Safety Alerts Management Policy

Version Number	1.2	Version Date	October 2017
Policy Owner	Director of Nursing and Elective Care		
Author	Trust Risk and Patient Safety Manager		
First approval or date last reviewed	Previously these procedures were part of the Medical Devices Management Policy. This policy Version 1 was written in February 2014. Version 1.1 includes the updates from MHRA and the Medicines Safety Officer role.		
Staff/Groups Consulted	Deputy Director of Nursing Heads of Departments / Managers / Matrons Procurement Head of Clinical Engineering Chief Pharmacist Head of Estates and Facilities Management Facilities Manager Materials Management Manager Medical Devices Committee		
Discussed by Relevant Committee / Group	Reviewed through the Patient Safety Steering Group – 17 January 2018		
Approved by Governance and Quality Committee	24 January 2018		
Next Review Due	October 2020		
Equality Impact Assessment	October 2017		

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1. RATIONALE

1.1 Healthcare organisations are required to report to the Medicines and Healthcare products Regulatory Agency (MHRA) any actual or potential failures or defects of products, medicines and blood products concerns. The MHRA investigates these reports and takes appropriate action which may result in an alert being sent out nationally via the Central Alerting System (CAS). This combined with the Patient Safety Incident reporting process through the National Reporting and Learning Service (NRLS) provides a comprehensive identification of safety issues.

1.2 To support this process in January 2014, NHS England formed the National Patient Safety Alerting System (NPSAS) taking over from the closure of the National Patients Safety Agency (NPSA) to communicate safety critical guidance through the CAS system. The system builds on the strengths of the previous NPSA patient safety alerts and rapid response reports and is based on systems used in other high risk industries.

2. AIM

2.1 Yeovil District Hospital NHS Foundation Trust is committed to protecting patients, staff, and service users, ensuring that safety alerts are acted upon within the required timescales. The purpose of this document is therefore to give comprehensive and clear guidance in the effective, distribution and action requirements of safety alerts, notices and other communication concerning safety that have been issued via CAS.

2.2 This procedural document supports the Risk Management Strategy, Incident Reporting Policy, Medical Devices Management and Medicines Management Policy.

3. DEFINITIONS

3.1 **The Medicines and Healthcare products Regulatory Agency (MHRA):** - The MHRA is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

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

3.3 **National Patient Safety Alerting System (NPSAS)**: - NHS England through NPSAS issues 3 stages of alerting and reporting that the Trust is required to action in accordance with the following:

Stage One Alert: Warning

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

Stage Two Alert: Resource

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

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

- sharing of examples of local good practice that mitigates the risk identified in the stage one alert;
- access to tools and resources that help providers implement solutions to the stage one alert; and
- access to learning resources that are relevant to all healthcare workers and can be used as evidence of continued professional development.

Stage Three Alert: Directive

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

3.7 **Categories of Alerts**: - As well as those alerts issued through the NPSAS under the 3 stage process there are a number of categories that an alert might fall into under CAS which require a response:

- **Immediate Action**: Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice
- **Action**: Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to follow up manufacturers Field Safety Notices
- **Update**: Used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow up safety information is judged beneficial
- **Information Request**: Used to alert users about a specific issue that may become a problem and where feedback is required. These alerts may be sent out with additional questions to be completed

3.5 **CAS Liaison Officer (CASLO)**: - The CASLO receives and disseminates safety alerts through the CAS system. They are the point of reporting for the Trust.

3.6 **Medical Devices**: - Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does not include general workshop equipment such as power or machine tools, or general purpose laboratory equipment. Examples of medical devices can be found in the Trust's Medical Device Management Policy.

3.7 **Medical Device Alerts (MDAs)**: - Medical Device Alerts (MDAs) are the Medicines Healthcare products Regulatory Agency (MHRA) prime means of communicating safety information to medical device users in health and social care. This includes products purchased through procurement systems.

3.8 **MHRA Drug Alerts**: - Drug alerts are published by the Defective Medicines Reporting Centre at the MHRA with the resulting alerts distributed via a national cascade system.

3.9 There are four types of Drug Alerts:

- **Class 1** - Action now (including out of hours)

- **Class 2** - Action within 48 hours
- **Class 3** - Action within 5 days
- **Class 4** - Caution in use

3.10 **DH Estates and Facilities Alerts (EFA**): – The prime means of communicating safety information relating to non-medical equipment, engineering plant, installed services and building fabric.

3.11 **'Ulysses Safeguard'**: - The Trusts on-line risk management system will be used to record and track responses to safety alerts within the Trust. The system has a cascade system which is managed by the CASLO.

3.12 **Field Safety Notices (FSNs)**: - Actions identified by the manufacturers or distributors of medical devices or consumables relevant to the safety performance of the product. These come through sources outside CAS and may be distributed through the on-line reporting system.

3.13 **Internal Safety Alerts**: - Safety alerts may be cascaded internally to raise issues that require action or information. These will be raised through the Trust Risk and Patient Safety Manager.

4. RESPONSIBILITIES

Chief Executive

4.1 The Chief Executive has overall responsibility for ensuring effective arrangements are in place for managing risk.

Director of Nursing and Elective Care

4.2 Responsible for ensuring appropriate systems are in place to enable the effective management of safety alerts. This responsibility is passed down to the Head of Governance and Assurance who ensures the reporting process for safety alerts are managed and reported through the appropriate committee.

CAS Liaison Officer (CASLO)

4.3 Responsibilities include:

- Receiving and reporting on alerts via CAS on behalf of the Trust
- Maintaining a central record of alerts
- Distributing alerts to responsible persons through on-line systems using 'Ulysses Safeguard'', the risk management system
- Liaising with the Leads and managers to monitor status of alerts
- Maintaining records and confirming actions
- Updating the status of alerts within the Trust in the CAS system

- Providing support and guidance to staff regarding alerts
- Reporting medical device adverse events to the MHRA
- Responsible for monitoring the status of alerts to ensure actions are completed and the alert is closed when appropriate
- Providing training regarding alert processes for relevant members of staff
- Maintaining a monthly summary of alerts to the monitoring committee – Patient Safety Steering Group
- Maintaining a quarterly summary of alerts to the Medical Devices Committee
- Responsible for monitoring the status of alerts to ensure actions are completed and the alert is closed when appropriate
- Manage medical device incident reporting in the organisation
- Ensure that medical device incidents are sent to the NRLS as soon as possible and at least once a week
- Receive and respond to requests for more information from the Patient Safety Domain in NHS England and the MHRA about medical device incident reports

Trust Risk and Patient Safety Manager

4.4 Responsible for supporting the CASLO and for ensuring the systems for reporting are managed in line with this policy. Where risks are identified from non-compliance the Trust Risk and Patient Safety Manager is to liaise with those persons responsible for escalating the alert and raising risks to the appropriate level. The Trust Risk and Patient Safety Manager covers for the CASLO when they are away.

Head of Clinical Engineering

4.5 Responsible for ensuring that safety alerts for medical devices are acted upon in accordance with this policy and the instructions issued within alerts. They are responsible for having systems in place to cascade information to departments of affected devices and in liaising with the managers of service areas to act upon Medical Device alerts.

4.6 Alerts from Manufacturers/FSNs received through the Head of Clinical Engineering are to be notified to the CASLO and Trust Risk and Patient Safety Manager to escalate to the service area as appropriate. Where there are technical issues required to be addressed as the result of a Device alert or FSN Head of Clinical Engineering will action this. If it is a user or consumable issue we would refer this back to the CASLO for distribution.

4.7 Requirements include nominating staff who will be responsible for reporting through the on-line alerts system in ‘Ulysses Safeguard’’’ including having an alternative reporter for continuity.

Medical Devices Safety Officer (MDSO)

4.8 The MDSO role is integral to improving medical device incident reporting and learning within organisations. One of the MDSO's key roles is to promote the safe use of medical devices across their organisation and provide expert advice. As well as improving the quality of reporting, the MDSO will be the essential link between the identification and implementation of (local and national) medical devices safety initiatives and the daily operations to improve the safety of medical devices.

4.9 The MDSO will be an active member of the National Medical Devices Safety Network through participation in the National webex meetings.

4.10 The MDSO will improve reporting of and learning from medical devices incidents by participating in the investigation of "equipment/device" related incidents and participating in the Trusts Patient Safety Steering Group (monitoring Committee)

4.11 The MDSO will manage medical device incident reporting in the organisation and review all medical devices incident reports to ensure data quality for local and national learning and where necessary investigate and obtain additional information from reporters.

4.12 The MDSO will be a member of the Medical Devices Safety Committee and the Patient Safety Steering Group (Monitoring committees).

4.13 The MDSO will act as an additional senior point of contact for manufacturers and support local actions on Field Safety Notice. The MDSO will review and action "equipment/device" related Field Safety Notices.

Chief Pharmacist

4.14 Responsible for safe use of medicines supply and distribution throughout the Trust ensuring actions against managing safety alerts for drugs and medicines are carried out 24/7 in accordance with the regional cascade system and through CAS and the on-line alerts system in 'Ulysses Safeguard'''. Requirements include nominating staff who will be responsible for reporting including having an alternative reporter for continuity.

Head of Estates & Facilities Management

4.15 Responsible for ensuring compliance with the management of CAS alerts relevant to DH Estates and Facilities Alerts managed through the on-line alerts reporting system in 'Ulysses Safeguard'''. Requirements include nominating staff who will be responsible for reporting including having an alternative reporter for continuity.

Head of Procurement

4.16 Responsible for ensuring that products purchased through the procurement systems are recorded and monitored for distribution and use. This is essential when tracking and tracing medical device products used within the Trust.

4.17 The procurement team will receive and manage alerts through the on-line alerts system in 'Ulysses Safeguard'''. Requirements include nominating staff who will be responsible for reporting through including having an alternative reporter for continuity.

Facilities Manager

4.18 Responsible for staff in relation to the distribution of products and consumables in the

Trust and acting upon safety alerts through the on-line system in 'Ulysses Safeguard"'. The Materials Management Manager and team are responsible for responding to safety alerts notified to them through the procurement department, through the CASLO and through FSNs received outside the CAS system.

Heads of Departments/Managers

4.19 Responsible for ensuring that safety alerts are acted upon as notified through the on-line reporting system in the areas they are responsible for and for communicating the nature and seriousness of the alert as appropriate.

4.20 Responsibilities include:

- responding to alerts in the time frames set out in the alert
- ensure the distribution of alerts to appropriate departments/teams
- providing confirmation of actions taken to the CASLO relevant to the alert issued

All staff

4.21 Responsible for acting upon alerts notified to them in accordance with the alert issued. On receipt of an alert they will take the necessary actions within the required timeframes and submit response as required to the CASLO through the alert reporting procedure.

5. MANAGEMENT OF SAFETY ALERTS

Types of Safety Alerts issued through CAS

5.1 CAS is a key means to communicate important safety information to the NHS, requiring action to address risks to patient safety. There is a distinction between the two types of alerts sent via CAS:

- **NON-EMERGENCY ALERTS** – issued on behalf of MHRA, Medical Devices, NHS England and DH Estates and Facilities alerts have set deadlines for acknowledgment and completion of actions. NHS Trusts are required to submit responses on the action they have taken on alerts and are monitored on their compliance with completing such alerts within agreed deadlines.
- **EMERGENCY ALERTS** - are currently sent by the following originators – MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging. These alerts can be sent out of office hours (24/7) and are issued directly by the alert originator. Although these alerts do have deadlines, these relate to how quickly the information contained should be cascaded onwards and do not require a response through CAS. As a matter of course these will be monitored through the Trusts reporting process.

Management of NON- EMERGENCY ALERTS - (**Annex A**)

CAS Liaison Officer - Management of Alerts

5.2 Alerts notification through CAS will be received through email sabs@ydh.nhs.uk by the CASLO who then acknowledges the alert in the CAS system within the prescribed time frame of 48hrs.

5.3 The alert will identify the issues and actions to be taken within a set time frame and will set out who the alert is to be cascaded to for action/information.

5.4 The CASLO assesses the relevance of the alert with assistance through key contact filter as set out in Section 5.3 if necessary. The CASLO then notifies the alert to the relevant person/s. The on-line alerting system in 'Ulysses Safeguard'' is used for this process which allows the status and records of actions to be maintained.

5.5 Dates are set within 'Ulysses Safeguard''' to ensure internal deadlines are appropriate so that any required action can be followed up against alerts.

5.6 The notification will take one of 3 forms:

- **Action** – Alerts that target specific person/s required to lead and take action against the alert
- **Information (Info)** – Alerts that require to be notified where acknowledgement is required for internal monitoring. The person/s receiving the 'Info' alert are not the responsible person for leading the alert but should ensure their area acts upon the alert and informs relevant staff appropriately
- **Copied** (CC'd) – Alerts that need to be distributed but do not require a response

5.7 The CASLO will monitor all outstanding alerts to receive the responses within the timescales set out in the alert. They are to follow up with the person/s responsible no later than 1 week before the alert is due to end if no action has been received (to trigger this action a date is set within 'Ulysses Safeguard''').

5.8 The CASLO is to ensure CAS is updated within the specified timescales on actions taken, liaising with the person/s responsible for implementation.

5.9 Section 5.17 sets out the response and action deadlines that are required to be reported through CAS.

The Recipient - Management of Alerts

5.10 The alert recipient will be notified via email when the CASLO enters the alert into the on-line system in 'Ulysses Safeguard'''.

5.11 The person/s receiving the alert for **action** or **information** are those persons who the alert is targeted at within the alert. They are the responsible person/s to act on the alert.

5.12 Those notified are required to login into the managers section of the 'Ulysses Safeguard''' reporting system responding on-line to **acknowledge** the alert noting the deadline dates. The alert has a link that accesses the CAS page where the alert is described in detail with attachments relevant to the alert.

5.13 For all copied alerts (CC'd) via email there is no requirement to acknowledge the alert, but the information must be acted upon as appropriate to that department.

5.14 The responsible person/s must assess the relevance of the alert and then act upon the details set out in the alert.

5.15 If at this point they feel they are not the appropriate person to action the alert they must notify the CASLO immediately.

5.16 The alert may be disseminated as appropriate to others for assessment and relevance however the responsibility remains with the person notified through the on-line reporting system.

5.17 Responses required through 'Ulysses Safeguard"' are as follows:

- Where the alert is **not relevant** details of why the alert is not relevant must be notified to the CASLO at the earliest opportunity
- Where the alert is **relevant** actions must be taken to manage the implementation of alerts as necessary. 'Ulysses Safeguard"' must be updated as soon as possible to inform the CASLO as to the status as follows:
- Action Not Started
- Action Required: On-Going

5.18 Once the deadline is reached the actions are to have been **completed**. The person/s responsible for action are to report back through 'Ulysses Safeguard"'. This is to be notified as soon as possible before the deadline is reached providing any information relevant to the implementation of the alert.

Note:

- If the deadline for closure is nearing the closure date but the actions will be **on-going** the CASLO must be informed of the status for reporting through CAS
- Where there are issues implementing the alert within a service or Strategic Business Unit area, the status must be notified through the relevant senior management team at the earliest opportunity for escalation of risk

Key Contact Filter

MHRA Medical Device Alerts

- Head of Clinical Engineering
- Procurement and Material Management
- Chief Pharmacist or nominated pharmacist
- MDSO

DH Estates and Facilities Alerts

- Head of Estates and Facilities Management (EFM)
- Maintenance Manager

Patient Safety Alert

- Head of Governance and Assurance
- Trust Risk and Patient Safety Manager

- Specialist Lead
- Clinical Director of Patient Safety
- Patient Safety Coordinator

Alert Responses and Action Deadlines

5.19 All non-emergency CAS alerts are issued Monday to Friday with action deadlines requirements which relate to the seriousness of the identified safety issue.

5.20 The CASLO is responsible for updating the CAS website in relation to the action status:

- **Acknowledgement**: all alerts received are to be acknowledged within 48hrs (Monday to Friday)
- **Assessing Relevance**: this option is available to record that enquiries are being made as to the relevance of the alert within the Trust
- **Action Not started**: this option indicates that there is an agreement that the alert is relevant and actions are required to address the issues raised in the alert
- **Action Required – On-Going**: this option identifies that action is needed and these are being implemented, but on-going action is anticipated. The deadline for action completed may have been reached but not yet fully implemented. In this case supporting text should be documented within CAS
- **Action Not Required**: this option may be selected if there is no relevance to the alert having consulted as necessary. Supporting text should be documented in CAS to support this status
- **Action completed:** this option is the date the DoH requires the Trust to have had completed any necessary action. Reporting the alert completed means the Trust is fully compliant with the alert and processes are to be in place to address on-going requirements, including training and awareness as necessary

Management of EMERGENCY ALERTS

5.21 Emergency alerts sent out through the Central Alerting System (CAS) will be received through notification via the central email sabs@ydh.nhs.uk.

5.22 MHRA Drug Alerts, MHRA Dear Doctor Letter and CMO Messaging alerts are not required to be acknowledged through CAS but will be cascaded internally for action and information through the on-line reporting system in ‘Ulysses Safeguard’’.

5.23 Alerts will be cascaded through the CASLO (Monday to Friday) and out of hours they are notified to the appropriate manager.

5.24 MHRA Drug alerts will be received directly through the pharmacy team 24/7 via the South West Medicines Information and Training (SWMIT) service for action in line with the alert category.

Management of MHRA Alerts for Drug Updates

5.25 For Drug safety updates issued through the MHRA, the Medication Safety Officer (MSO) will receive updates via email through subscription through the MHRA site. The relevance of each alert will be assessed by the MSO and then cascaded through the 'Ulysses Safeguard' Alerts module. The MSO will feed back on the relevant alert action to the Safer Medicines Group. Refer to **Annex B**.

6. REPORTING TO THE MHRA

6.1 Defective medical devices and reporting of adverse blood reactions/events to the MHRA will follow the procedures set out in the Medical Devices Policy and the Blood Transfusion Policy. The Incident reporting identifies the requirements for externally reporting incidents.

7. MONITORING OF ALERTS

7.1 A monthly status report will be provided by the CASLO to the monitoring committee (Patient Safety Steering Group) to identify the status of alerts and actions required to close down the alerts. Outstanding actions must be followed up through Heads of Service or Strategic Business Unit senior teams. Alerts and incidents will be provided to the Medical Devices Committee for review on a quarterly basis.

8. TRAINING

8.1 Training on the on-line system in 'Ulysses Safeguard' will be provided to users through the CASLO on a needs basis. A user reference guide is available from the Clinical Governance Team to support training.

9. APPLICABILITY

9.1 This policy applies to all staff employed by the Trust, whether on a permanent or temporary basis. Failure to action alerts will mean that the safety issues may not be implemented and put the Trust in breach of its license to safeguard patients. Disciplinary action may be taken for failure to follow this policy.

10. SUBSIDIARY COMPANIES OF YEOVIL DISTRICT HOSPITAL (YDH)

10.1 Any employees of subsidiary companies of YDH will adhere to this policy and will receive consistent training in relation to policy implementation.

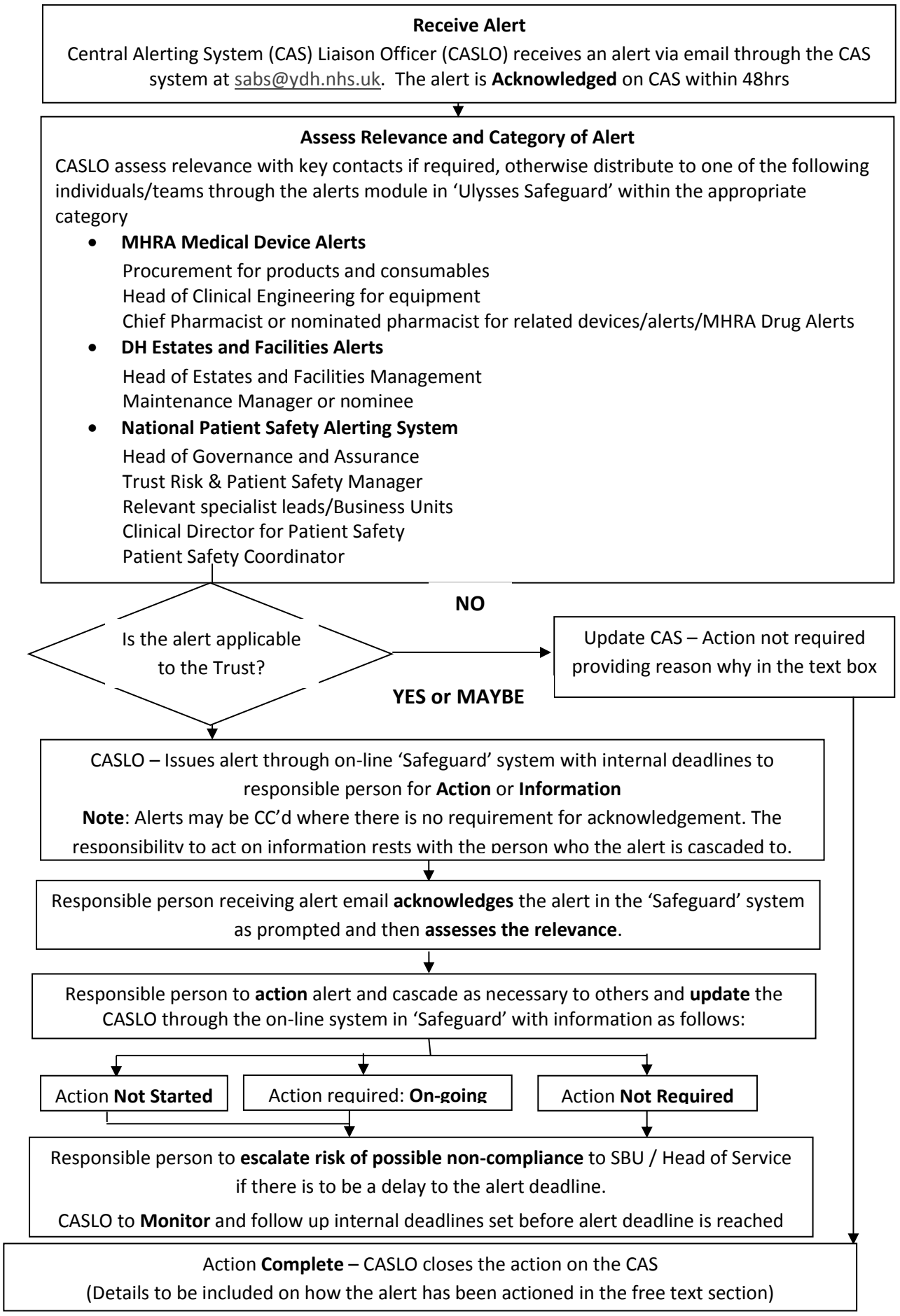
11. REFERENCES AND ACKNOWLEDGEMENTS

- Central Alerting System Website (Department of Health)
- Medicines and Healthcare Products Regulatory Agency
- An Introduction to the NHS England Patient Safety Alerting System, published: 31 January 2014 (NHS England)
- Care Quality Commission (CQC), Core Standards
- MHRA Defective Medicines Products

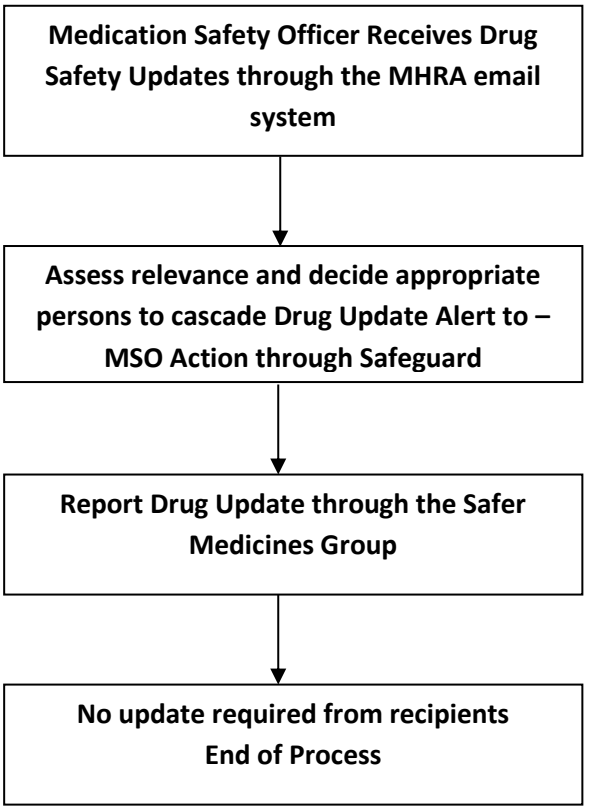
12. EQUALITY IMPACT ASSESSMENT

12.1 This policy has been assessed and implemented in line with the policy on procedural documents and an equality impact has been carried out to ensure the policy is fair and does not discriminate any staff groups. A completed Equality Impact Assessment can be found at **Annex C.**

ANNEX A – PATHWAY FOR ALERTS REPORTED THROUGH CAS



ANNEX B – PATHWAY FOR MHRA DRUG SAFETY UPDATES



ANNEX C – EQUALITY IMPACT ASSESSMENT

Name of Document: **Safety Alerts Management Policy**

1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:	Assessment	Comment
	• Race	**No**	
	• Ethnic origins (including gypsies and travellers)	**No**	
	• Nationality	**No**	
	• Gender	**No**	
	• Culture	**No**	
	• Religion or belief	**No**	
	• Sexual orientation including lesbian, gay and bisexual people	**No**	
	• Age	**No**	
	• Disability	**No**	
2.	Is there any evidence that some groups are affected differently?	**None**	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	**None Identified**	
4.	Is the impact of the policy/guidance likely to be negative?	**No**	
5.	If so can the impact be avoided?	**Not Applicable**	
6.	What alternatives are there to achieving the policy/guidance without the impact?	**Not Applicable**	
7.	Can we reduce the impact by taking different action?	**Not Applicable**	

For advice or if you have identified a potential discriminatory impact of this procedural document, please refer it to The Equality & Diversity Lead, Yeovil Academy, together with any suggestions as to the action required to avoid/reduce this impact.

Signed: **Samantha Hann** (Trust Risk and Patient Safety Manager) Date: **October 2017**