CENTRAL ALERT 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 Department of Health.
Document Type	X Policy SOP Guideline
Reference Number	Solent NHST/Policy/HS14
Version	Version 3
Name of Approving Committees/Groups	Policy Steering Group Assurance Committee
Operational Date	September 2016
Document Review Date	September 2019
Document Sponsor (Job Title)	Chief Nurse
Document Manager (Job Title)	Patient Safety Manager
Document developed in consultation with	Head of Medicines Management Health & Safety Officer
Intranet Location	Business Zone / Policies, SOPs and Clinical Guidelines
Website Location	Publication Scheme / Policies and Procedures
Keywords (for website/intranet uploading)	Arrangements, procedures ,dissemination of, replying to Safety Alerts, Department of Health

Intranet and Website Upload

Intranet	Electronic Document Library Location:	*Insert the location of the document on the intranet*
Website	Location in FOI Publication Scheme	Our Policies and Procedures
Keywords:		

Amendments Summary:

Amend No	Issued	Page(s)	Subject	Action Date
1	DK	20-23	Alert Safety Tool	
2				
3				
4				
5				
6				
7				

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)

Summary of Policy

This revised Central Alert 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.

The Trust receives safety notices and alerts from a number of agencies that require consideration and in many cases action by managers and employees. In January 2014 the NHS England Patient Safety Domain launched the National Patient Safety Alerting System (NPSAS) an improved three level system for highlighting patient safety risks in the NHS organisations. The method of receiving alerts and notices is via the Central Alert System (CAS) which is an electronic system developed to distribute patient safety alerts and other safety critical guidance to the NHS and other health and social care providers. This policy outlines the scope and good practice to meet standards within the service. Solent NHS Trust has the responsibility to ensure that all alerts are appropriately cascaded as indicated to Solent NHS Trust Services and that the organisation maintains evidence of alerts being acknowledged appropriately by all of its services.

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1. INTRODUCTION - CENTRAL ALERT SYSTEM (CAS)

1.1 The Trust receives safety notices and alerts from a number of agencies that require consideration and in many cases action by managers and employees. In January 2014 the NHS England Patient Safety Domain launched the National Patient Safety Alerting System (NPSAS) an improved three level system for highlighting patient safety risks in the NHS organisations The methods of receiving alerts and notices is via the Central Alert System (CAS) which is an electronic system developed to distribute patient safety alerts and other safety critical guidance to the NHS and other health and social care providers.

1.2 **The three stages of NPSAS alerts are:**

(1) **Stage One Alert: Warning-**This stage 'warns' organization of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information.

(2) **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.

(3) **Stage Three Alert: Directive** -When this stage of alert is issued organizations 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

1.3 This policy and the procedures contained within outline how the alerts from the following agencies are received, distributed and actioned:

- Department of Health
- Medicines and Healthcare products Regulatory Agency (MHRA),
- NHS Estates
- NHS England Patient Safety Expert Groups (PSEGs)
- Security Alerts (NHS Protect)

2. PURPOSE

2.1 The policy has been compiled to provide guidance to Directors, Managers and Employees on the arrangements for inward and outward reporting of alerts. Whilst comprehensive, the document is not exhaustive and as such all employees are required to take reasonable care of their own health and safety and that of others who may be affected by their activities, i.e. patients and visitors.

3. SCOPE

3.1 This is a Trust-wide policy which applies to all Solent NHS employees and services without any exceptions. The policy applies to all Directors, managers and employees and extends to all sites, buildings and areas where the Trust owes a duty of care and responsibility to employees, patients, visitors, contractors, or any other person affected by its undertaking.

3.2 In order to ensure patient safety and minimise risk, the Trust has a responsibility to distribute Safety Alerts to the relevant Solent NHS Trust Services and feedback is required from the Trust's independent contractors in accordance with this policy and procedure.

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

4. EQUALITY AND HUMAN RIGHTS STATEMENT

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

4.2 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 F Equality Impact Assessment*

5. ORGANISATION AND ARRANGEMENTS FOR IMPLEMENTATION

5.1 The organisational chart of this policy identifies the organisational structure within the Trust for the inward and outward reporting of alerts in general terms. *Refer to Appendix A Central Alert Organisational Chart*

6. MONITORING AND REVIEWING

6.1 The management of the CAS systems will be monitored on a regular basis by the Trust's CAS Liaison Officer.

6.2 The CAS Liaison Officer will 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 Sub-committee. This will detail the performance of the distribution system and any operational issues or lack of compliance. *Refer to Appendix E Safety Alert Audit Tool*

6.3 This policy will be reviewed tri annually or sooner on new legislation or guidance.

7. REFERENCES

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

8. ROLES AND RESPONSIBILITIES

8.1 **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.

8.2 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.

8.3 **The Nominated Board level Director for health and safety (Chief Nurse)** will through the Solent Health & Safety Committee 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 .

8.4 **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 appropriate departmental managers/line managers appointed at all times to act as Nominated Points of Contact to whom the notices can be disseminated.

8.5 **CAS Liaison Officer**

8.5.1 The Department of Health requires the Trust to nominate CAS Liaison Officer to receive the CAS alerts through a dedicated e-mail address.

8.5.2 The Head of Patient Safety is the Trust's CAS Liaison Officer, or in their absence the Clinical risk and safety Manager will act as their deputy. In the absence of either party the Health and Safety Manager will act in their stead.

8.5.3 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;
- Receiving responses from the nominated leads on action taken, collating this information and confirming completion when all responses have been received;

- 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;

- Providing 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;

- Undertaking risk assessments on any alerts not actioned within the given timescale and adding the alert to the Corporate Risk Register until the alert has been fully actioned and signed off as complete;

- Ensuring that the Central Alert 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

8.6 **CAS Administrator** duties and responsibilities include, but may not be limited to:

- Liaise with CAS Liaison Office or designate regarding any Alert considered to have an organisational impact in order to ensuring 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 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 central registrar 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.

8.7 **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.

8.8 **All Employees** will,

- Ensure 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;

9. DISTRIBUTION PROCEDURES, INWARD REPORTING & DISSEMINATION

9.1 All alerts will be sent by email to the Trust's designated e-mail address SCHRiskManagementTeam-SISS@solent.nhs.uk and posted on the CAS Website.

9.2 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.

9.3 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 E Safety Alert Flow Chart and Appendix C Central Alerting System Response Status Definitions

9.4 The CAS Administrator will monitor the returns and issue up to 3 reminders for those not returned by the due date. . What happens after that?

9.5 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.

9.6 Trust's performance will be monitored by the Board through the Health and Safety Sub – committee.

9.7 The nominated leads are responsible for:

- Reviewing each alert received to determine its relevance;
- Actioning each alert as appropriate;
- Having systems in place to ensure that all their staff are aware of the relevant alerts, any actions required or changes in procedure;
- Responding to the CAS Liaison Officer within the timescale specified on the notice and detailing action taken;
- Ensuring that in their absence there is another person within their team to take responsibility for checking receipt of alerts, actioning them as appropriate and communicating with staff.
- Any significant risks identified or inability to maintain compliance within the stated deadlines must be notified to the Head of Service, who will carryout a risk assessment and follow the Trust's risk management procedures (as detailed on the Trust's Risk Management Policy).

10. OUTWARD REPORTING TO CAS

10.1 After quarantine the medical device and preventing its inadvertent reuse, all adverse incidents involving medical devices are to be reported immediately using the Trust's electronic reporting system Ulysses. *Refer to Appendix B Medical Devices Reporting Adverse Incident*

10.2 To avoid any delay, line/services manager are also to report the incident to the following at the earliest opportunity:

- CAS Administrator:023 8053 8721
- email: SCHRiskManagementTeam-SISS@solent.nhs.uk

10.3 The CAS Administrator will outwardly report all adverse incidents involving medical devices to the MHRA when they have investigated the incident and have all the relevant information following review and agreement of the CAS Liaison Officer or designate.

10.4 The CAS Administrator will monitor the replies from the MHRA and manufactures and where necessary, inform staff of the outcome.

10.5 Nominated leads within respective areas are responsible for:

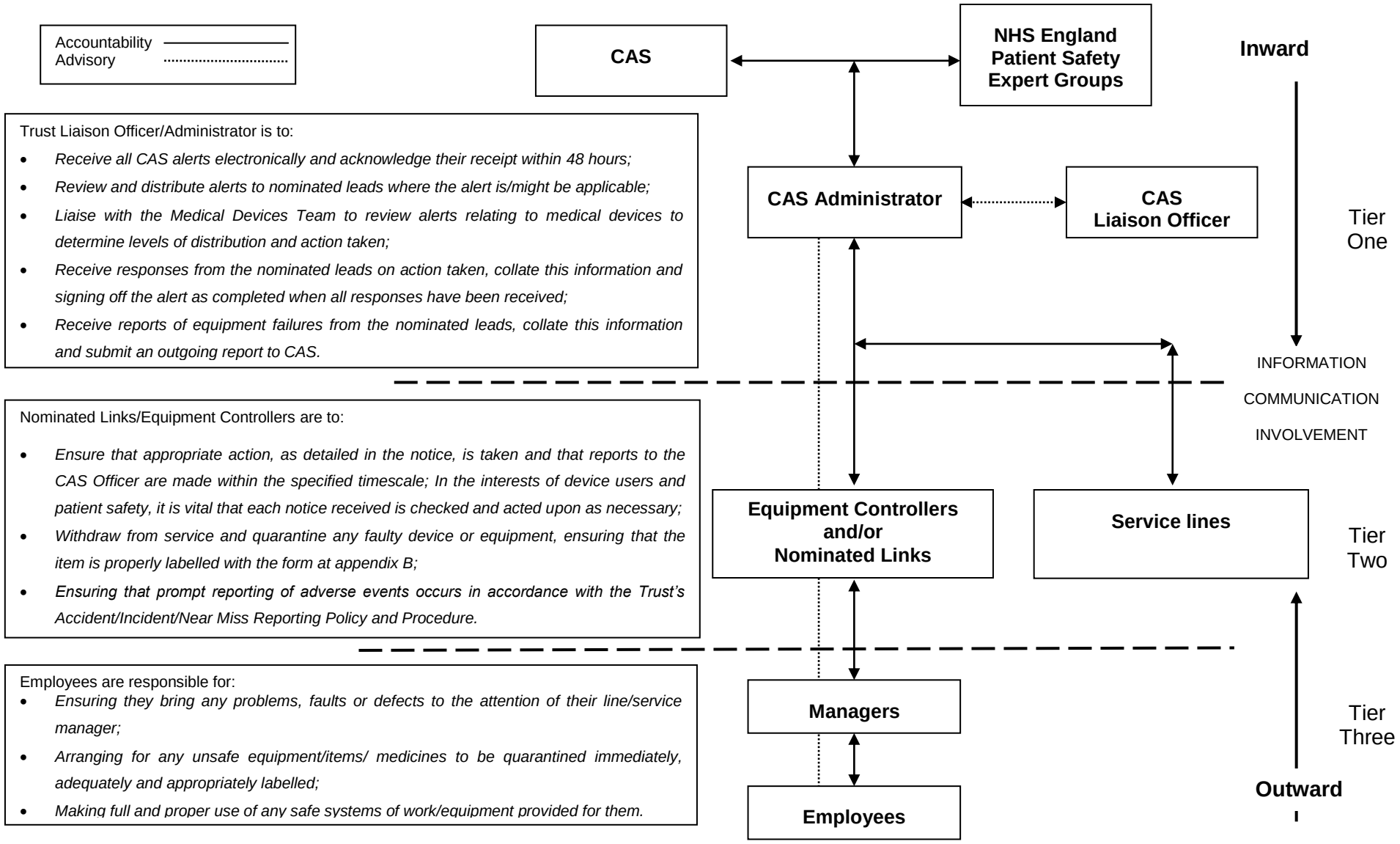
- Isolating and quarantining the medical device immediately with quarantine tape;
- Inform the CAS Liaison Administrator ;
- Having robust systems in place to ensure staff are aware of what to do in the event of an adverse incident with medical device and that the device cannot be inadvertently used, maintained or disposed of.
- Ensuring that in their absence, another person within their team is available to take responsibility for reporting adverse incident with medical device.

11. DRUG SAFETY ALERTS

11.1 Drug Safety Alerts to the Medicines Management Team come via the CAS system. Please refer to the Procedure for Drug Recalls

Solent NHS
NHS Trust

APPENDIX A- CENTRAL ALERT ORGANISATIONAL CHART



Appendix B - 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 help 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 be 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 **023 8053 8721** email SCHRiskManagementTeam-SISS@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 obtained from the Trust's CAS Liaison Officer or CAS Administrator.

Appendix C - 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 give any reasons for

.**Action Not Required**
Select this response if, having considered the alert carefully and having consulted colleagues as necessary, it is clear that 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 D 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*)*

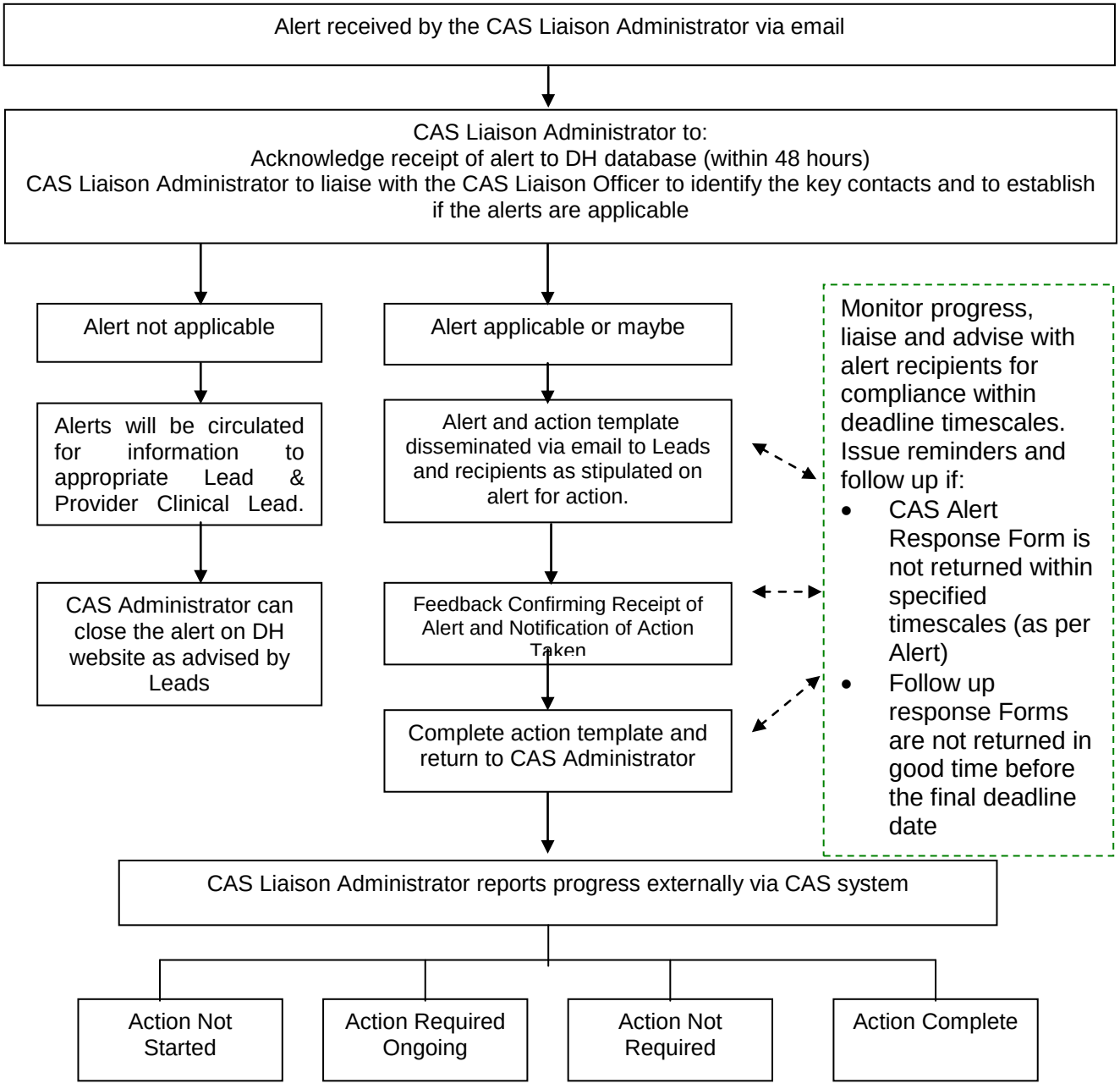
Communication within the service/
department ?

Date :

Auditors name:

Auditors signature :

Appendix E Safety Alert Flow Chart



Completed in consultation

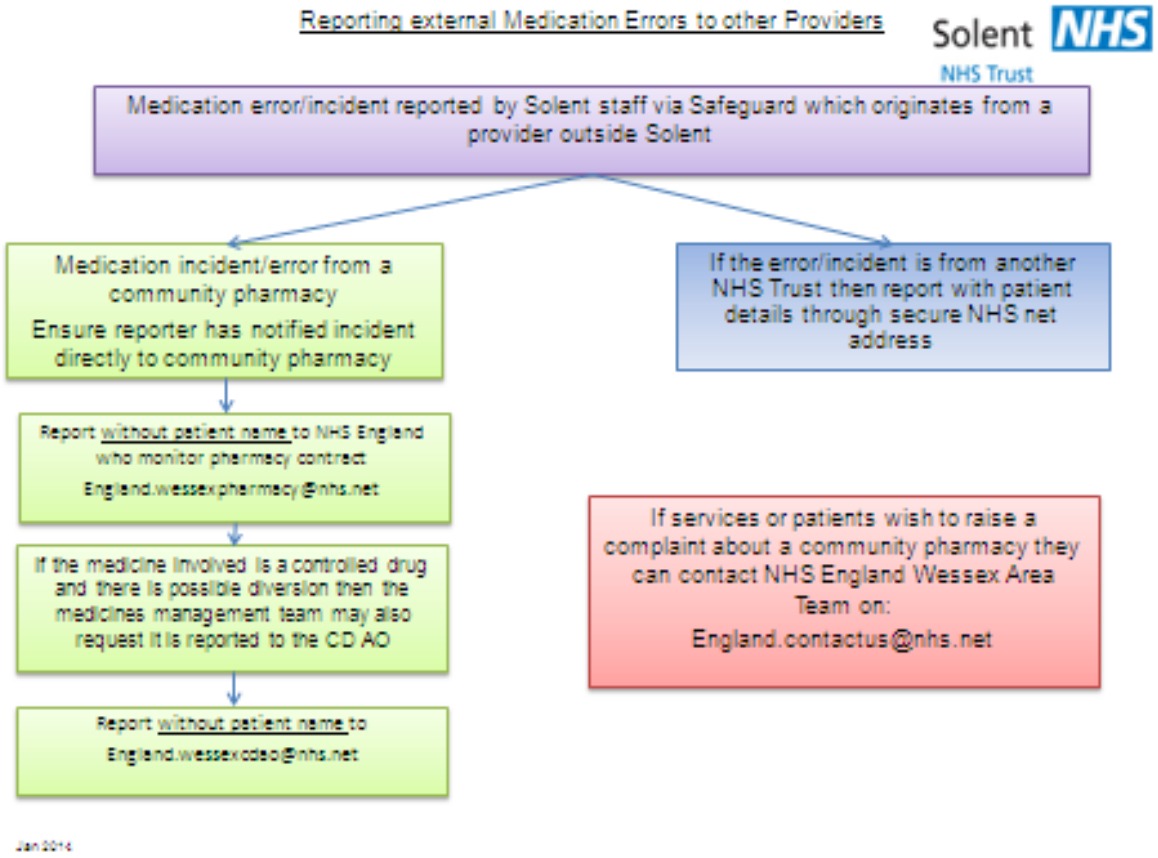
Step 1 – Scoping; identify the policies aims	**Answer**
1. What are the main aims and objectives of the policy?	Explain what the process for Central Alert System and how we disseminated alert.
2. Who will be affected by it?	All staff and patients/service users of Solent Healthcare services.
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	
4. What information do you already have on the equality impact of this policy?	
5. Are there demographic changes or trends locally to be considered?	
6. What other information do you need?	

Step 2 - Assessing the Impact; consider the data and research	**Yes**	**No**	**Answer** (Evidence)
1. Could the policy unlawfully against any group?		x	
2. Can any group benefit or be excluded?		x	
3. Can any group be denied fair & equal access to or treatment as a result of this policy?		x	
4. Can this actively promote good relations with and between different groups?		x	
5. Have you carried out any consultation internally/externally with relevant individual groups?		x	
6. Have you used a variety of different methods of consultation/involvement		x	
Mental Capacity Act implications		x	
7. Will this policy require a decision to be made by or about a service user? (Refer to the Mental Capacity Act policy for further information)		x	

If there is no negative impact – end the Impact Assessment here.

Step 3 - Recommendations and Action Plans	**Answer**
1. Is the impact low, medium or high?	
2. What action/modification needs to be taken to minimise or eliminate the negative impact?	
3. Are there likely to be different outcomes with any modifications? Explain these?	

Step 4 - Publishing the Results	**Answer**
How will the results of this assessment be published and where? (It is essential that there is documented evidence of why decisions were made).	


Reporting external Medication Errors to other Providers
Solent NHS
NHS Trust
Medication error/incident reported by Solent staff via Safeguard which originates from a provider outside Solent
Medication incident/error from a community pharmacy
Ensure reporter has notified incident directly to community pharmacy
If the error/incident is from another NHS Trust then report with patient details through secure NHS net address
Report without patient name to NHS England who monitor pharmacy contract
England.wessexpharmacy@nhs.net
If the medicine involved is a controlled drug and there is possible diversion then the medicines management team may also request it is reported to the CD AO
If services or patients wish to raise a complaint about a community pharmacy they can contact NHS England Wessex Area Team on:
England.contactus@nhs.net
Report without patient name to
England.wessexcdao@nhs.net
Jan 2014