Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Central Alerting System Policy

This procedural document supersedes: CORP/RISK 6 v.4 – Central Alerting System Policy

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Executive Sponsor(s):	Mr Ray Cuschieri
Author/reviewer: (this version)	Andrew Leverton – Head of Medical Technical Services
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Target audience:	Trust wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 5	5 September 2019	• Removal of references to NHS England, replaced with NHS Improvement. • Updated distribution procedure to include all clinical Governance leads • Updated Monitoring Compliance to include monthly NHSi alert activity to PSRG	Andrew Leverton
Version 4	18/2/2015	• Removal of the section on reporting Medical Device incidents as this is now catered for in the new DATIX system. • Title change • Policy reformatted to Trust style. • Removal of NPSA and inclusion of NHS England alerts. • Addition of RAG rating to the monitoring section.	Andrew Leverton
Version 3	December 2011	• Policy name change. • Addition of a table of contents. • Reference made to CQC outcome 11D – section 1 • Addition of accountability chart – section 2. • Updated information on NPSA Rapid Response Reports – section 4.1 • Reference to Trust based online alerting management system – section 4.2 • Inclusion of NPSA monitoring regime – section 5. • Inclusion of Equality and Impact assessment and useful information paragraphs – section 6 and 7. • Appendix 2 - Inclusion of flowchart for alert pathway. • References to Safety Alert Broadcast system changed to Central Alerting System. References to SABS changed to CAS. • Updated guidance on monitoring, action plans, risk assessments and audits relating to alert recommendations.	Andrew Leverton
Version 2	September 2007	• Inclusion of the NPSA's new Rapid Response Report (RRR) • Reference made to the Clinical Risk group meeting • Updated references to current MHRA documents • Updated forms in appendices	Andrew Leverton

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1. INTRODUCTION

This policy and accompanying procedure covers the dissemination of alert notices issued by the Central Alerting System (CAS) within the Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust.

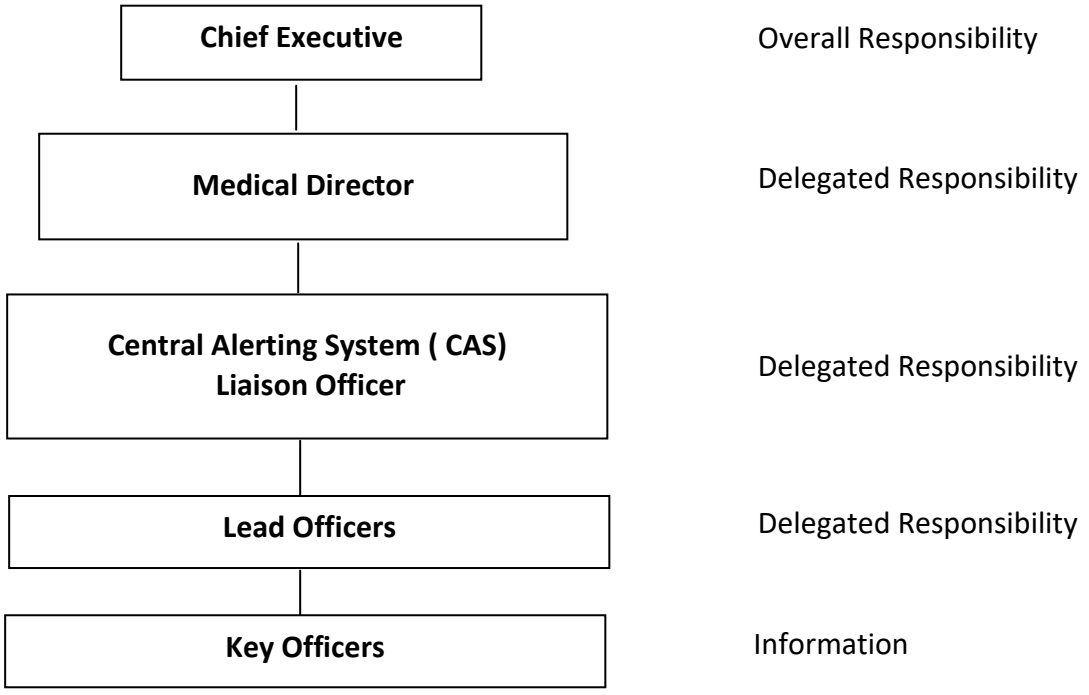
The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.

Alerts available on the CAS website include safety alerts, Chief Medical Officer messages, drug alerts, Dear Doctor letters and Medical Device Alerts.

This policy covers the issue of Medical Device alerts generated from Medicines and Healthcare Regulatory Agency (MHRA) (note that Drug alerts follow a different route via Pharmacy), NHS Improvement alerts, NHS Estates and facilities alerts, and other appropriate external or internally generated alerts.

2. PURPOSE

The policy ensures that the Trust has a robust mechanism for recording, disseminating and reporting back on alerts issued by national bodies. Its aim is to make the process seamless, user friendly and easy to access. Using a nominated lead officer to take ownership of the alert ensures accountability with key supporting officers and wider Trust special interest groups to assist dependent on the alert content.
The policy reporting and accountability arrangements are shown in the flowchart below:



3. DUTIES AND RESPONSIBILITIES

3.1 CAS Liaison Officer

The CAS liaison officer is responsible for arranging prompt dissemination of all information and in particular, device and safety alerts issued by the Central Alerting System. This officer also accesses the CAS to close alerts once final reports have been received.

3.2 Lead Officer

Lead officers are responsible for ensuring the actions identified in the alert are completed in a timely manner and that the initial and final reports are submitted by the deadlines set. See section 4.4 for more detail.

3.3 Key Officer

Key officers are sent alerts for information and awareness they are responsible for liaising with the lead officer advising, supporting and sharing information relating to the alert. See section 4.5 for more detail. In most cases Clinical Governance leads are nominated as key officers.

4. PROCEDURE

4.1 Central Alerting System

The Central Alerting System is operated by the Department of Health and provides a mechanism for the swift dispatch of a number of safety related alert and information notices, comprising of:

- Medical Device Alerts from the Medicines and Healthcare products Regulatory Agency.
- NHS England patient safety alerts.
- Safety Notices and Safety Bulletins from NHS Estates.
- Guidelines on specific subjects from the Department of Health.

The alert system has an associated website, which holds copies of all alert notices, together with statistics on responses from Trusts and Strategic Health Authorities.

The Central Alerting Website can be found at https://www.cas.mhra.gov.uk

It is imperative that all of these notices are disseminated promptly throughout the organisation and the necessary actions taken by relevant staff as appropriate.

The Head of Medical Technical Services is the nominated CAS Liaison Officer for the Trust and is responsible for:

- Receiving the documents on e-mail, via the CAS. Promptly (normally the same day) forwarding the documents through the dissemination system described below, noting any priority action.

- Updating the CAS website to acknowledge receipt and necessary action rating for the notices.

- Collating returns from the identified lead officers and finally closing down the notice on the CAS website when the issue has been completely dealt with.

- Holding a library copy of all CAS notices.

- Providing a list of all CAS notices and statistics to the Patient Safety Review Group and other forums as deemed appropriate and necessary.

- Regular production of reports identifying the activity of the alerting system in relation to the Trust.

4.2 Dissemination Procedure

The procedure may be slightly different for each type of CAS notice issued. At present CAS issue the following notices on behalf of the respective agencies:

Medical Device Alerts
Medical device alerts are issued in response to MHRA incident investigations and or manufacturer recommendations. The alerts are sometimes categorised by priority, there are four such categories:

- Immediate For immediate action
- Action For action as soon as possible
- Update Update of a previous alert
- Feedback request for feedback to the MHRA

NHS Improvement Safety Information
These are alerts issued by NHS Improvement. They cover in general broader issues concerning patient safety such as cleanliness, and more specific advice and guidance such as use and storage of devices and best practice in clinical procedures.
These have been developed to communicate messages rapidly to NHS professionals about important patient safety issues. They are divided into the following categories:

Stage One Alert: Warning

This stage 'warns' organisations of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information.

Stage Two Alert: Resource

This alert may be issued some weeks or months after the stage one alert, and could consist of:

- sharing of relevant local information identified by providers following a stage one alert;

- sharing of examples of local good practice that mitigates the risk identified in the stage one alert;

- access to tools and resources that help providers implement solutions to the stage one alert; and access to learning resources that are relevant to all healthcare workers and can be used as evidence of continued professional development.

Stage Three Alert: Directive

When this stage of alert is issued, organisations will be required to confirm they have implemented specific solutions or actions to mitigate the risk. A checklist will be issued of required actions to be signed-off in a set timeframe. These actions will be tailored to the patient safety issue.

NHS Estates and Facilities Alerts

Alerts are also issued by NHS Estates and facilities; these draw attention to issues that might affect the Estate and plant or equipment used therein. They follow the same format as MHRA alerts and may have actions that could include remedial work or recall of assets.

Department of Health Guidelines

From time to time the Department of Health will issue advice and guidelines that the Trust must acknowledge and action. These can cover any aspect of healthcare and are usually issued in response to high profile investigations and report recommendations.

Other Notices/Advice

Other types of safety alert notice that may be issued, for example from a supplier or manufacturer may also be disseminated using this process.

Internally Raised Notices

Occasionally the Trust will identify a potential risk issue involving the use or practice of medical devices or patient safety issues. To ensure swift communication of the potential risk to patients and the organisation an internal alert will be issued via the dissemination process described below. (See Appendix 1.)

Most notices issued have deadline dates by which actions must be reported back to the CAS website. The Strategic Health Authority have been charged with ensuring trusts maintain their responses by monitoring the feedback for alerts on the website.

4.3 The Process

The process for disseminating all of these alerts and notices follows the same principles as set out below. Appendix 2 shows a flowchart of the process.

On receipt of an alert notice, via CAS the alert message will be assessed and an appropriate Lead Officer identified to ensure that the required actions are carried out and to complete the initial and final reports (see 4.4 - Lead Officers Responsibilities).

Depending on the nature and origin of the alert, advice and guidance will be sought from the senior management as appropriate.

Additionally, alerts will be sent to key officers depending on the nature and content.

An internal alert management system has been developed to manage these alerts and this can be accessed by any member of staff by logging into a Trust PC and using the following web address. **http://dbhintranetapps/mhra/login.asp** This will allow access to the home page where any staff can see the alerts and actions taken. As alerts are received they are issued to appropriate staff using this system.

To ensure that notices have been received they must be acknowledged, this is done by following the **My Alerts** link embedded in the email. This will open up the Trust's alert management system.

As the process is based on your winframe address you will not be able to log on and sign off anyone else's alerts but your own. Reminders are automatically generated if you have not acknowledged an alert sent to you.

Responses to issued alerts are monitored and reported on. Regular checks are carried out and non-responders are targeted.

4.4 Lead Officers Responsibilities

Wherever possible, lead officers will be contacted in advance of the notice being issued to ensure that they understand and agree to carry out the actions required.

Lead Officer Notices are issued with response due dates, these are based on the initial and final dates that the Trust is required to respond back to the CAS website by. Where no CAS deadline dates are indicated the CAS liaison officer will insert appropriate dates to ensure the actions are logged within a timely manner.

To assist in the feedback process the Lead Officer will receive emails indicating that the initial and then final responses are due for completion. Logging onto the 'My Alerts' section of the Trusts internal alert management website will allow access to these on-line forms.

Lead officers should ensure that each bullet point action in the alert is addressed.

Included in the final report is a risk matrix, lead officers are asked to assess the risk outstanding to the organisation in relation to the alert by clicking in the appropriate box.

Copies of any supporting evidence such as audits, action plans, meeting minutes etc. should be sent to the Technical Support facilitator, Medical Technical Services DRI. These will be uploaded and attached as supporting documentation.

Reminders will be automatically sent out if reports are not received within the allocated time. Should the report/s still be outstanding, the issue will be raised with the Risk Manager for appropriate action.

Note: Lead Officers should ensure that CAS notices are actioned promptly; they must therefore make arrangements for action to be taken when they are on leave or away from the site.

If an alert cannot be completed in the allocated time for any reason, the lead officer should advise the CAS Liaison officer and the alert issue will be raised with the appropriate director.

4.5 Key Officers Responsibilities

On receipt of an alert notice, the key officer must acknowledge the email by following the instructions. Clicking on the Menu tab next to the alert number will reveal a drop down box with a number of options. One of these is 'view distribution list' this will show who else has been sent this alert. **Please note who else has received the information before you forward it to avoid duplication**.

The notice should be read and understood and depending on the content, key officers may need to share the information with staff at meetings or via internal communication methods. Any actions taken as a result of the notice must be fed back to the Lead Officer to allow them to compile their response to the CAS Liaison officer.

Additionally any advice or guidance relating to the notice must be directed to the Lead Officer **not** the CAS Liaison officer (Unless this is the same person).

Although the CAS website is situated within the public domain, at present access to Trust specific information, including the time taken for the Trust to action and close down the relevant notice is password restricted. All notices issued however are available to the general public and further information may be made available to the general public in the future.

5. TRAINING/ SUPPORT

Medical Device incident reporting is now captured as part of the DATIX incident system. Support and use of this system is provided by the Datix Systems Manager
Access and use of the both the Central Alerting System and the Trust's dissemination system are straightforward and user friendly. On line help is available for both systems and a video tutorial is being prepared.

Should further assistance be required please contact the Medical Technical Services Department.

6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

Compliance with CAS alerts is monitored on a daily basis and reported monthly.

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Compliance to CAS closing dates	CAS Liaison Officer	On-going, + Monthly review	Review of CAS datasheets. Monthly Report submitted to Clinical Commissioning Group (CCG) Monitoring meeting.
NHSi alert activity	CAS Liaison Officer	Monthly	Reported to the Patient Safety Review Group
Internal distribution system/RAG follow on	CAS Liaison Officer	Monthly	Review of Alerts, allocation of outstanding risk, follow up for outstanding information. Reported as above.
Quarterly report on Alert activity	CAS Liaison Officer	Quarterly	Reported to the Patient Safety Review Group (PSRG).

Red, Amber Green (RAG)Rating of all Alerts

When an alert has been closed down a risk assessed rag rating system is used as a quick method of categorising alerts based on their status to ensure that any alerts that may need to be reviewed and or followed up are captured. Additional information is then attached to the original alert documentation.

Red – these alerts require regular follow up to ensure that the actions that were originally required, continue to be in place.

Amber – These alerts are usually a lower risk and may require a broader refresh reminder on a regular basis.

Green – These alerts are those that have been assessed as unlikely to have a requirement for documented follow up.

7. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. See Appendix 3.

8. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

CORP/RISK 13 - Reporting and Management of Incidents and Near Misses

CORP/RISK 2 - Medical Equipment Training for Trust Staff

CORP/RISK 33 – Incident Management Policy

CORP/EMP 4 - Fair Treatment For All Policy

CORP/EMP 27 - Equality Analysis Policy

9. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/uk-data-protection-legislation-eu-general-data-protection-regulation-gdpr/

10. USEFUL LINKS

The Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk

NHS England: http://www.england.nhs.uk/ourwork/patientsafety/psa/

National Reporting & Learning System:
email

The Chief Medical Officer (for England):
https://www.gov.uk/government/people/sally-davies

The Care Quality Commission
http://www.cqc.org.uk/

APPENDIX 1 - EXAMPLE OF AN INTERNAL ALERT

Internal Alert Ref: xx/xx/xxxx

Issued by: **A Leverton**
Date Issued: **xx/xx/xxxx**

Medical Technical Services

Issue
Batches of **PROBACT transport Swabs** may fracture at the base if dropped. This could lead to leakage of the sample causing an infection control risk. Sample integrity will also be compromised.

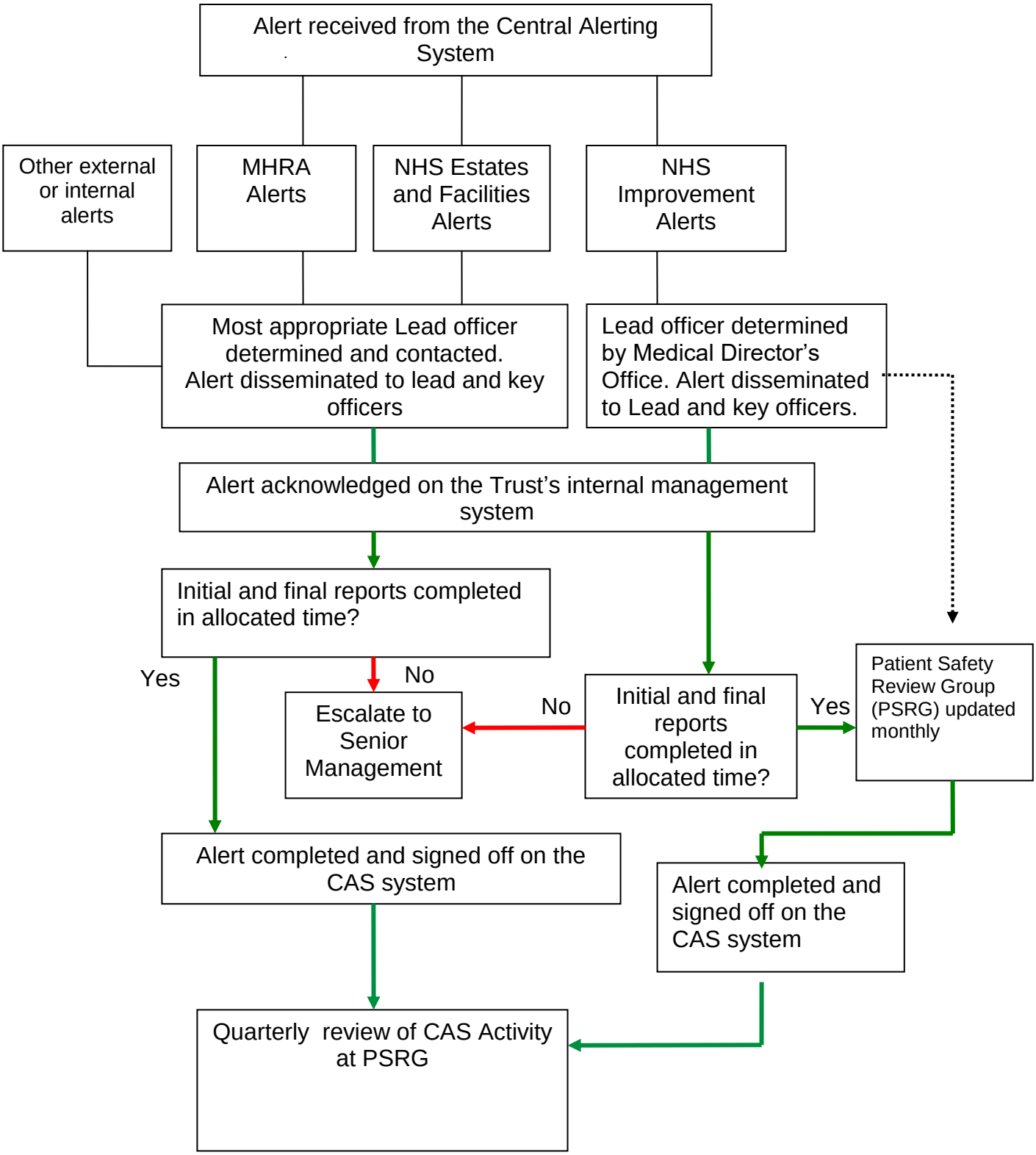
Background
Following a manufacturer's modification it has come to our attention that a recently introduced recessed moulding at the base of the tube has potentially weakened it. If dropped the tube base may fracture leaking the contents and or allowing the sample to become exposed to the atmosphere rendering it *unusable. These swabs are widely used in wards and departments and have an* NSV code of HHD501.

Action
Users should take extra care when handling these swabs. Any swabs dropped should be checked immediately for damage at the base, if damaged, ensure there is no risk of cross infection and report the incident to Pathology. Isolate damaged swabs to enable further investigation. The Manufacturers and Medicines and Healthcare products Regulatory Agency (MHRA) have been informed of this issue.

Damaged Swab

Sample of packaged swab

APPENDIX 2 - FLOWCHART OF CAS ALERT DISSEMINATION



APPENDIX 3 – EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Central Alerting system	**Corporate**	**A Leverton**	**Existing**	**25/7/2019**

1) Who is responsible for this policy? Name of Division/Directorate: **CORPORATE**

2) Describe the purpose of the service / function / policy / project/ strategy? Process for dissemination and management of external and internal alerts

3) Are there any associated objectives? Legislation, targets national expectation, standards, **CQC Standard 11, Premises Assurance Model**

4) What factors contribute or detract from achieving intended outcomes? Constant monitoring of Central Alerting System using the internal system

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation]

6) Is there any scope for new measures which would promote equality? [any actions to be taken **None noted for this policy**

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	**NO**	
b) Disability	**NO**	
c) Gender	**NO**	
d) Gender Reassignment	**NO**	
e) Marriage/Civil Partnership	**NO**	
f) Maternity/Pregnancy	**NO**	
g) Race	**NO**	
h) Religion/Belief	**NO**	
i) Sexual Orientation	**NO**	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: May 2022

Checked by: A Leverton **Date: July 2019**