has similarities to an incident that occurred in the trust in 2004 that they identified in December 2009 and another in April 2010. Following a root cause analysis and look back exercise, recommendations have been made, however, no action plan with time frames is in place and this serious incident occurred over two months prior to our visit. It was clear from the documents seen and discussions with staff that internal management expectations and expected time lines for serious incidents (SUIs) were not in most cases being complied with.

Whilst the Clinical Governance Committee has SUI updates as a standing agenda item - the Board of Directors meetings do not. There were only two examples seen in twelve sets of minutes of actual SUIs discussed and practice changes implemented. No references to near misses were seen in the minutes of meetings at Clinical Governance or Board level since April 2010 although references were made regarding medication incidents and management practices. It was reported by a senior clinical manager that collective governance meetings are limited and there is no over arching quality strategy to provide a full assurance framework. An overarching quality strategy was in the process of being written. It was reported that the Strategic Health Authority provides some training in root cause analysis but the frequency and grades of staff attending including board members is not clear. From observing several incident records there are key issues around the quality of documentation, witness statements and reports following serious incidents at the trust.

The trust policy refers to the reporting of near misses should also be recorded by the Trust in order to identify potential trends for analysis. Any emerging trends, which constitute a significant risk in specified categories, should be reported as a SI using this procedure. There is no trend analysis of SUIs and 'near misses'. An email from a consultantbiochemist dated 26 May 2010 regarding an incident noted “I can think of half a dozen (SUI) incidents across Pathology and Imaging disciplines where significant results were not acted upon”. This raises concerns of the possibility of under reporting as there were four SUIs in 2009 and 10 reported to date in 2010, with only two were regarding pathology.

The SUI spreadsheet kept by the Trust notes the date an incident occurred. When this is cross referenced with Clinical Governance and Board meeting minutes quality reports and the NPSA log around the same time there are gaps in reporting. An example is an SUI resulting in a missed diagnosis of cancer through lack of histopathology reporting dated 09 December 2009. At the Clinical Governance committee meeting dated 14th December 2009 it was reported that there had been no serious SUIs reported since the last meeting which was incorrect. On 11 January 2010 meeting no reference was made to this incident. It was not until 14 February 2010 that it was raised. There is no evidence of the incident being discussed or reported at any of the Board meetings, which is against the Trust's own policy which notes “Following a serious incident (Sis) a brief outline will be presented to the Board of Directors by the lead director. The Board of Directors will then receive reports from the Clinical Governance Committee relating to the management of SIs within the Trust and ensure that action plans are developed, monitored and, where necessary, reviewed and changed.” Two recent SUIs of 16 April 2010 and 23 July 2010 again resulted in a delayed cancer diagnosis due to poor reporting and follow up practices, which raises questions regarding lessons learnt from the previous incident. There was no evidence in the Board minutes for 12 May 2010 or 28 July 2010 that these incidents had been reported.
to the Board of Directors.

We looked in depth at histopathology reporting practices because of the recent SUI (see outcome 4 inspection notes). A number of staff interviewed reported that there was no consistent system for reporting histopathology and the reliance on a paper system increases the risk of error. In the absence of any reliable process, some staff have made considerable efforts to introduce failsafe systems and have taken on additional responsibility which has put them under significant pressure. This raises questions regarding appropriate lessons learnt and practice changes following the first incident in December 2009. The time frames for this incident do not appear to have been complied with in the past and an updated report was originally sent to the PCT on 26 March. Feedback was received and a meeting was held with SHA Patient Safety Manager, PCT Head of Governance, the trust Patient Safety Manager and the investigating officer to review and revise the report. An agreed timescale was decided at this meeting for return of updated version. This was sent on 08 June 2010, within the agreed timescale. Neither the PCT nor SHA have closed this incident to date.’

The interim Director of Nursing (DON) was interviewed and was aware of the concerns regarding SUIs and NPSA assurance frameworks. From evidence seen, roles and responsibilities regarding the management of incidents was not always clear and the quality of investigation reports were poor. The DON demonstrated that changes are currently being actioned to address the issues outlined above. There was evidence of discussions in August 2010 at the clinical governance committee regarding the management of Serious Untoward Incidents and the need for the trust’s processes to be strengthened to improve senior clinical engagement. There was also a need for SUI investigations to be completed in an appropriate format and it was agreed that the Associate Medical Director, Patient Safety and Interim Director of Nursing would discuss the matter outside the meeting and bring an update to the next meeting for further discussion.

A clear timeline for responses to SUIs for the organisation has been recently developed and has gone to the Primary Care Trust, Strategic Health Authority and the Board for approval. It was reported that the interim DON is introducing a standard agenda item to the Board meetings regarding serious incident updates and reporting procedures are being reviewed in line with the Strategic Health Authority guidelines. However, this had not been actioned at the time of this inspection.

There remain issues around board assurance practices to manage SUIs and ensure everyone is made aware of practice changes trust wide and to date there is minimal evidence currently that assessing and monitoring the quality of service provision is robust enough to ensure that actions are taken to protect people who use the services from risks associated with unsafe care, treatment and support.

A member of the senior clinical staff reported to us that they had a planned management day arranged for their team leaders to look at clinical incidents, with a focus on poor communication and the consequences of poor record keeping, this is a positive initiative.
Improvement actions

The table below shows where improvements should be made so that the service provider **maintains** compliance with the essential standards of quality and safety.

<table>
<thead>
<tr>
<th>Regulated activity</th>
<th>Regulation</th>
<th>Outcome</th>
</tr>
</thead>
</table>

The provider must send CQC a report about how they are going to maintain compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

CQC should be informed in writing when these improvement actions are complete.
Compliance actions

The table below shows the essential standards of quality and safety that are not being met. Action must be taken to achieve compliance.

<table>
<thead>
<tr>
<th>Regulated activity</th>
<th>Regulation</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of disease, disorder or injury</td>
<td>9</td>
<td>How the regulation is not being met</td>
</tr>
<tr>
<td>Surgical procedures</td>
<td></td>
<td>There was no consistent system for reporting histopathology results. There is evidence that these inconsistent practices are putting patients at risk and that people are experiencing delays in receiving care that is for serious or significant needs.</td>
</tr>
<tr>
<td>Diagnostic or screening procedures</td>
<td></td>
<td>The outcome for people that should be achieved</td>
</tr>
<tr>
<td>Maternity and midwifery services</td>
<td></td>
<td>The trust must have a consistent system for reporting histopathology results trust wide so that patients are assured that early detection of ill health will be actioned to reduce the risk of deterioration in their health status.</td>
</tr>
<tr>
<td>Termination of pregnancies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment of disease, disorder or injury</td>
<td>10</td>
<td>How the regulation is not being met</td>
</tr>
<tr>
<td>Surgical procedures</td>
<td></td>
<td>The trust is not always fully investigating serious incidents, near misses or adverse events which may impact on patient safety. Learning from these incidents or events is not always identified, and cascaded to staff for implementation.</td>
</tr>
<tr>
<td>Diagnostic or screening procedures</td>
<td></td>
<td>The outcome for people that should be achieved</td>
</tr>
<tr>
<td>Maternity and midwifery services</td>
<td></td>
<td>The trust must ensure it protects patients and others against the risks of inappropriate or unsafe care and treatment through the implementation of robust incident reporting procedures and ensuring lessons learnt are cascaded and implemented by staff.</td>
</tr>
<tr>
<td>Termination of pregnancies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The provider must send CQC a report that says what action they are going to take to achieve compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The provider's report should be sent to us within 28 days of this report being received.
Where a provider has already sent us a report about any of the above compliance actions, they do not need to include them in any new report sent to us after this review of compliance.

CQC should be informed in writing when these compliance actions are complete.
Enforcement action we are taking

The table below shows enforcement action we have taken because the service provider is not meeting the essential standards of quality and safety shown below. Where the action is a Warning Notice, a timescale for compliance will also be shown.

<table>
<thead>
<tr>
<th>Enforcement action being taken</th>
<th></th>
</tr>
</thead>
</table>