1. Purpose of Report (Including link to objectives)

The RUH NHS Trust is statutory bound to apply for HCAI registration with the CQC, as of 1st April 2009. The on line application for registration opens on the 12th January through to the 6th February. The application needs to be considered by the Trust Board and signed off by the Chief Executive.

HCAI registration is linked to the number one RUH strategic objective Patient Safety, which includes breakthrough aims in delivering zero preventable MRSA bacteraemias and zero primary cause deaths related to Clostridium Difficile.

2. Summary of Key Issues for Discussion

The application process detailed in section 3.2 requires the Trust to make a declaration on the extent to which we meet the overarching regulatory requirement in relation to HCAI (part 2).

The Trust is further required (part 3) to provide a statement on whether the criteria set out in the revised Code of Practice about compliance with the regulations on HCAI are being, and will continue to be, met.
The CQC will cross check information submitted in our application to test the data which will result in one of three possible registration outcomes.

Actions are in place to address identified gaps derived from the Saving Lives assessment last undertaken in December 2008. (Appendix two). This latest assessment outlines an improved RUH position.

All four recommendations relating to sub duties of the Hygiene Code (revised January 2008) that arose from the Healthcare Commission (HCC) unannounced inspection in February 2008, have been fully addressed. (Part 4) Appendix one.

### 3. Recommendations (Note, Approve, Discuss etc)

The Trust Board to approve the completed CQC application (Appendix one) in preparation for Chief Executive sign off and registration prior to 6th February 2009.

The Trust Board to discuss the identified gaps deriving from the Saving Lives assessment in line with the new Hygiene Code in order to approve the actions required.

### 4. Standards for Better Health (which apply)

The relevant HCC Core Standards are C4a, C4c, and C21.

As part of the 2008 / 09 Annual Health Check, trusts will still be required to declare retrospectively against these 3 standards, but will not be required as in previous years to make a separate statement.

### 5. Legal / Regulatory Implications (NHSLA / ALE etc)

The Health and Social Care Act 2008 will require trusts to protect people from the risks of HCAI. While the main Act has been passed, the necessary secondary legislation “The Regulations” have yet to be laid before Parliament.

The Government is introducing a system of HCAI registration one year ahead of a new general system of registration that will apply equally to all providers of health or adult social care. The CQC will be the new Regulator. From April 2009, trusts that provide patients with care will be legally required to register with the CQC. Registration gives trusts an opportunity to show that they are doing all that they can to face up to the challenge of HCAI.
The new NHS HCAI registration system is underpinned by a restructured Hygiene Code with nine criteria. The Code sets out compliance criteria that will be used to monitor whether trusts are complying with the regulations.

To be granted registration, a trust does not have to comply straightaway with every detailed aspect of the revised Hygiene Codes nine criteria.

The RUH NHS Trust must, by law, comply with one overarching regulation about HCAI, which requires us to operate in a way that, as far as practicable protects patients, workers and others from identifiable risks of acquiring an HCAI.

If the CQC determines that an NHS Trust does not meet the registration requirement, then registration may be rejected. An unregistered trust that continues to provide healthcare would be committing a criminal offence and may be prosecuted. An appeals process has been designed.

The Enforcement Policy 2008 outlines the CQC powers ranging from the issue of warning notices through to prosecution for trusts with the most serious and/or repeated failings.

### 6. Risk (Threats or opportunities link to risk on register etc)

The risks as entered on the RUH NHS Trust corporate risk register relate to improvements being made in the areas of aseptic pharmacy facilities, decontamination, pipeworks and isolation facilities.

The 2008 / 09 Q4 RUH NHS Trust unannounced HCC Hygiene Code (January 2008) inspection is awaited. The findings will be used as part of the CQC triangulation process for registration.

The Trust continues a year on year improvement with HCAI reduction targets with current year performance on trajectory.

### 7. Resources Implications (Financial / staffing)

The improvements planned in the above identified areas of risk are costed and outlined within the year on year capital programmes 2008 – 2010.
8. **Equality and Diversity**
No issues identified.

9. **Communication**
Both the Department of Health consultation with regard to the regulations and HCAI compliance criteria and the CQC consultation with regard to enforcement, have taken place.

The HCAI registration system will use information that is already available and an inspection regime that is targeted to check that the required standards are being met. The CQC aim to provide assurance to the public in a cost effective way by publishing the register.

10. **References to previous reports**

11. **Freedom of Information**
Public
1. Introduction / Strategic Context

1.1.1 The new Care Quality Commission (CQC) will bring together independent regulation of health, mental health and adult social care. Patients expect clean, safe care and through new legislation, trusts will be required to protect people from the risks of HCAI.

1.1.2 To ensure that trusts undertake this duty the Government is introducing a system of HCAI registration – one year ahead of a new general system of registration that will apply equally to all providers of health or adult social care.

1.1.3 From April 2009, trusts that provide care will be legally required to register with the CQC; and as a legal requirement of registration, must operate in a way that protects patients, workers and others from the identifiable risks of acquiring all HCAI.

1.2 HCAI Registration System CQC principles

1.2.1 Will make trusts focus on their responsibilities for managing the risks of HCAI, therefore helping to prevent and reduce the spread of infections, resulting in fewer avoidable deaths and improved quality of life.

1.2.2 Will use information that is already available and inspection that is targeted to check that the required standards are being met.

1.2.3 Will provide assurance to the public in a cost effective way.
2. Impact on Trusts of new Registration Systems

Table 1

<table>
<thead>
<tr>
<th>Current system</th>
<th>New system</th>
</tr>
</thead>
<tbody>
<tr>
<td>• At the moment trusts are legally obliged to “observe the provision” of the hygiene code.</td>
<td>• The new legal requirement is that each trust is, and will continue to be, in compliance with the regulations setting out the requirements on HCAI.</td>
</tr>
<tr>
<td>• The detailed provisions of the hygiene code are fairly prescriptive.</td>
<td>• Trusts will need to apply to the Care Quality Commission for registration – any unregistered trust that continues to provide services without CQC permission would be acting illegally.</td>
</tr>
<tr>
<td>• The annual health check links three core standards to the provisions of the hygiene code (C4a, C4c, C21) and trusts must make a statement on the measures they have in place to comply with the code.</td>
<td>• The Care Quality Commission will decide whether trusts are meeting the legal requirements. CQC will make this decision by referring to the high level compliance criteria of the revised code, using information provided by the trust on its application, and other relevant evidence.</td>
</tr>
<tr>
<td>• Each acute trust receives an annual inspection visit from the Healthcare Commission’s HCAI team. The Healthcare Commission is also visiting some non-acute trusts during 2008/09.</td>
<td>• Applications for registration look at the present and also the future. Trusts will, in this transitional year, still be required to declare retrospectively against the three relevant core standards for the 2008/09 annual health check, but will not be required to make an additional statement about HCAI.</td>
</tr>
<tr>
<td>• The Healthcare Commission has powers to issue improvement notices and recommend special measures.</td>
<td>• Following registration the Care Quality Commission will continue to monitor all trusts and carry out inspections.</td>
</tr>
<tr>
<td>• The Care Quality Commission will have a wider range of enforcement powers.</td>
<td></td>
</tr>
</tbody>
</table>
3. Key dates in the Registration Process

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health’s consultation on the new legal framework relating to HCAI.</td>
<td>11 August – 20 October 2008</td>
</tr>
<tr>
<td>Regional workshops to explain the registration process and answer any questions.</td>
<td>November – December 2008</td>
</tr>
<tr>
<td>Draft HCAI regulations laid before Parliament for approval.</td>
<td>Early January 2009</td>
</tr>
<tr>
<td>Trusts apply to register.</td>
<td>12 January – 6 February 2009</td>
</tr>
<tr>
<td>The regulations come into force (if approved by Parliament).</td>
<td>March 2009</td>
</tr>
<tr>
<td>The Care Quality Commission assesses applications, makes registration decisions and informs trusts electronically.</td>
<td>February – March 2009</td>
</tr>
<tr>
<td>Date from which trusts must be registered with the Care Quality Commission.</td>
<td>1 April 2009</td>
</tr>
<tr>
<td>The Care Quality Commission issues registration certificates and makes the register available to the public.</td>
<td>April 2009</td>
</tr>
<tr>
<td>Any representations and/or appeals from trusts are considered and registration decisions modified as necessary.</td>
<td>From April 2009</td>
</tr>
<tr>
<td>As part of ongoing monitoring and inspection, the Care Quality Commission carries out further checks and revises registration classifications, as necessary.</td>
<td>From April 2009</td>
</tr>
<tr>
<td>The Care Quality Commission takes any enforcement action that it considers necessary.</td>
<td>From April 2009</td>
</tr>
<tr>
<td>An aligned registration system for the NHS, independent healthcare and adult social care is in place, including HCAI.</td>
<td>From April 2010</td>
</tr>
</tbody>
</table>

Source: Registering with the Care Quality Commission in relation to healthcare associated infection – Guidance for Trusts 2009/10
3.1 Trust Application Process

3.1.1 On-line application takes place between the dates of 12th January and 6th February 2009.

3.1.2 Preparation prior to Trust Board consideration, approval and Chief Executive application sign off, is crucial. This has been duly completed by the DIPC and Senior Nurse in Infection Control and is outlined within Appendices one, two, three and four of this paper. Trusts need to have systems that continue to protect patients and others, and be able to show that they have action in hand to make any improvements needed to ensure that these systems are effective and robust.

3.1.3 Assurance is provided to the Trust Board by the DIPC that due diligence has been undertaken in using the Department of Health guidance *Changes to arrangements for regulating NHS bodies in relation to healthcare associated infections for 2009/10 – A consultation for the NHS (August 2008)* in preparation for application. In addition the DIPC attended one of the Regional road shows on behalf of the RUH NHS Trust.

3.1.4 To be granted registration, a trust does not have to comply straightaway with every detailed aspect of the revised Hygiene Codes, nine criteria:

- Weaknesses in a trusts arrangement for meeting one or more of the compliance criteria may not automatically represent evidence that the regulation itself is being breached.

- The revised code is not overly prescriptive. It contains good practice guidance on how trusts can go about tackling HCAI, but this advice is not necessarily the only way and must allow for local solutions. Therefore, if a trust does not fully comply with some aspect of the Code and guidance, it does not necessarily mean that it is breaching the Regulations; the trust could have found another way to comply with the regulations.

- Future risks need to be considered. Some detailed aspects of a trusts systems may need strengthening to make sure that it is managing any future risk of breaching the regulations.
3.2 Trust Registration Process

The application forms are likely to comprise the following:

Part 1 asks for factual information

Part 2 requires the trust to state whether it complies with the legal requirement for registration:

Requirement: A service provider in respect of carrying on of a regulated activity must, so far as practicable, ensure that patients, healthcare workers and others who may be at risk of acquiring a healthcare associated infection, are protected against identifiable risks of acquiring such an infection by the means specified in the regulations.

Statement: The Trust considers it is, and will continue to be, in compliance with this requirement that will, subject to parliamentary approval, come into force on 1 April 2009.

<table>
<thead>
<tr>
<th>Compliant</th>
<th>Not Compliant</th>
</tr>
</thead>
</table>

Part 3 uses a three box structure that relates to each of the Hygiene Codes nine compliance criteria:

Box 1 (meets) indicates that a trust has reviewed its system for meeting a particular compliance criterion and is confident it is robust and can withstand most foreseeable challenges. The trust will need to know what is in place in practice and that it has been appropriately tested and proved to be sound.

Box 2 (partly meets) indicates that although a trust has an appropriate system in place it has identified circumstances where it may not be fully reliable and needs strengthening. However, the trust does not consider that the weakness presents a significant risk that the registration regulation will be breached. Local action plans are strongly encouraged by the CQC to be submitted against these entries.

Box 3 (not met) indicates that a trust has identified serious weaknesses that may present a significant risk of the registration requirement itself being breached under certain circumstances. In these circumstances, the CQC expect there to be determined action underway to deal with the problem, and some explanation of any steps that have been taken to
mitigate the risk in the meantime. Depending on the details, the Commission may need to agree or impose conditions if it is to grant registration.

Part 4 allows a trust to record additional significant information.

3.3 RUH NHS Trust Registration

It is proposed following preparation and due diligence that the RUH NHS Trust registers with the CQC in part 2 as **Compliant** and in part 3 as **all nine criterion met**.

It is further proposed that the RUH NHS Trust submits the supporting information as detailed in Appendix one part 4, in part 4.

3.4 Proposed CQC Registration categories

Registered

Registered with conditions

Not Registered

3.4.1 The CQC will use available information to identify trusts that are most at risk of failing to protect patients from HCAI, and will systematically target the registration assessment activity. This will include:

- Views of local people i.e. patient surveys
- Trusts most recent core standard declaration
- Evidence from the HCC current HCAI inspection programme
- PEAT reports
- Issues raised by SHA’s
- A screening dataset of outcome and other information

3.4.2 All applications that may potentially be other than registered will be further reviewed by a team of HCAI assessors. The team may contact trusts to discuss the evidence with a view to understanding the extent of any
risk of non compliance and obtaining the trusts agreement to any remedial action considered necessary.

4. **Summary**

The most important factors in protecting RUH patients from HCAI are that;

- Our management systems underpinning performance are robust.

- We have a culture, starting with the Trust Board and present at every level, that focuses on the ever present risks posed by HCAI and that is sensitive to how patients feel about the way that they are treated in relation to HCAI prevention.

- We ensure that specific, important measures are in place such as cleanliness, screening to detect infected patients, effective isolation and appropriate prescribing of antimicrobials.

5. **Recommendation**

The Board is asked to approve the CQC HCAI registration documentation as proposed in Section 3.3 of this paper.