Central Alerting System (CAS) Policy

Solent NHS Trust policies can only be considered to be valid and up-to-date if viewed on the intranet. Please visit 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
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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
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Amendments Summary:

Amend No	Issued	Page(s)		Subject	Action Date
1	DK	20-23		Alert Safety Tool	
2	DK				

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

Executive 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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Central Alert System (CAS) Policy

1. INTRODUCTION & PURPOSE

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. The Department of Health introduced the Central Alerts System (CAS) as a means of sending, electronically, these notices to nominated leads in Trusts in a more streamlined way, to improve the method in which they are issued, delivered and implemented.

1.2 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 Improvment Estates
- Chief Medical Officer
- Patient Safety Alerts
- Dear Doctor Letters (DDL)

1.3 The policy has been compiled to provide guidance to Solent staff on the arrangements for inward and outward reporting of alerts.

1.4 In order to ensure patient safety and minimise risk, the Trust has a responsibility to distribute the Safety Alerts to the relevant Solent NHS Trust Services and outward distribute the alert if relevant to the Trust's independent contractors.

1.5 Solent NHS Trust has the responsibility to ensure that all alerts are appropriately cascaded and that the organisation maintains evidence of alerts being acknowledged appropriately by all of its services, and the CAS Officer/ Administrator completes the feedback functions on the CAS Website

2. SCOPE & DEFINITIONS

2.1 This policy applies to 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), bank staff, 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 10 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 CASalerts@solent.nhs.uk .

3.2 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.

3.3 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 D Safety Alert Flow Chart and Appendix B Central Alerting System Response Status Definitions

3.4 The CAS Administrator will submit their return to the CAS web site using the pre-selected actions and "notes" boxes as appropriate. Return forms will be completed and sent back to the CAS web site within the stipulated timescale.

OUTWARD REPORTING TO CAS

Medical Devices

3.5 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

3.6 The medical device and preventing its inadvertent reuse the devices is to be quarantined, the adverse incident involving medical devices are to be reported immediately using the Trust's electronic reporting system Ulysses.

3.7 To avoid any delay, line/services manager are also to report the incident to the Trust's designated e-mail address CASalerts@solent.nhs.uk

3.8 The CAS Officer will outwardly report all adverse incidents involving medical devices to the Medicines & Healthcare Products Regulatory Agency MHRA using the Yellow Card

System after the services have investigated the incident and have all the relevant information following review and agreement of the CAS Officer or designate.

Medicines

3.9 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

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

3.11 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 investigated and all the relevant information has been established

3. 12 The CAS Officer and CAS Administrator will monitor the replies from the MHRA and manufactures and where necessary, inform staff of the outcome.

4. ROLES & RESPONSIBILITIES

4.1 **The Chief Executive Officer** for Solent NHS Trust 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 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 and 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.

4.3 **CAS Officer** responsibilities 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.
- Ensuring that the Central Alert System is informed of any changes to the CAS Officer contact details;
- Ensuring that cover is provided for the CAS Officer if he/she is absent.
- Ensuring that the key contacts are identified and established

4.5 **CAS Administrator** duties and responsibilities include,:

- Liaise with CAS Office or designate regarding any Alert considered to have an organisational impact in order to ensuring that the key contacts are identified and established
- Daily 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, 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;
- On a bi monthly basses re distribute the nominated contact list requesting contact requesting them to be reviewed asking for contact details to be either added or deleted to maximise accuracy of the nominated contact details.
- 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.

4.6 **CAS Service lines Points of Contact**, duties and responsibilities include,:

- Reviewing each alert received to determine its relevance
- 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 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 CAS Administrator;
- Ensuring that if equipment or supplies are identified on notices that are not owned by the Trust, but staffs are expected to use, they inform the appropriate line/service manager.
- Making certain that local action is taken as necessary to ensure the safety of patients, users and others.

4.7 **All Employees** will,

- Ensure they understand and comply with any alerts actions that are brought to their attention
- 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 A: Equality impact assessment)

6. SUCCESS CRITERIA / MONITORING EFFECTIVENESS

6.1 The management of the CAS systems 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 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. This will detail the performance of the

distribution system and any operational issues or lack of compliance. *Refer to Appendix C Safety Alert Audit Tool*

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

Procedure for Drug Recalls Version 3
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.
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

9. GLOSSARY and DEFINITIONS

Central Alerting System **(CAS)**
Department of Health **(DoH)**
Medicines & Healthcare Products Regulatory Agency **(MHRA)**
Dear Doctor Letter (**DDL)**

Definition

APPENDIX A

Equality Impact Assessment

Solent NHS Trust

Step 1 – Scoping; identify the policies aims	**Answer**		
1. What are the main aims and objectives of the document?	To inform all staff on the procedures to be followed when dealing with an alerts distributed from the Central Alert System from the Department of Health and the arrangements that are in place for acting accordingly and responding within the stipulated timeframe		
2. Who will be affected by it?	All NHS Trust staff. Independent Contractors and Patients.		
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	Local targets, Legal requirements Outcomes		
4. What information do you already have on the equality impact of this document?	N/A		
5. Are there demographic changes or trends locally to be considered?	No		
6. What other information do you need?	N/A		
Step 2 - Assessing the Impact; consider the data and research	**Yes**	**No**	**Answer** (Evidence)
1. Could the document unlawfully discriminate against any group?		✓	
2. Can any group benefit or be excluded?		✓	
3. Can any group be denied fair & equal access to or		✓	

treatment as a result of this document?			
4. Can this actively promote good relations with and between different groups?	✓		
5. Have you carried out any consultation internally/externally with relevant individual groups?	✓		Please see routes of consultation and ratification process.
6. Have you used a variety of different methods of consultation/involvement	✓		Consultation within organisation. Please see above.
<u>Mental Capacity Act implications</u>			
7. Will this document require a decision to be made by or about a service user? (Refer to the Mental Capacity Act document for further information)		✓	
<u>External considerations</u>			
8. What external factors have been considered in the development of this policy?	✓		External health and safety legislation
9. Are there any external implications in relation to this policy?		✓	
10. Which external groups may be affected positively or adversely as a consequence of this policy being implemented?		✓	N/A

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

<u>Step 3 - Recommendations and Action Plans</u>	**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- Implementation, Monitoring and Review	**Answer**
1. What are the implementation and monitoring arrangements, including timescales?	
2. Who within the Department/Team will be responsible for monitoring and regular review of the document?	
Step 5 - 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).	

Appendix B - 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.

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 *)*

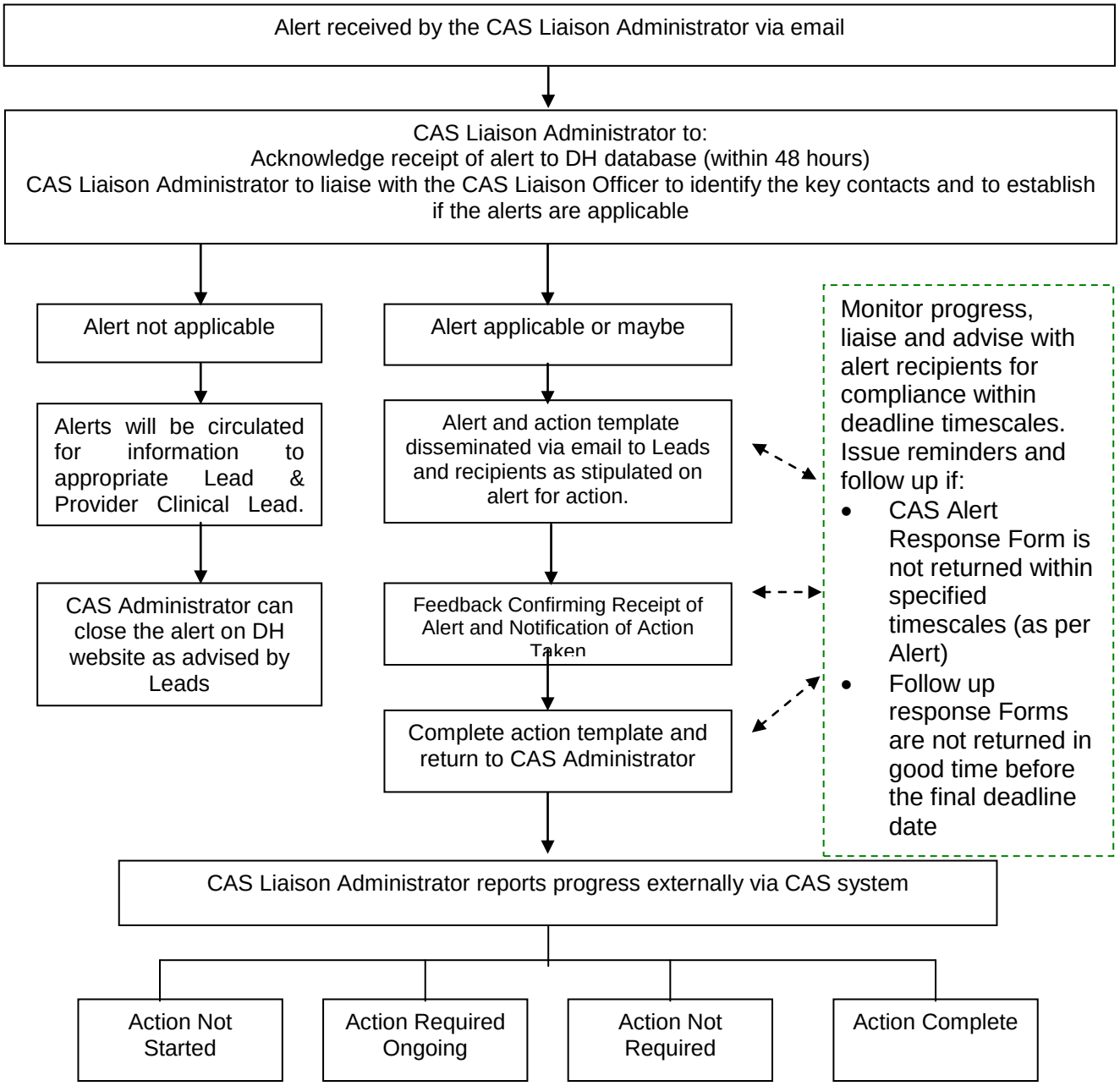
View action Plan	

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: Auditor's signature

Appendix D Safety Alert Flow Chart



The CAS Liaison Officer will also produce regular audit response for the Health and Safety Sub - Committee detailing the performance of the distribution system and any operational issues or lack of compliance