

Reference Number: UHB 377 Version Number: 1.1	Date of Next Review: July 2024
Safety Notices and Important Documents Management Procedure	
Introduction and Aim This procedure details Cardiff and Vale University Health Board (the UHB) arrangements for the management of Safety Notices and Important Documents. The aim of the procedure is to:- <ul style="list-style-type: none"> • Ensure that there is a consistent approach to the dissemination of Safety Notices and Important Documents. • Ensure appropriate actions are taken with regard to Safety Notices and Important Documents. • Assist staff with identifying their roles and responsibilities. • Ensure that there is a robust audit trail providing evidence of compliance and action taken. 	
Objectives To ensure the UHB has appropriate effective arrangements to support staff managing important safety and governance information received by the UHB.	
Scope This procedure applies to all of our staff in all locations including those with honorary contracts and will be particularly important for the nominated Liaison Officers. It also includes the arrangements for ensuring that primary care contractors are kept apprised of certain categories of information.	
Equality and Health Impact Assessment	This procedure is covered by the Generic EHIA for Administrative Type Policies.
Documents to read alongside this Procedure	UHB 082: Medical Equipment Management Policy.
Approved by	Quality, Safety and Experience Committee
Accountable Executive or Clinical Board Director	Director of Corporate Governance

Author(s)	Risk and Regulation Officer
<p><u>Disclaimer</u></p> <p>If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.</p>	

Summary of reviews/amendments			
Version Number	Date of Review/ Approved	Date Published	Summary of Amendments
1	06/12/17	21/12/17	In line with revised formatting rules for policies and procedures, this procedure has been extracted from the UHB's former policy. The opportunity was taken to update the content to reflect revised structures, titles and responsibilities to ensure more robust implementation (Appendix 1).
1.1	21/07/2021	23/07/2021	Reviewed according to policy schedules. Designated Liaison Officer details updated. Algorithm illustrating process steps added.

SAFETY NOTICES AND IMPORTANT DOCUMENTS MANAGEMENT PROCEDURE

CONTENTS		Page No.
1	Introduction	4
2	Policy Statement	4
3	Types of Safety Notices and Important Documents Included in this Policy	4
4	Arrangements for Managing Safety Notices and Important Documents	5
5	Roles and Responsibilities	6
6	Resources	8
7	Training	8

8	Further Information	8
9	Implementation	9
10	Audit	9
11	Distribution	9
12	Review	9

Appendices:

1	Designated Liaison Officers and Responsible Committees	10-11
2	Managing Safety Notices and Important Documents Algorithm	12
3	Safety Notices/Important Documents Compliance Form (cover sheet)	13
4	Audit Tool for the Management of Safety Notices and Important Documents	14

1. INTRODUCTION

1.1 Cardiff and Vale University Local Health Board ('The UHB') receives safety information notices and other important documents e.g. Inspection Reports from a number of different organisations. The majority will be sent to the Chief Executive but they may also be sent to other key departments and individuals. Some notices require an immediate response and action. Due to the variety of ways that this information can enter the UHB it may be difficult to identify whether appropriate action has been taken and required responses have been sent by the UHB.

1.2 From time to time, internal safety notices are also issued within the UHB. These also need to be communicated and monitored in a controlled way.

1.3 The UHB must be able to demonstrate that it has responded appropriately to information that is received. There must be robust audit trails which confirm that appropriate actions occurred within a designated or reasonable time period.

1.4 This procedure outlines:

- The importance of the correct management of safety information notices and other important documents.
- The arrangements for disseminating safety information notices and other important documents.
- The roles and responsibilities of individuals within the UHB for the dissemination of safety notices and other important documents.
- The arrangements for the audit of compliance.

2. POLICY STATEMENT

It is policy of the UHB that appropriate and effective arrangements are made to ensure relevant actions are taken by individuals in response to any safety or governance information received by the UHB. For the purpose of this document this type of information will be described as Safety Notices and Important Documents. The categories/types of notices covered by the policy and procedure are outlined below. All staff responsible for taking action on receipt of a Safety Notice or Important Document will be clearly identified.

3. TYPES OF SAFETY NOTICES AND IMPORTANT DOCUMENTS INCLUDED IN THIS POLICY

3.1 The policy and procedures are applicable to the following information for which the generic term Safety Notices and Important Documents is used:

- MHRA Medical Device Alerts
- Estates and Facilities Alerts
- Pharmaceutical Alerts

- Product recalls and Manufacturer Field Safety Alerts
- External Patient Safety Alerts
- NICE Guidance
- NCEPOD Documents
- Security Alerts
- Welsh Risk Pool Technical Guides
- Healthcare Inspectorate Wales (HIW) Reports
- Regulatory agency reports e.g. Health and Safety Executive, Fire Authority, Human Tissue Authority
- Accreditation visit reports
- Ministerial Letters
- Internal Safety Notices

3.2 This list is not exhaustive and from time to time other “Important Documents” may be received which require an equivalent response by the UHB.

4. ARRANGEMENTS FOR MANAGING SAFETY NOTICES AND IMPORTANT DOCUMENTS

4.1 Within the UHB the following overarching arrangements have been put in place to ensure the appropriate distribution and collation of information:-

4.1.1 For each category of information there is a nominated lead known as the “Liaison Officer” who is responsible for distributing the information to the designated leads within the UHB (see Appendix 1).

4.1.2 The Liaison Officers will act in accordance with the algorithm at Appendix 2 to ensure that the Safety Notices and Important Documents are sent to appropriate staff for action. They will have written procedures explaining these arrangements and they will endeavour to ensure that information is appropriately targeted.

4.1.3 Safety Notices and Important Documents will be divided into categories A and B. Category A documents will require immediate action. Category B documents must have action taken within a specified time scale. This may be mandated within the document or determined by the Liaison Officer following consultation with the appropriate Director.

4.1.4 The UHB will attempt to direct external agencies to send Safety Notices and Important Documents to the appropriate addressee. The majority will also be sent to the Chief Executive. However, with the high volume of information being sent to the UHB there may be occasions when a document is received by an individual who is not the designated Liaison Officer or the Chief Executive. This may occur when, for example, a Ward Sister/Charge Nurse receives a product safety notice from a manufacturer, or a Director is sent a Ministerial Letter or similar document. If this should occur the Safety Notice or Important Document must be forwarded to the identified Liaison

Officer (see Appendix 1). The Liaison Officer will then distribute the information in accordance with this policy.

5. ROLES AND RESPONSIBILITIES

5.1 UHB Board. The UHB Board has ultimate responsibility for ensuring that effective arrangements are in place to ensure the appropriate dissemination and action following the receipt of Safety Notices and Important Documents.

5.2 Committees/Sub Committees. Each of the Safety Notices and Important Documents will be monitored for compliance via appropriate committees/sub committees of the Board/management group; the responsible committee/group is listed in Appendix 1. Each committee will determine how they will undertake this monitoring role. They will provide a report to Corporate Governance detailing the findings from this monitoring function at the end of each financial year.

5.3 Director of Corporate Governance. The Director of Corporate Governance has delegated responsibility for ensuring that there are clear arrangements in place to ensure the appropriate dissemination and review of Safety Notices and Important Documents. She is supported in this role by the Directors who have delegated responsibility for the specific areas covered within the Safety Notices and Important Documents e.g. the Executive Nurse Director will be responsible, via the appropriate Liaison Officer, for the dissemination and review of HIW Reports.

5.4 Liaison Officers. Liaison Officers have been identified for each type of Safety Notice and Important Document (see Appendix 1). They are responsible for:

5.4.1 Documenting the procedure that they will follow on receipt of a Safety Notice or Important Document.

5.4.2 Ensuring that Safety Notices and Important Documents received are reviewed and wherever practical identifying the specific Directorates/Clinical Boards that are required to take action.

5.4.3 Ensuring that all relevant Safety Notices and Important Documents are forwarded in an appropriate and timely fashion to the identified leads within the Directorates/Clinical Boards for action or information.

5.4.4 Ensuring that where a Safety Notice or Important Document is sent to a Directorate or Clinical Board it is also sent to the Clinical Board Director of Operations for information to allow them to fulfil their responsibilities.

5.4.5 Ensuring that where appropriate the UHB Covering Sheet is attached to the Safety Notice or Important Document (see Appendix 3)

identifying that action is to be taken and a response is required, or that it is for information only.

5.4.6 Discussing with other Liaison Officers or key individuals any Safety Notices or Important Documents not covered by this procedure that require clarification/agreement of the action to be taken.

5.4.7 Collating all responses received from the Clinical Boards and Directorates following receipt of a Safety Notice or Important Document for their action and escalating non-compliance to the appropriate Executive Director.

5.4.8 Co-ordinating the audits as specified in the procedure.

5.4.9 Maintaining a record of the Safety Notices and Important Documents for which they are the Liaison Officer and a summary of the action taken that can be shared with the appropriate committee/management group for assurance.

5.5 Clinical Board Teams/Executive Directors. Clinical Board Teams and Executive Directors have overall responsibility for ensuring that appropriate action is taken within their Clinical Board/Directorate or area of responsibility. Where necessary they will ensure that information is considered at their Clinical Board Quality and Safety/Health and Safety/Risk etc meetings.

5.6 Directorate/Locality Teams. If it is identified that a Safety Notice or Important Document is of relevance to a specific Directorate or Locality a copy will be sent to the Clinical Director, Directorate/Locality Manager and Lead Nurse. On receipt of a Safety Notice or Important Document the Directorate/Locality Teams will:

5.6.1 Confirm to the Liaison Officer the relevance of the Safety Notice or Important Document to their area of responsibility and inform them of the Nominated Lead. This will depend on the nature of the document e.g. Lead Nurses may act as the Nominated Lead for clinical supplies, Clinical Directors may act as the Nominated Lead for NICE guidance.

5.6.2 Ensure that information received is forwarded, if necessary, in an appropriate and timely fashion to the appropriate areas under their control in accordance with a written Directorate Procedure.

5.6.3 Ensure that appropriate action is taken by the areas under their control and that they receive confirmation of this.

5.6.4 Risk assess the issues involved and add the assessment to the Risk Register as appropriate.

5.6.5 Collate the Directorate/Locality response and report the actions that have been taken to the identified Liaison Officer, using the covering sheet provided.

5.7 Director of Operations – Primary Care. The Director of Operations – Primary Care will ensure that appropriate arrangements are in place to disseminate Safety Notices and Important Documents to primary care contractors. These arrangements are as follows:

5.7.1 The NHS Wales Shared Services Partnership (SSP) will send Safety Notices and Important Documents to primary care contractors on behalf of the UHB. The information will include MHRA Medical Device Alerts, Patient Safety Alerts and Public Health Wales Alerts. These publications will be sent direct to the SSP from the Welsh Government.

5.7.2 The SSP will also send other Important Documents to primary care contractors at the request of the UHB. This will include NICE Guidance and Ministerial Letters.

5.7.3 A copy of all information sent to primary care contractors will be sent to nominated individuals within the Primary Care Directorate. These are as follows:

- Clinical Governance Manager – Primary Care
- Locality Pharmacy Leads (Title to be agreed)
- Head of Unscheduled Care – Primary Care

5.8 Director of Nursing – PCIC. The Director of Nursing PCIC will ensure that appropriate arrangements are in place to disseminate Safety Notices and Important Documents to nursing homes. This will be facilitated by the Locality Lead Nurse – Cardiff North and West. The SSP will send them the information to assist them to fulfil this function.

6. RESOURCES

This procedure largely reflects existing practice and therefore no additional resources are required.

7. TRAINING

It is not envisaged that any formal training will be required as a result of the review of the policy and procedures. However, the policy and procedures will need to be brought to the attention of the identified Liaison Officers, Directorate, Locality and Clinical Board Teams who will need to take note of their responsibilities.

8. FURTHER INFORMATION

Medical Devices Agency (MDA) Liaison Officer Information Pack:

- MDA: Reporting Adverse Incidents and Disseminating Medical Device Alerts (DB2011 (11)).
- Welsh Assembly Government/Department of Health Estates and Facilities Alert ((2008) 001).

9. IMPLEMENTATION

These procedures reflect existing practice and therefore can be implemented immediately. Where changes have been made to manage the process more robustly, this has been done in agreement with the departments concerned.

10. AUDIT

10.1 An audit against compliance with this policy and procedures will be undertaken by the appropriate Liaison Officer. This will be on 10 percent, or a minimum of 5 Safety Notices and Important Documents (whichever is the greater) received within each financial year (see Appendix 3).

10.2 Each of the Safety Notices and Important Documents will be monitored for compliance via specific committees/sub committees of the board or, where appropriate, a management group; the responsible committee/management group is listed in Appendix 1.

10.3 Each committee/management group will determine how it will undertake this monitoring role. They will provide a report to Corporate Governance detailing the findings from this monitoring function at the end of each financial year.

11. DISTRIBUTION

The policy and procedure will be available via the UHB Intranet and Internet sites. Where staff do not have access to these resources the line manager must ensure that they are aware of the contents where appropriate.

12. REVIEW

The policy and procedure will be reviewed to reflect any changes in guidance or legislation. As a minimum it will be reviewed 2 years from the date of approval.

DESIGNATED LIAISON OFFICERS AND RESPONSIBLE COMMITTEES

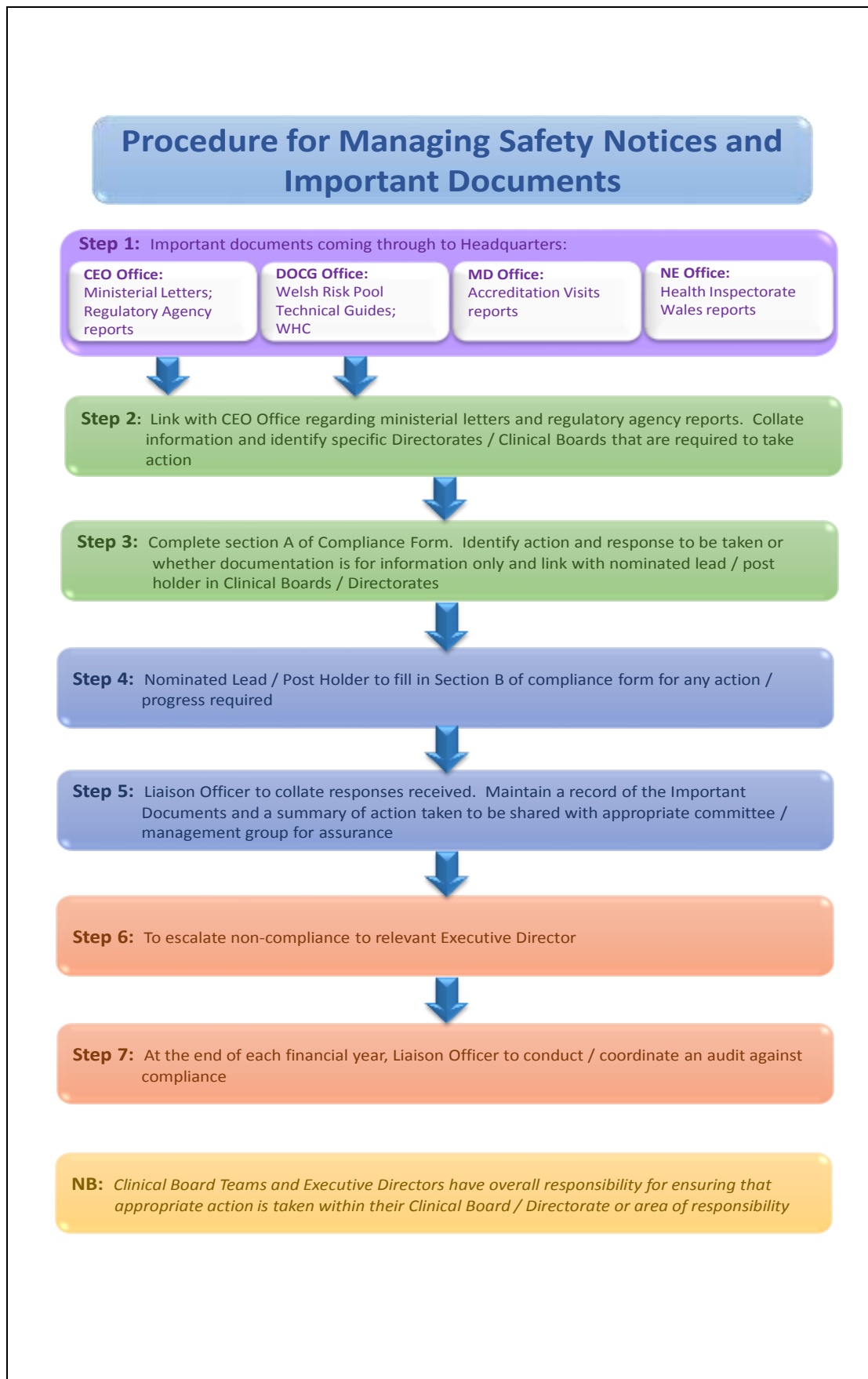
CATEGORY "A" ALERTS FOR IMMEDIATE ACTION

Type of Safety Notice	Liaison Officer	Department	Responsible Committee / Group
MHRA Medical Device Alerts*	Head of Procurement Claire Salisbury	Procurement Department	Medical Equipment Group
Estates and Facilities Alerts	Head of Performance and Energy Jon.mcgarrigle@wales.nhs.uk and Tina.neale@wales.nhs.uk	Capital Estates and Facilities, Lakeside UHW	Health and Safety Operational Group
Internal Safety Notices (Health and Safety)	Head of Health and Safety Robert Warren	Health & Safety Unit 4 th Floor Denbigh House UHW	Health and Safety Operational Group
Internal Safety Notices (Patient Safety)	Patient Safety & organisational Learning Manager Cav.patientsafetysolutions@wales.nhs.uk Annie Burrin	Patient Safety & Quality	Quality Safety and Experience Committee
Pharmaceutical Alerts	Clinical Director of Pharmacy Darrell Baker	Pharmacy Department	Medicine Management Group
Ministerial Letters	Director of Corporate Governance Nicola Foreman	Governance Directorate	To be determined by subject
Product Recalls and Manufacturer/Field Safety Notices*	Head of Procurement Claire Salisbury	Procurement Department	Medical Equipment Group
Security Alerts	Head of Performance and Energy Jon.mcgarrigle@wales.nhs.uk And Tina.neale@wales.nhs.uk	Capital Estates and Facilities	Personal Safety and Security Strategy Group

CATEGORY “B” ALERTS FOR ACTION WITHIN SPECIFIED TIMESCALE

Type of Safety Notice	Liaison Officer	Department	Responsible Committee
External Patient Safety Information/Notices/Patient Safety Solutions	Patient Safety & Organisational Learning Manager Cav.patientsafetysolutions@wales.nhs.uk	Patient Safety & Quality Team	Quality Safety and Experience Committee
NICE Guidance	Quality and Safety Improvement Manager Angharad Oyler	Patient Safety & Quality Team	Quality Safety and Experience Committee
NCEPOD Documents	Quality and Safety Improvement Manager	Patient Safety & Quality Team	Quality, Safety and Experience Committee
Healthcare Inspectorate Wales Reports (excluding Mental Health Act)	Assistant Director of Patient Safety and Quality Carol Evans	Patient Safety & Quality Team	Quality, Safety and Experience Committee
Healthcare Inspectorate Wales Reports (Mental Health Act)	Director of Nursing Mental Health Clinical Board Mark Warren	Mental Health , Clinical Board	Mental Health and Capacity Legislation Committee
Welsh Risk Pool Technical Guides	Head of Risk & Corporate Governance	Governance Directorate	Quality, Safety and Experience Committee
Regulatory Agency Reports/Accreditation Visit Reports	Director of Corporate Governance	UHB HQ	Quality, Safety and Experience Committee

*** In addition Clinical Engineering will be sent directly all of these Safety Notices to allow them to co-ordinate a response with the Head of Health and Safety and Assistant Director of Finance/Procurement**



SAFETY NOTICE/IMPORTANT DOCUMENT COMPLIANCE FORM

Section A (to be completed by Liaison Officer)

Organisation From: Click here to enter text.

Document Title: Click here to enter text.

Document Reference: Click here to enter text.

Electronic Link: Click here to enter text.

Date of Issue: Click here to enter a date.

Status of Document: Choose an item.

Name of post holder Document sent to: Click here to enter text.

Date response from post holder required by: Click here to enter a date.

Response to be sent to: Click here to enter text.

Section B - Action Taken/Progress to Date:

Click here to enter text.

Name: Click here to enter text. **Role/Designation:** Click here to enter text.

Directorate: Click here to enter text. **Clinical Board:** Click here to enter text.

Date: Click here to enter a date.

Section C - Office Use Only

Data Entry Number: Click here to enter text. **Date:** Click here to enter a date.

Initials: Click here to enter text.

APPENDIX 4

AUDIT TOOL FOR MANAGEMENT OF SAFETY NOTICES AND IMPORTANT DOCUMENTS

An audit against compliance with this policy will be undertaken by the appropriate Liaison Officer. This will be on 10 percent, or a minimum of 5 randomly selected Safety Notices and Important Documents (whichever is the greater) received within each financial year

1.	Reference Number	Click here to enter text.
2.	What is the type of Safety Notice/Important Document	Click here to enter text.
3.	What date was the Safety Notice/Important Document received in the UHB?	Click here to enter a date.
4.	Which department/departments received the Safety Notice/Important Document?	Click here to enter text.
5.	What date was the Safety Notice/Important Document circulated within the UHB?	Click here to enter a date.
6.	Who was the Safety Notice/Important Document circulated to?	Click here to enter text.
7.	How many responses were received?	Click here to enter text.
8.	How many responses indicated action had been taken?	Click here to enter text.
9.	Comments Click here to enter text.	

Name: Click here to enter text. **Role/Designation:** Click here to enter text.

Directorate: Click here to enter text. **Clinical Board:** Click here to enter text.

Date: Click here to enter a date.