CENTRAL ALERTING SYSTEM (CAS) POLICY

Please be aware that this printed version of the Policy may NOT be the latest version. Staff are reminded that they should always refer to the Intranet for the latest version.

Purpose of Agreement	This document aims to provide managers and employees with guidance on the arrangements and procedures regarding the dissemination of and replying to Safety Alerts from the Medicines and Healthcare products Regulatory Agency (MHRA).
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Document Manager (Job Title)	Health and Safety Manager
Document developed in consultation with	Head of Medicines Management, Policy Steering Group Solent NHS Health and Safety group, CAS Officer and CAS Administrator, Medical Devices Safety Officer, Patient Safety Specialist Quality and Governance Team
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Intranet and Website Upload

Intranet	Electronic Document Library Location:	*Insert the location of the document on the intranet*
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Amendments Summary:

Amend No	Issued	Page(s)	Subject	Action Date
1	DK	20-23	Alert Safety Tool	
2	DK	9	Removed old three stages	
3	DK	Variable	Revised policy flow throughout	

Review Log

Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes
V1.2	Dec 2009	M Holder	H&S, PSG, TB	Complete rewrite
V2	Dec 2013	D Keates	H&S Committee, Policy Steering Group	Re write and audit tool attached
V 3	April 2014	Tracy Beck	Policy Steering Group Assurance Committee	Change to outward distribution of alerts and changes made to the system for highlighting patients' safety risks (three level system)
V4	August 2019	D Keates		Various sections moved in line with new policy format. CAS email changed, Roles and responsibilities section reviewed, Outward alerts cascade updated to capture medicines recall procedure
V5	September 2021	D Keates		Removed old three stages of old NPSA's, re-structure of arrangements and processes section, additional roles and responsibilities added. Further assurance around evidence of actions taken

Summary of Policy

This Central Alerting System (CAS) Policy underpins the key principles of Solent NHS Trust's reporting procedure for the distribution of patient safety alerts and other safety critical guidance to the NHS. In September 2008 the Department of Health launched a new web-based system to enable health care professionals to access urgent and important safety guidance. Subsequently, in January 2014, the NHS England Patient Safety Domain launched the National Patient Safety Alerting System (NPSAS), a system for highlighting patient safety risks in NHS organisations and issued notices via CAS. This system has been developed and is now operated by the Medicines and Healthcare products Regulatory Agency (MHRA). In September 2020 the MHRA issued alert CHT/2020/002 guidance on changes to the system, and these have been incorporated into this policy.

This policy identifies the distribution of MHRA alerts in accordance with the instructions within the alert to the Trust's CAS Leads with specific responsibilities detailing how these alerts will be distributed to the medical devices safety officer, pharmacy, estates and facilities to initially evaluate those subject specific alerts before general distribution to the Trust's Nominated Points of Contacts and Independent Contractors

The policy has been written to provide guidance to Directors, Managers and Employees on the arrangements for the management of National Patient Safety Alerts, this policy identifies the arrangements and rapid dissemination of notices, acknowledgement of these alerts, and contains details and guidance of roles and responsibilities for Solent NHS Staff around the management of these alerts, arrangements that ensure replies are properly completed and returned to the CAS administrator within the specified alert deadline throughout Solent and covers the good practices to meet standards within the services.

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CENTRAL ALTERING SYSTEM (CAS) POLICY

1. INTRODUCTION and PURPOSE

1.1 The Trust receives safety notices and alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) via the Central Alerting System (CAS) which is an electronic system developed to distribute National Patient Safety Alerts (NatPSAs) and other safety critical guidance to the NHS and other health and social care providers.

1.2 The MHRA is an accredited issuer of National Patient Safety Alerts (NatPSAs). All safety-critical alerts for medical devices and medicines that require a system-wide response will be issued as National Patient Safety Alerts. These alerts follow the criteria and template agreed by the NatPSAs. The other issuers of alerts from CAS are working through the National Patient Safety Alert accreditation process for accreditation.

1.3 Medical Devices – when safety issues with medical devices meet the criteria of a National Patient Safety Alert (more likely than not to cause a death or disability in a year) these will be issued as National Patient Safety Alerts and the MHRA will collect responses from NHS Trusts and Foundation Trusts via the CAS website. For other issues the MHRA will progress using Field Safety Corrective Actions and Field Safety Notices which are not issued via CAS. Targeted approaches via email will be made where safety issues with medical devices can be locally identified. The MHRA Devices Division has developed a Safety Bulletin which includes information for health and care professionals on medical device safety, and this is issued via CAS. Responses to the bulletin will not be collected via the CAS website and the bulletin will not require the executive level oversight required for National Patient Safety Alerts.

1.4 Drug Alerts – All Class 1 Drug Alerts and some Class 2 Drug Alerts will meet the National Patient Safety Alert criteria and will be issued as National Patient Safety Alerts. Responses will be collected via the CAS website from NHS Trusts and Foundation Trusts. The MHRA has asked that CAS Liaison Officers identify an escalation route to ensure senior oversight for these alerts. Other Class 2 Drug Alerts and those which are Class 3 and Class 4 will be issued via CAS, but responses will not be collected via the CAS website.

PURPOSE

1.5 The policy applies to all Directors, Managers and Employees on the arrangements for the management of National Patient Safety Alerts.

1.6 Solent NHS Trust has the responsibility to ensure that all National Patient Safety Alerts are appropriately cascaded as indicated to Solent NHS Trust Services and that the organisation maintains evidence of alerts being acknowledged appropriately by all its services

1.7 Solent NHS Trust has a responsibility to obtain evidence of any National Patient Safety Alerts that require an action by Services within the Trust.

2. SCOPE

2.1 The main aspects covered are the health and safety management arrangements and applies to all bank, locum, permanent and fixed term contract employees (including apprentices) who hold a contract of employment or engagement with the Trust, and secondees (including

students), volunteers (including associate hospital managers), Non-Executive Directors, and those undertaking research working within Solent NHS Trust, in line with Solent NHS Trust's Equality, Diversity and Human Rights Policy. It also applies to external contractors, agency workers, and other workers who are assigned to Solent NHS Trust.

DEFINITIONS are found in Section 9 Glossary and Definition

3. PROCESS/REQUIREMENTS

DISTRIBUTION PROCEDURES, INWARD REPORTING & DISSEMINATION

3.1 All alerts will be sent by email to the Trust's designated e-mail address Quality&Safety@solent.nhs.uk and posted on the CAS Website. The CAS Administrator will distribute the notices, in accordance with the instructions within the alert to the Trust's Nominated Points of Contact and Independent Contractors with copies of all correspondence being retained by the CAS Administrator.

3.2 The Nominated Point of Contact will then decide whether this notice is applicable to their area of responsibility and sanction what actions if any that will need to be undertaken and will complete reply slip and return it, by e-mail, to the CAS Administrator no later than the specified date on the alert.

Refer to Appendix A Safety Alert Flow Chart and Appendix D Central Alerting System Response Status Definitions

3.3 The CAS Administrator will monitor the returns and issue where necessary for those not returned by the due date. The CAS Administrator will submit their return to the CAS web site using the pre-selected actions and "notes" boxes as appropriate. Return forms must be completed and sent back by the return date as the CAS Liaison Officer must complete the Trust's report to the CAS web site within the stipulated timescale.

REPORTING TO MHRA

Medical Devices

3.4 Staff must report a suspected problem ('adverse incident') with a medical device as soon as possible, for example if:

- someone's injured (or almost injured) by a medical device, either because its labeling or instructions aren't clear, it's broken or has been misused.
- a patient's treatment is interrupted because of a faulty device.
- someone receives the wrong diagnosis because of a medical device.
- you or third party think a medical device is fake or counterfeit.

3.5 To prevent the medical device being inadvertently reused the devices is to be quarantined, the adverse incident involving medical devices should be reported immediately using the Trust's electronic reporting system Ulysses.

3.6 The Medical Devices Safety Officer (MDSO) will outwardly report all adverse incidents involving medical devices to the Medicines & Healthcare Products Regulatory Agency MHRA using the Yellow Card System after an investigation and all the relevant information has been established.

Medicines

3.7 Staff must report a suspected problem ('adverse incident') with a medicine as soon as possible, for example if:

- a medicine causes side effects.
- a medicine doesn't work properly.
- a medicine is of a poor quality.
- you or third party think a medicine is fake or counterfeit.

3.8 All staff MUST refer and follow the Safe Operating Procedure for Drug Recalls Version 3.

3.9 The on-call pharmacist/technician must assess whether the subject medicine is to be outwardly reported to the Medicines & Healthcare Products Regulatory Agency MHRA using the Yellow Card System, after an investigation and all the relevant information has been established.

3. 10 The MDSO and Deputy Chief Pharmacist & Medicines Safety Officer (MSO) will monitor the replies from the MHRA and manufacturer and where necessary, inform staff of the outcome.

4. ROLES & RESPONSIBILITIES

4.1 **The Chief Executive Officer (CEO)** has overall responsibility for all matters of risk management; this includes the safe use of all medical and non-medical equipment and devices within the Trust. The Chief Executive Officer will also have overall responsibility for ensuring that the necessary management systems are in place to enable the effective management of CAS alerts.

4.2 **The Nominated Board Level Director for health and safety (Strategic Transformation Director and Director of Estates)** will through the Solent Health & Safety Group be responsible for monitoring compliance with the CAS Policy, with the generation of status reports reporting any significant risks associated with CAS Alerts from the CAS Officer to the Assurance Committee.

4.3 **CAS Liaison Officer** will receive the CAS alerts through a dedicated e-mail address. The Health and Safety Manager is the Trust's CAS Liaison Officer, or in their absence the CAS Administrator will act in their stead.

4.3.1 The duties and responsibilities of the CAS Liaison Officer are to assure that the organisation is:

- Receiving all CAS alerts electronically through the Trust's dedicated CAS e-mail address.
- Ensuring that the alerts are acknowledged on the CAS website within 48 hours of receipt of the alert.
- Reviewing and distributing alerts to nominated leads in departments where the alert is or might be applicable.

- Ensuring that, in the first instance, alerts and safety bulletins relating to medical devices are emailed to the Trust's Medical Devices Safety Officer who will advise if wider distribution of the alert is required.
- Ensuring that, in the first instance, alerts relating to Medicines are emailed to the Trust's Pharmacy who will advise if wider distribution of the alert is required.
- Ensuring that, in the first instance, alerts relating to Estates and Facilities are emailed to the Trust's Estates and Facilities team Estatemaintenance@solent.nhs.uk who will advise if wider distribution of the alert is required.
- Receiving responses from the nominated leads on action taken, collating this information, and confirming completion when all responses have been received through the CAS system.
- Ensuring that the Trust's section on the CAS website is kept up to date with the position of the alert within the Trust and that alerts are signed off as addressed appropriately.
- Audit a sample of reports from the CAS reporting system and complete the safety alert audit tool and report findings to the health and safety group and in the annual health and safety report. Provide reports to Trust Committees and Groups that indicate how the Solent NHS Trust is managing the CAS alerts and highlight any alerts that have not been started or completed by the deadline detailed on the alert.
- Ensuring that the Central Alerting System is informed of any changes to the CAS Liaison Officer contact details.
- Ensuring that cover is provided for the CAS Liaison Officer if he/she is absent.
- Ensuring that the key contacts are identified and established.

4.4 **CAS Administrator** duties and responsibilities are:

- Liaise with CAS Liaison Office or designate regarding any Alert considered to have an organisational impact is to ensure that the key contacts are identified and established.
- Regularly review the CAS e-mail address for the receipt of safety alerts. Alerts must be acknowledged within 2 working days.
- Distribute alert notices and bulletins within the stated time frame via email, fax or post to the appropriate Nominated Points of Contact including the Trust's Independent Contractors when applicable.
- Ensure that response is returned from the Trust's Nominated Points of Contact within the time specified on the alert notice.
- Maintain a record of all the notices sent, together with details of to whom they were sent, and the action taken and audit returns.
- Monitor the Trust's CAS web site and enter all required reports within the stipulated timescale.
- Arrange for cover by a nominated deputy if they are to be absent.

4.5 **Medical Devices Safety Officer** responsibilities are:

- to establish and maintain a record of evidence of the actions taken, and responses sent to the CAS Administrator to enable the Administrator to report the response correctly on the Trust's CAS account and for the alert to be audited effectively.
- Outwardly report all adverse incidents involving medical devices to the Medicines & Healthcare Products Regulatory Agency MHRA.

4.6 **Pharmacy** responsibilities are:

- to establish and maintain a record of evidence of the actions taken, and responses sent to the CAS Administrator to enable the Administrator to report the response correctly on the Trust's CAS account and for the alert to be audited effectively.
- Outwardly report all adverse incidents involving medicines to the Medicines & Healthcare Products Regulatory Agency MHRA.

4.7 **Estates and Facilities** responsibilities are to establish and maintain a record of evidence of the actions taken, and responses sent to the CAS Administrator to enable the Administrator to report the response correctly on the Trust's CAS account and for the alert to be audited effectively.

4.8 **Managers (Facility Managers, Support Services Managers, Premises Managers, and responsible persons both clinical and non-clinical)** must ensure that they provide the necessary support and advice to their staff. They must also ensure that there are always appropriate departmental managers/line managers appointed to act as Nominated Points of Contact to whom the notices can be disseminated.

4.9 **CAS Leads/Points of Contact**, duties and responsibilities include, but may not be limited to:

- Ensuring the development, implementation, and monitoring of a system within their area of responsibility for the rapid dissemination of notices to their staff, paying particular attention if key people are absent.
- Ensuring that existing and new staff are aware of this policy and procedure and of the notices that are received, if relevant.
  Ensuring that the reply is properly completed and returned to the CAS Administrator within the specified alert deadline.
- Ensuring that the appropriate action, inclusive of time scales as detailed in the notice, is taken. In the interests of device users and patient safety, it is vital that each notice received is checked and acted upon as necessary.
- Withdrawing from use any faulty device or equipment until dealt with and ensure that the item is properly labelled stating it is faulty and not to be used.
- Pursue any outstanding actions with relevant staff, ensuring that they fulfil their legal obligations.
- Ensuring that if they step down as the Nominated Point of Contact, they handover their responsibilities to the new appointed person and inform the Trust Liaison Officer/ CAS Administrator.
- Ensuring that if equipment or supplies are identified on notices that are not owned by the Trust, but staff are expected to use, they inform the appropriate line/service manager.
- Ensuring that local procedures (which must be reviewed on a regular basis) are drawn up to make sure that all new staff are made aware of recent alerts. (For example, set up a folder of Medical Device Alerts for all staff to see in the ward/dept/service).
- Making certain that local action is taken as necessary to ensure the safety of patients, users, and others.

4.10 **All Employees** will:

- Ensure that they understand and comply with any alerts actions that are brought to their attention by the line managers.

- Bring any problems/faults/defects to the attention of their line/service manager; and arrange for any unsafe equipment/items to be taken out of service immediately, quarantined and labelled as such, stored safety when requested by their line/service manager.

5. EQUALITY IMPACT ASSESSMENT AND MENTAL CAPACITY

5.1 A thorough and systematic assessment of this policy has been undertaken in accordance with the Trust's Policy on Equality and Human Rights.

5.2. The assessment found that the implementation of and compliance with this policy has no impact on any Trust employee on the grounds of age, disability, gender, race, faith, or sexual orientation.

(Refer to Appendix E: Equality impact assessment)

6. SUCCESS CRITERIA / MONITORING EFFECTIVENESS

6.1 The management of the CAS system will be monitored on a regular basis by the Trust's CAS Officer and CAS Administrator.

- They will report quarterly:
  - To the Health and Safety Group, bimonthly to the head of performance and the quality Information & system officer on the type of alerts received and completion rate of closure of alerts within stipulated time frames.
  - Audit a sample of reports from the CAS reporting system and complete the safety alert audit tool and report findings to the health and safety group and in the annual health and safety report.

(Refer to Appendix B: Safety Alert Tool)

- MDSO will maintain a record of dates evidence of the actions taken and report through the medical devices group.
- Pharmacy will maintain a record of dates evidence of the actions taken and report through the Medicines management group.
- Estates and Facilities will maintain a record of dates evidence of the actions taken and collate evidence within the Estates and Facilities Secured R drive folder.

7. REVIEW

7.1 This document may be reviewed at any time at the request of either staff side or management but will automatically be reviewed 3 years from initial approval and thereafter on a triennial basis unless organisational changes, legislation, guidance, or non-compliance prompt an earlier review.

8. REFERENCES AND LINKS TO OTHER DOCUMENTS

The Health and Safety at Work Act 1974
The Management of Health and Safety at Work Regulations 1999 as amended, Managing Health and Safety HSG65
Provision and Use of Work Equipment Regulations 1998

Medical Devices (Amendment)Regulations 2013
Supply of Machinery (Safety) Amendment Regulations 2011
Lifting Operations and Lifting Equipment Regulations 1998
NHS Litigation Authority – Risk Management Standards.
The Management of Health and Safety at Work Regulations 1999
A Guide to Defective Medicinal Products Reporting, Investigating and Recalling Suspected Defective Medicinal Products. An Interim Guide for Healthcare Professionals, Manufacturers and Distributors. Medicines and Healthcare products Regulatory Agency 2004 Edition.
Health Service Guideline HSG(93)13 "Reporting adverse incidents and reactions and defective products relating to medicinal and nonmedical equipment and supplies, food, buildings and plant and medicinal products."
Annex F: "Reporting Defective Medicines"; (as updated in NHSE Communications Summary, November 1994, Ref: CU11/94).
Reporting Defects in Medicinal Products for Human Use, MAIL 133, September/October 2002 (MCA Publication)
Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 (the 'Orange Guide'), Medicines Control Agency
Medicines and Healthcare products Regulatory Agency (MHRA) alert CHT/2020/002, 17 September 2020
MHRA Central Alerting System website

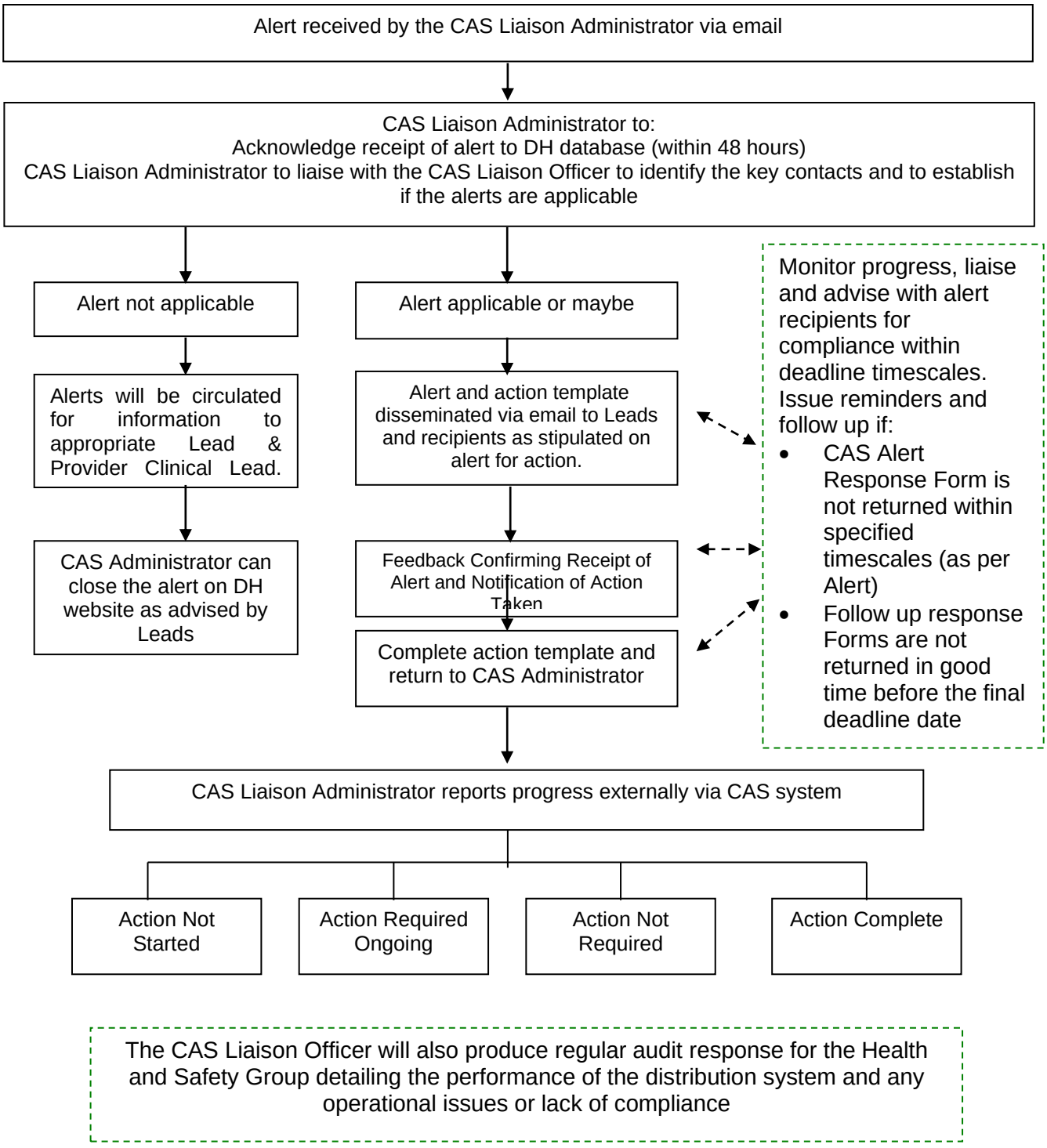
Related Trust Policies

- Moving and Handling of Patient and Inanimate loads Policy
- Management of Medical Devices policy
- Slips, Trips and Falls (Patient) Policy
- Medical Gas Policy
- All Occupational Health policies relating to Health and Safety
- All Clincal policies and safe operating procedures

9. GLOSSARY and DEFINITION

Central Alerting System **(CAS)**
National Patient Safety Alerting Committee **(NaPSAC).**
Department of Health **(DoH)**
Medicines & Healthcare Products Regulatory Agency **(MHRA)**
Dear Doctor Letter (**DDL)**

Appendix A – Safety Alert Flow Chart



Appendix B – Safety Alert Audit Tool

Safety Alert Audit Tool

ALERT Ref: TITLE / NUMBER:

CAS REPORTING SYSTEM RESPONSE

Step 1 -	**Yes**	**No**	**Answer** (Evidence date/ time)
Acknowledge receipt of alert to DH database (within 48 hours)			

Step 2 -	**Answer** *Identify who was the nominated point of contact/s (name/ service and when they were informed*
Review and Cascade Alert within timescale to the nominated point of contact/s	
Have the appropriate Nominated persons been informed?	

Step 3 -	**Answer** (Evidence *Date, time and to who)*
Number of reminders (if any) the CAS administrator sent and who received them ?	

Step 4 -	**Yes**	**No**	**Answer** (Evidence date/ time)
Completed action template returned to CAS Administrator within timescale			

Step 5 -	**Yes**	**No**	**Answer** (Evidence date/ time)
CAS Liaison Administrator reports progress externally via CAS system within specified time scale relevant to the alert the alert			

SERVICE RESPONSE and **ACTIONS UNDERTAKEN**

Step 6 -	**Yes**	**No**	**Answer** (Evidence *Date, time and by who)*
Alert acknowledged by nominated point of contact/s?			

Step 7 – Service Response	**Yes**	**No**	**Answer** (Evidence)
1. Action Not Required			
2. Action Not Started			
3. Action Required Ongoing			
4. Action Complete			

Step 8 -	**Answer** (Evidence of action plan *)*
View action Plan	

Step 9 -	**Yes**	**No**	**Answer** (Evidence)
1. Completed?			

2. Outstanding actions to address?			

Step 10 -	**Yes**	**No**	**Answer** (Evidence what, how etc*)*
Communication within the service/ department?			

Date: Auditor's name: Auditor's signature

Appendix C – Medical Devices

Reporting Adverse Incidents

1. Introduction

Medical devices (equipment) are items used for the diagnosis and/or treatment of disease, the monitoring of patients as well as aids for daily living. Examples of medical devices include, but are not limited to:

- Blood glucose monitors
- Defibrillators, monitors and scanners
- Imaging equipment
- Surgical implants
- Syringes and needles
- Urine and blood test kits
- Wheelchairs, walking frames and sticks

2. Adverse incidents

An adverse incident is an event that causes or has the potential to cause unexpected or unwanted effects involving the safety of patients, or other persons. Causes of incidents involving medical devices may include:

- Design or manufacture problems
- Poor user instruction and training
- Inappropriate local modifications
- Inadequate maintenance
- Unsuitable storage and use conditions

3. Reporting Adverse Events

Any adverse incident involving a medical device should be reported, especially if the incident has led to or, were it to occur again, could lead to:

- Death or serious injury
- Medical or surgical intervention (including implant revision) or hospitalisation
- Unreliable test results (and risk of misdiagnosis).

Other minor safety or quality problem should be reported as these helps identify trends or highlight inadequate manufacturing or supply systems.

4. Patient Safety

It is imperative that medical devices and devices used for decontamination involved in an incident are isolated and quarantined using the quarantine tape provided. ***It is vital that the device does not re-enter service, is not repaired, returned to the manufacturer, or discarded until the MHRA have been given the opportunity to carry out their own investigation.***

5. Medicines

Medicines must be clearly marked, returned to supplying Pharmacy for credit

6. Reporting

Adverse incidents MUST be reported at the earliest opportunity. In all cases:

- Isolate the equipment from further use using the quarantine tape.
- Report the incident using the Trust's reporting system.
- Contact the CAS Administrator Tel **07990550698** email Quality&Safety@solent.nhs.uk
- **DO NOT** send contaminated items through the post.
- **DO NOT** dispose of packaging or any item or part of the equipment.
- **DO NOT** repair or attempt to repair the device.

Further advice can obtain from the Trust's CAS Liaison Officer or CAS Administrator.

Appendix D - Central Alerting System (CAS) Response Status Definitions

Acknowledged
Is automatically chosen when you select your response to the alert.

Assessing Relevance
This option indicates that you are making enquiries within your organisation to determine whether action is required. We would expect this option to be used for as brief a period as possible and should not remain at this status beyond the action underway deadline date.

Action Not Started
This option indicates that there is agreement within your organisation that action is required to address the issues raised in the alert. Planning of action may already be taking place; however, the work required has not yet started.

Action Required: On-going
This option indicates that the people in your organisation, who need to take action in response to the alert, have started to implement the agreed action plan.
Where all the actions for compliance have been implemented, but an ongoing requirement is anticipated, for example the periodic checking of equipment, the Action Completed option should be selected.
For guidance, alerts will clearly state an action underway deadline (a deadline by which you would normally be expected to have an action plan in place and to have begun the work required). You would be expected to have moved your status to 'action required: ongoing' by this date. You may wish to provide reasons for your decision.

Action Not Required
Select this response if, having considered the alert carefully and consulted colleagues as necessary, the action required in the alert is not relevant to your organisation. You should provide a brief, clear explanation as to why no action is necessary in the response notes text box.
Also, use this response if the alert is for information only, but only after you have distributed the alert to the appropriate people in your organisation.
If you are in a Commissioning only NHS Trust and the alert is not relevant, please select 'Action Not Required' once you have cascaded the alert to your independent contractors. Please see the CAS Help section for more information on the role of Commissioning NHS Trust's within CAS
Please do not select 'Action Not Required' to indicate your organisation has already implemented the actions covered by the alert. In this case, select 'Action Completed' instead and add a response note as appropriate.

(Note on re-issued alerts: If an alert is re-issued due to an error in the original, please, select 'Action Not Required' to close the original, with a note in the text box, indicating that it has been replaced by a later alert. Please see the CAS Recipient's Manual for further information).

Action Completed
This option indicates that your NHS organisation considers that it has carried out all the actions stated in the alert that are applicable. Your organisation should be fully compliant with the requirements set out in the alert and processes should be in place to address ongoing requirements, such as training. Where an alert specifies an ongoing requirement (e.g., the periodic checking of equipment), once an action plan is in place to manage these requirements, you should select 'Action Completed' to close the alert.

If, having carried out a full risk assessment, your organisation cannot complete all the actions detailed within an alert (e.g., if a replacement device is not yet available), it is acceptable to put the remaining issues on the trust risk register as long as there is an action plan in place with clear deadlines for achieving compliance and the action plan is monitored internally. Once an action plan is in place, you may select this option to sign off the alert.

Other points to note

The response form will be deemed signed off once it has been marked action completed or you have indicated that no action is required.

Liaison Officers are expected to use the above responses to map their progress towards implementing alerts. As such, it is best practice to use CAS to record each relevant step in the process of receiving and closing alerts.

Appendix E - Equality Analysis and Equality Impact Assessment

Equality Analysis is a way of considering the potential impact on different groups protected from discrimination by the Equality Act 2010. It is a legal requirement that places a duty on public sector organisations (The Public Sector Equality Duty) to integrate consideration of Equality, Diversity and Inclusion into their day-to-day business. The Equality Duty has 3 aims, it requires public bodies to have due regard to the need to:

- **eliminate unlawful discrimination**, harassment, victimisation, and other conduct prohibited by the Equality Act of 2010.
- **advance equality of opportunity** between people who share a protected characteristic and people who do not.
- **foster good relations** between people who share a protected characteristic and people who do not.

Equality Impact Assessment (EIA) is a tool for examining the main functions and policies of an organisation to see whether they have the potential to affect people differently. Their purpose is to identify and address existing or potential inequalities, resulting from policy and practice development. Ideally, EIAs should cover all the strands of diversity and Inclusion. It will help us better understand its functions and the way decisions are made by:

- **considering the current situation**
- **deciding the aims and intended outcomes of a function or policy**
- **considering what evidence there is to support the decision and identifying any gaps**
- **ensuring it is an informed decision**

Equality Impact Assessment (EIA)

Step 1: Scoping and Identifying the Aims

Service Line / Department	All NHS Trust staff Independent Contractors	
Title of Change:		
What are you completing this EIA for? (Please select):	Policy	*(If other please specify here)*
What are the main aims / objectives of the changes	To outline the Organisational arrangements for the effective Management of External Alerts	

Step 2: Assessing the Impact

Please use the drop-down feature to detail any positive or negative impacts of this document /policy on patients in the drop-down box below:

Protected Characteristic	Positive Impact(s)	Negative Impact(s)	Action to address negative impact: *(e.g. adjustment to the policy)*
Sex			This Policy does not have Negative or positive impact on any protected characteristic such as Sex
Gender reassignment			This Policy does not have Negative or positive impact on any protected characteristic such as Gender Reassignment
Disability			This Policy does not have Negative or positive

			impact on any protected characteristic such as Disability
Age			This Policy does not have Negative or positive impact on any protected characteristic such as Age
Sexual Orientation			This Policy does not have Negative or positive impact on any protected characteristic such as Sexual Orientation
Pregnancy and maternity			This Policy does not have Negative or positive impact on any protected characteristic such as Pregnancy and Maternity
Marriage and civil partnership			This Policy does not have Negative or positive impact on any protected characteristic such as Marriage and Civil Partnership
Religion or belief			This Policy does not have Negative or positive impact on any protected characteristic such as Religion or Belief
Race			This Policy does not have Negative or positive impact on any protected characteristic such as Race

If you answer yes to any of the following, you MUST complete the evidence column explaining what information you have considered which has led you to reach this decision.

Assessment Questions	Yes / No	Please document evidence / any mitigations
In consideration of your document development, did you consult with others, for example, external organisations, service users, carers, or other voluntary sector groups?)	Yes	There has been regular consultation with occupational health and wellbeing team, head of risk and litigation, and the health and safety group members, Medical Devices Safety Officer, Pharmacy, Estates and Facilities
Have you taken into consideration any regulations, professional standards?	Yes	Health and safety, fire and environmental executive regulative requirements, Health Technical Memorandum and Health Building Notes
In drafting your document have you identified any discrimination issues, and, if so, how have they been mitigated?	No	No, this policy has no effect on the diversity of people it relates to and does not discriminate against any one person or organisation based on the protected characteristics.

Step 3: Review, Risk and Action Plans

How would you rate the overall level of impact / risk to the organisation?	Low	Medium	High
	■	☐	☐
What action needs to be taken to reduce or eliminate the negative impact?	N/A no negative impact identified		
Who will be responsible for monitoring and regular	The Review of this policy and EIA was conducted by		

review of the document / policy?	the H&S manager and chair of the health and safety group

Step 4: Authorisation and sign off

I am satisfied that all available evidence has been accurately assessed for any potential impact on patients and groups with protected characteristics in the scope of this project / change / policy / procedure / practice / activity. Mitigation, where appropriate has been identified and dealt with accordingly.

Equality Assessor:		*Date:*	*01/06/2021*

This section is to be agreed and signed by the Head of Diversity and Inclusion in agreement with the Diversity and Inclusion Strategy Lead:

Diversity and Inclusion authoriser name:	
Date:	