Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Alert Management System (AMS) Policy

This procedural document supersedes: CORP/RISK 6 v.5 – Central Alerting System Policy

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Sponsor by:	Medical Director
Author/reviewer: (this version)	Medical Devices Safety Officer
Date written/revised:	May 2022
Approved by:	Medical Devices Management Group/Patient Safety Committee
Date of approval:	January 2023
Date issued:	February 2023
Next review date:	May 2025
Target audience:	Trust-wide

Amendment Form

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

Version	Date Issued	Brief Summary of Changes	Author
Version 6	May 2022	• This policy has been subject to substantial changes and as such should be read in its entirety as a new policy	Andrew Ferguson
Version 5	September 2019	• Removal of references to NHS England, replaced with NHS Improvement. • Updated distribution procedure to include all clinical Governance leads • Updated Monitoring Compliance to include monthly NHSi alert activity to PSRG	Andrew Leverton
Version 4	February 2015	• Removal of the section on reporting Medical Device incidents as this is now catered for in the new DATIX system. • Title change • Policy reformatted to Trust style. • Removal of NPSA and inclusion of NHS England alerts. • Addition of RAG rating to the monitoring section.	Andrew Leverton
Version 3	December 2011	• Policy name change. • Addition of a table of contents. • Reference made to CQC outcome 11D – section 1 • Addition of accountability chart – section 2. • Updated information on NPSA Rapid Response Reports – section 4.1 • Reference to Trust based online alerting management system – section 4.2	Andrew Leverton

		• Inclusion of NPSA monitoring regime – section 5. • Inclusion of Equality and Impact assessment and useful information paragraphs – section 6 and 7. • Appendix 2 - Inclusion of flowchart for alert pathway. • References to Safety Alert Broadcast system changed to Central Alerting System. References to SABS changed to CAS. • Updated guidance on monitoring, action plans, risk assessments and audits relating to alert recommendations.	
Version 2	September 2007	• Inclusion of the NPSA's new Rapid Response Report (RRR) • Reference made to the Clinical Risk group meeting • Updated references to current MHRA documents • Updated forms in appendices	Andrew Leverton

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1. INTRODUCTION

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust ('the Trust') recognises that healthcare provision and the activities associated with caring for patients, employing staff, providing premises and managing finances all, by their very nature, involve a degree of risk. The management of risk is therefore a key organisational responsibility and is the responsibility of all staff employed by the Trust. Failure to manage risk effectively can lead to harm, loss or damage in terms of both personal injury but also in terms of loss or damage to the Trust's reputation; financial loss; potential for complaints; litigation and adverse or unwanted publicity.

The Trust has adopted an integrated approach to the overall management and risk management is embedded within the Trust's overall performance management framework and links with business planning and investment.

The Board of Directors has overall responsibility for corporate governance, including risk management. The Board has legal and statutory obligations to ensure that there are robust and effective risk management processes and structures in place.

This policy is intended for use by all employees and contractors engaged on Trust work and although the management of key strategic risks is monitored by the Board, operational risks are managed on a day to day basis by employees throughout the Trust. The Trust's Board Assurance Framework and Corporate Risk Register provide a central record of the organisation's principal risks.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been set up to promote public health and patient safety and part of its brief it offers guidance to health organisations on developing systems "that promote the use of medical devices for safe and effective healthcare".

"A medical device is defined by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), as:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception".

(MHRA) 2021[1].

Within its guidance it requires healthcare organisations to have systems in place for the management and reporting of adverse incidents and it offers advice on how to undertake this and this is incorporated into this and the Medical Devices Management and Training policy.

2. PURPOSE

This policy has been designed to outline a systematic approach by the Trust to the governance, management and distribution arrangements of alerts irrespective of their nature or origin and manufacturers Field Safety Action Notices (FSAN).

There is specific guidance published by the National Patient Safety Alerting Committee (NaPSAC), around the management of National Patient Safety Alerts (NatPSA) which this policy also follows.

It also aims to help the Trust ensure its compliance with legislation, regulation and national guidance as outlined in the Medicines and Healthcare products Regulatory Agency (MHRA) Managing Medical Devices Guidance for Health and Social care Organisations (2021)[1] and should contribute to the provision of quality healthcare by the Trust, the principles of which are summarised in:

- Outcome 11 of the Care Quality Commission (CQC) standards [1] CQC Regulation 15.
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 18.

By:

- Ensuring good governance structures are in place.
- The optimisation of cost, risk and performance of medical devices.
- Developing strategies for ownership and use of medical devices.
- Identifying relevant legislation.
- Identifying sources of additional guidance.
- Providing balanced information to help local groups develop policy and procedures.

3. DUTIES AND RESPONSIBILITIES

The policy reporting and accountability arrangements are shown below

Chief Executive

The board member with overall responsibility for medical devices safety and management and for ensuring all staff are aware of this policy.

Medical Director (Executive Lead)

The board member (in this case the Medical Director) with responsibility of ensuring the implementation of this policies governance arrangements.

The Executive Lead shall have oversight of governance systems that provide evidence that the required actions have been fully completed before any NatPSA is recorded as 'action completed' on the MHRA Central Alerting System (CAS).

The Executive Lead shall ensure that the Trust has appointed a MDSO.

Medical Devices Safety Officer

Shall promote the safe use of medical devices across their organisations and be the main point of reference for medical devices safety.

Shall manage medical device incident reporting within the organisation and, improve the reporting and learning from these.

Shall know how to escalate issues to your organisation's Executive Board.

Shall ensure suitable arrangements are in place to receive, record, distribute, collate data and record on actions undertaken by the Trust in accordance with published alerts and manufacturer FSAN and to report back in appropriate timescales.

Shall report back to the MHRA CAS (in the case of alerts) or suppliers (in the case of FSAN) whenever there is a requirement to do so.

The MDSO should only be recording National Patient Safety Alerts as 'action completed' on the MHRA Central Alerting System (CAS) once all actions have been completed and they have the authorisation of the 'Executive Lead'.

Medication Safety Officer

The Medication Safety Officer (MSO) shall ensure that suitable arrangements are in place to ensure that any work on drug related issues that is required as a result of an alert/FSAN is carried out in appropriate timescales.

Incident Reporting Systems Manager

The Incident Reporting Systems Manager is the Trust lead for the system used by all staff to report risks and incidents.

Divisional Directors/Department Leads/Matrons

Shall ensure all staff are aware of this policy.

Divisional Directors/Department Leads/Matrons/Lead Nurses

Shall ensure that the actions required by an alert or FSAN that affects their areas of operation are carried out in appropriate timescales.

Medical Technical Services Manager

The Head of Medical Technical Services (MTS) shall ensure that suitable arrangements are in place to ensure that any work on Trusts medical devices required as a result of an alert/FSAN is carried out in appropriate timescales except on medical devices that come under the management arrangements of the Trust's Imaging department.

Head of Radiology

The Head of the Trust's Imaging department shall ensure that suitable arrangements are in place to ensure that any work required on Trusts medical devices that come under the management arrangements of the Trust's Imaging department as a result of an alert/FSAN is carried out in appropriate timescales.

Medical Devices Management Group (MDMG)

The purpose of the committee is to advise the trust on matters relating to the general management and governance of medical devices used within the organisation. The committees work is based upon recommendations in the Medicines & Healthcare products Regulatory Agency (MHRA) Managing Medical devices Guidance for healthcare and social services organisations (January 2021).

This policy will be monitored and audited on an ad-hoc basis by the Medical Devices Management Group (MDMG) as part of their assurance framework.

Patient Safety Committee (PSC)

The purpose of the group is to review all open alerts/FSAN at monthly meetings and where necessary to ensure any actions are taken and completed in appropriate timescales.

Associate Director of Nursing/Midwifery/Therapies

To ensure that divisional matrons are aware of the policy. To be informed of incidents within their division relating to medical equipment.

Clinical Directors

To ensure that all consultant teams are aware of the policy and that medical professionals complete appropriate documentation.

Matrons

To ensure that all of their ward/department managers are aware of the policy. To investigate and action any incidents relating to medical equipment and escalate these incidents to Associate Director of Nursing /Midwifery/Therapies as appropriate.

Ward/Department Managers

Responsible for ensuring that staff within the ward/department are aware of this policy. Provide support to the training co-ordinator with monitoring compliance of staff training along with sourcing training opportunities as required. Training can be arranged by contacting Medical Technical Services.

Training co-ordinator

The designated person on the ward/department who will be responsible for ensuring that the equipment folder is kept up to date.

All staff

Are responsible for only using equipment that they have been trained to use and take note of and implement the actions of an alert/FSAN that impacts on user issues.

4. ALERT AND FSAN FORMATS

Alerts and FSAN come in various formats and from differing sources, this section outlines the format of each.

Alerts

National Patient Safety Alerts (NatPSA) have a distinct design and unique logo to make them stand out from other safety communication. Each NatPSA is designated as a safety-critical issue and are sub-divided into 'complex' or 'straightforward'.

- 'Complex' alerts require actions that cannot be delivered by any single division or professional group within an organisation and will require the organisation's executive leader to nominate a senior clinical leader relevant to the alert to coordinate delivery

- 'Straightforward' alerts may be actioned on behalf of the whole organisation by agreed senior leaders (for example, an agreement that the chief pharmacist will ensure all stocks throughout the organisation are checked for a National Patient Safety Alert requiring removal of a specific drug batch), or may be directed at a specific senior leader relevant to the alert.

Serious Hazard of Transfusion (SHOT) are those specifically related to transfusion practices and shall be treated as NatPSA.

Please note - All NatPSA shall require the written approval of completion of the Trust's Executive Lead to the MDSO before the MDSO can inform the MHRA of such.

CQC inspection will focus on implementation of NatPSA with the potential for regulatory actions for non-compliance.

Medicines Alerts are those specifically related to the procurement and use of a prescribed drug and they come in four classes, Class 1 – Recall (now published as a NatPSA), Class 2 or 3 - Recall, Class 4 - Caution in Use, company led (FSAN).

Device Safety Notifications (Device Alerts) are those that relate specifically to all issues relating to EU/UK registered medical devices.

Chief Medical Officer (CMO) Alerts are those that relate to therapy issues.

United Kingdom Health and Security Agency (UKHSA) Alerts are those that relate to the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats on the general public.

Supply Disruption Alerts (SDA) are those that relate specifically to issue around the supply/delivery of goods.

Estates and Facilities Alert (EFA) are those that are considered to affect the Estates and Facilities issues of hospitals.

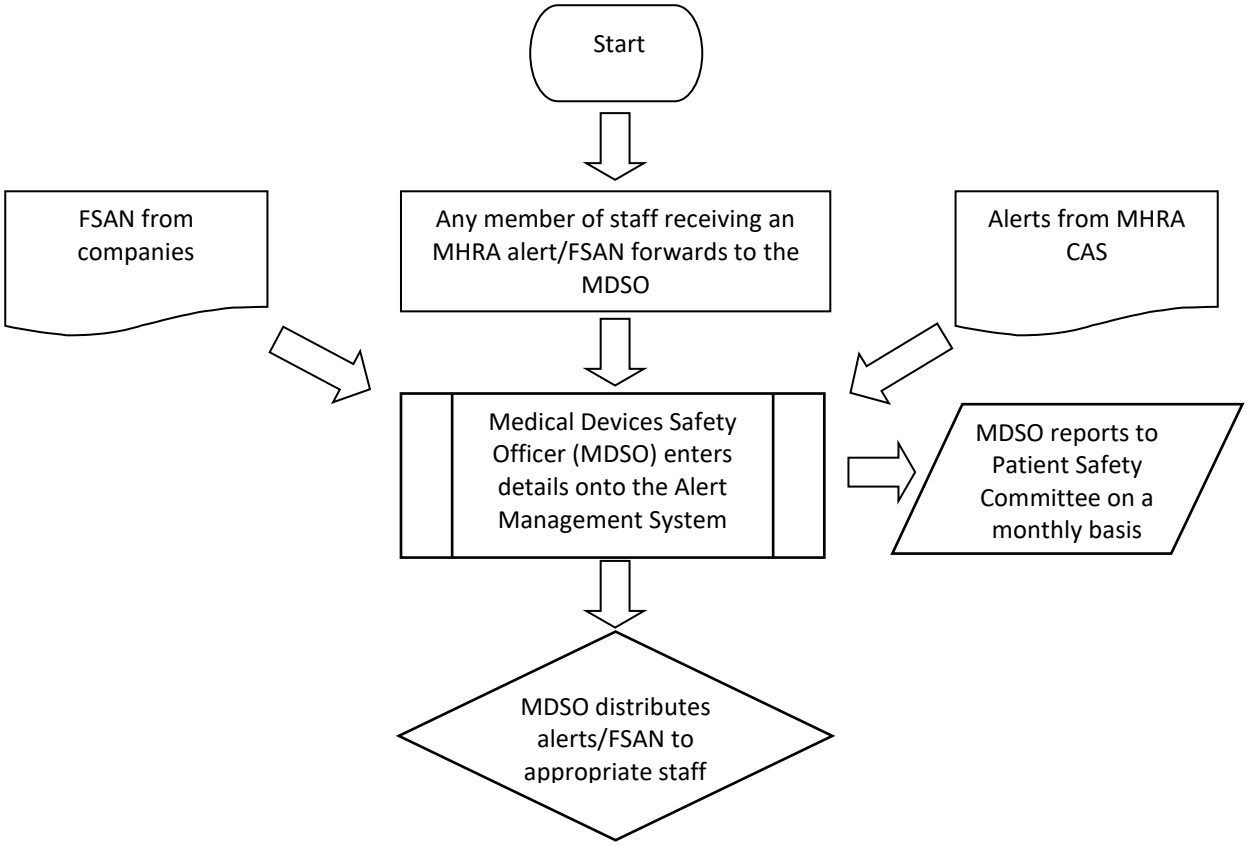
FSAN are those notices that are usually published by manufactures of medical devices and can come in many formats, but where a FSAN requires a response back to the publisher then this shall be undertaken by the Trust Medical Devices Safety Officer.

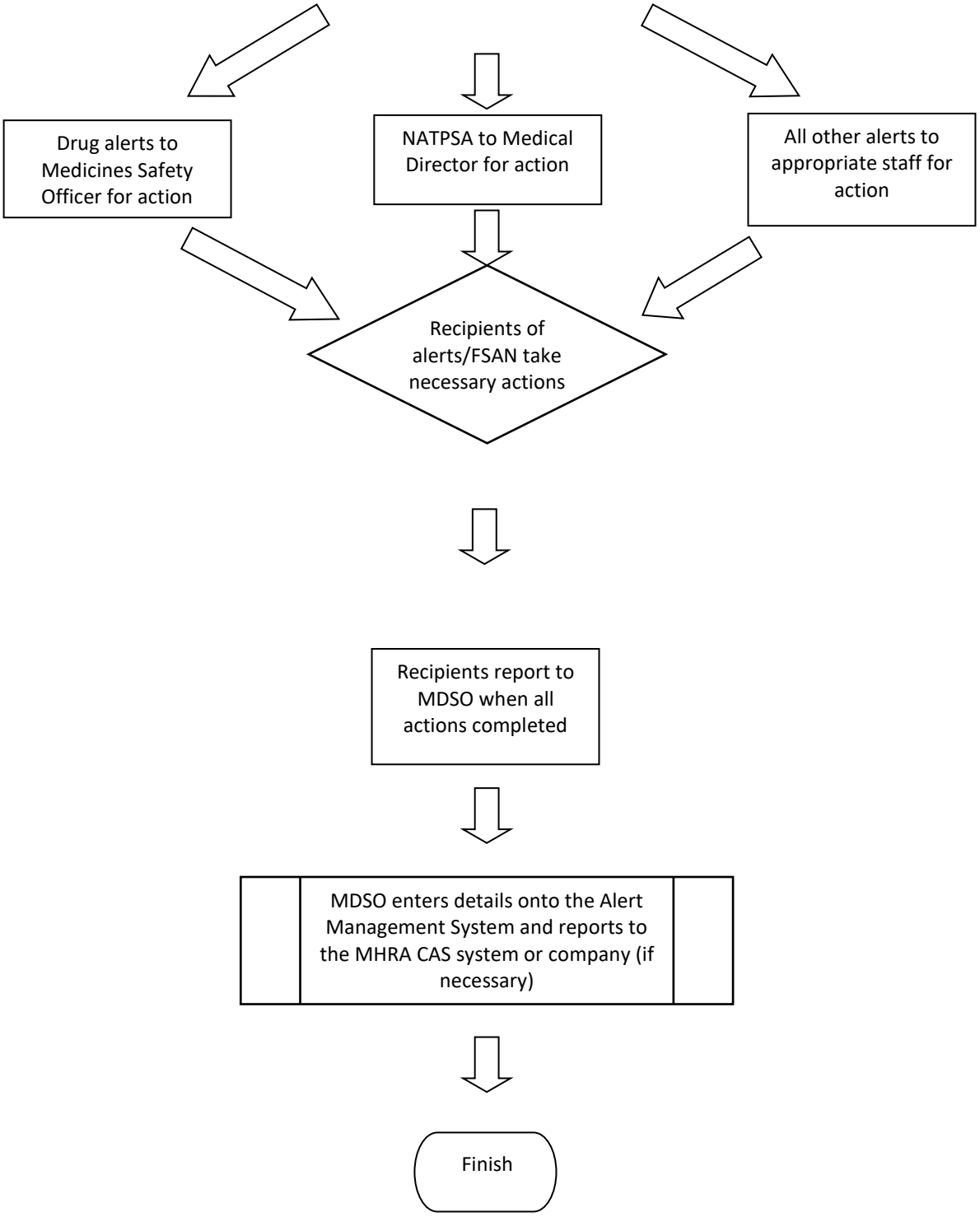
If anyone is in receipt of an FSAN can they please forward onto the Trust's MDSO for actioning.

5. PROCEDURES

The procedure for the management and distribution of alerts and FSAN within the Trust is outlined in the Trust procedure for The Management and Distribution of Alerts and Field safety Action Notices and is included in Appendix 1.

Flow diagram for the distribution of alerts/FSAN




Drug alerts to Medicines Safety Officer for action
NATPSA to Medical Director for action
All other alerts to appropriate staff for action
Recipients of alerts/FSAN take necessary actions
Recipients report to MDSO when all actions completed
MDSO enters details onto the Alert Management System and reports to the MHRA CAS system or company (if necessary)
Finish

6. MEDICAL DEVICES AND SHARED SERVICES

Where the trust provides clinical care in partnership with another healthcare provider either on or off our sites, it shall be the responsibility of the 'owner' (the organisation owning legal title to the equipment) to ensure that any actions required by an alert or FSAN shall be carried out in a timely manner.

7. TRAINING AND SUPPORT

Any training required by staff on the AMS can be accessed via the Trusts Medical Devices Safety Officer (MDSO).

8. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENTS

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Training records	Medical Devices Management Group	Annual	Ward/Department managers via Survey Monkey

Compliance with risk assessments, staff training and updates	Ward/department managers	6 months prior to annual review	EOG and divisional Governance Groups
All Medical Technical Services procedures	Medical Equipment Management Group	Every 5 years or after any changes	MEG

9. EQUALITY IMPACT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

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

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

10. DATA PROTECTION

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

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

11. REFERENCES

[1]MHRA. (2021). Managing Medical Devices Guidance for health and social care organisations [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf [Accessed 1/5/2021].

12. APPENDICES

APPENDIX 2 – NATIONAL GUIDANCE

Care Quality Commission (2017). Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15. Available from: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-15-premises-equipment

MHRA. (?). *Central Alerting System – CAS Liaison Officers Guide* [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf [Accessed: 1/6/2020].

MHRA . (2019) *Medical Device Safety Officer - MDSO Handbook v2* [Online]. Available at: https://namdet.org/wp-content/uploads/2017/12/MDSO-JD-Harrogate.pdf . [Accessed: 1/10/2021].

APPENDIX 2 – ASSOCIATED TRUST POLICIES

Medical Devices Management and Training Policy.

Incident Management Policy.

Risk Identification, Assessment, and Management Policy.

Procedure for the Management and Distribution of Alerts and Field Safety Action Notices.

APPENDIX 4 – EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Appendix 4 – Equality Impact Assessment

Service/Function/Policy/Project/ Strategy	Care Group/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Alert Management System (AMS) Policy	Trust wide	Andrew Ferguson	Existing	1/5/2022

1) Who is responsible for this policy? Medical Devices Management Group

2) Describe the purpose of the service / function / policy / project/ strategy? Providing guidance on the management and governance arrangements of MHRA alerts and FSAN within the Trust.

3) Are there any associated objectives? Compliance to CQC and DHSC outcomes.

4) What factors contribute or detract from achieving intended outcomes? – Financial constraints may impact on delivery of intended outcomes.

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

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

6) Is there any scope for new measures which would promote equality? [any actions to be taken] – No.

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

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

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

Outcome 1 √	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27

Date for next review: 1/9/2027

Checked by: Acting Director of Estates and Facilities **Date: 1/12/2022**