

## **ADVERSE INCIDENT REPORTING: POLICY & PROCEDURE**

### **1. INTRODUCTION**

As part of its commitment to risk management DRH will ensure that a system is in place to enable any adverse incident to be reported, recorded and investigated. An effective reporting system will enable DRH to identify and rectify any weaknesses, failings or defects helping to provide safer systems of work. This will also enable managers to provide effective support to those who may have been affected by an adverse incident.

An adverse incident is any occurrence or accident which has or could have resulted in an injury to a service user, staff member or member of the public. An adverse incident may be a complaint relating to service user care/support. It may also include property or equipment damage, equipment failure or aggression. Predictable and regular behaviours of a service user should not be considered as an adverse incident unless these involve physical assault. (see section 3)

An adverse incident report must be completed within 24 hours for any incident that has or may adversely affect any individual. In certain cases this is a legal requirement in some cases, (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 i.e. RIDDOR 95) but in all cases factual information must be gathered as soon as is practicable after the event in order to prevent a recurrence by accurately determining the causes and contributing factors.

In the event of a serious incident, the Chief Executive/Deputy Chief Executive should be contacted immediately by telephone.

### **2. OBJECTIVES**

The main objectives of this Policy are:-

- To enable prompt remedial action to be taken and to prevent recurrence.
- To ensure compliance with current legislation, e.g. RIDDOR.
- To comply with the National Minimum standards for Care Homes/Independent Hospitals.
- To provide statistical information for trend analysis, which can be used in the development of future safety strategies and safe systems of work?
- To enable Board members to monitor the effectiveness of health, safety and risk management arrangements
- To assist decision making, planning and future resource allocation
- To provide information to other interested parties, e.g. Insurance Company; Purchasers; Care Quality Commission, Commission for Health Audit and Inspection; DRH Board, DRH Health & Safety Committee, Managers, Trade Union Representatives.

### 3. SCOPE OF PROCEDURE

These procedures should be used in the case of any adverse incident involving a member of staff, service user or visitor (including Contractors) to DRH sites. This also includes adverse incidents involving any member of staff in the course of their duties away from a DRH site or service users on holiday, day outings or elsewhere whilst under the care of DRH.

These reporting procedures are not intended to replace “clinical” monitoring systems associated with individual service users. In the context of this policy, it is inappropriate to report the long-standing behaviours of a service user that regularly occur, which are clearly addressed within that service users support plan (e.g. verbal abuse) and which are more properly monitored by clinical charting. However, any incident, which results in physical injury or where the risk of physical injury is narrowly avoided, the incident must be reported using an Adverse Incident Report Form.

### 4. GENERAL PRINCIPLES

It is the responsibility of all staff to take reasonable care of themselves and of others who may be affected by their acts or omissions.

Verbal aggression, actual or attempted physical aggression is not an acceptable part of any job and requires a considered, co-ordinated and professional response. DRH is a specialist provider of services for people whose ability to communicate may be frustrated by significant intellectual impairment or serious mental illness. Our service users may also have underdeveloped or impaired emotional control. These factors may result in high levels of aggression at times. Crisis Prevention training is mandatory for all staff on a bi-annual basis. The Two day training programme is BILD accredited and examines various de-escalation and breakaway techniques.

It is the responsibility of each member of staff to inform their manager or shift leader promptly (within 24 hours) of any incident or dangerous occurrence. **Each member of staff must be fully aware of the reporting procedure** and it is the responsibility of the Manager to ensure that this is done. Adverse incidents should be reported to the appropriate regulatory body i.e. Care Quality Commission/ Commission for Healthcare Audit and Inspection. (see Appendix E). When it is suspected that a criminal offence may have taken place the police may be contacted after consultation with the Chief/Deputy Chief Executive.

When an adverse incident involves major injury the scene of the incident should not be disturbed until the critical incident investigators have had the opportunity to inspect. (See appendix B)

## 5. REPORTING AN ADVERSE INCIDENT

- The staff who were involved in, witnessed or discovered the incident, should complete the Incident form/s
- When completing the incident form, record only facts not opinions or assumptions
- The manager or deputy manager must ensure that as far as reasonably practicable all appropriate actions have been taken to remove or reduce the likelihood of the incident occurring again.

## 6. PROCEDURE

The following procedure should be followed in the case of all adverse incidents.

- In the event of injury the first priority is to identify the extent of the injury and ensure that appropriate treatment is given. Managers should ensure that, where deemed necessary, the injured person's next of kin or anyone else that needs to know is informed of the incident.
- Any faulty equipment, defective chemicals, drugs or other factors contributing to the adverse incident should be immediately withdrawn from use and the area made safe. However any material evidence relating to the incident should be retained for investigatory purposes.
- Any faulty equipment withdrawn from use should be clearly labelled as such and an entry made in the team's diary/communication book and staff informed at handover
- In the case of accidents resulting in an injury to a staff member, an entry must be made in the **Staff Accident Book (B1510)**, by the injured person or someone on their behalf. It is important that all details are filled in accurately. All staff should be aware of the location of his book.
- When completed the B1510 form is given to the Home Manager and stored within the Home in a safe confidential manner, a copy given to the injured staff member if requested.
- The employee's union safety representative is entitled to a copy of the B1510 form if the employee has ticked the box in section 4.
- In the case of accidents involving a service user, full details should always be recorded in the service user's records.

### *When completing an Adverse Incident form.*

- Take care to include all information available on the form, including names of witnesses to the adverse incident.
- When recording injuries always state clearly whether the left or right side of the body is involved.
- Be as precise as possible concerning the cause of the incident, actions taken at the time and any follow up action.

- A record should be made of any action taken to investigate the incident and/or any advice or treatment given, e.g. taken to Accident and Emergency or Minor Injuries Unit., GP visit, etc.
- Particular attention should be given to identifying the causes of any incident and to the specific actions that should be taken to prevent re-occurrence.
- All forms should read and countersigned by the Manager or Deputy Manager prior to submitting to Head Office.
- The form should be sent to the Health & Safety Advisor (H&SA) at DRH Head Office as soon as possible.
- If it is considered that the adverse incident is serious or comes into the category of a *critical incident*, inform the Chief Executive or the Deputy Chief Executive immediately.
- All medication errors should be reported as soon as practicable using the DRH on-call system.
- Incident forms reporting any medication errors are automatically brought to the attention of the Chief or Deputy Chief Executive.
- Where applicable, adverse incidents should be reported to the appropriate Care Standards regulatory body by the Manager – usually by faxing a copy of the Adverse Incident Report. Any notification, which is given orally, shall be confirmed in writing by submitting a copy of the adverse incident form. (Appendix E)
- Evaluate the accident/incident and eliminate or reduce the risk of it happening again.
- Some accidents are subject to RIDDOR reporting. Any 3-day absence by staff as a result of an accident at work is subject to RIDDOR reporting. Also if a visitor sustains an injury on the premises and taken directly to hospital that this also needs a RIDDOR Report Form. The Health and Safety Advisor will complete all RIDDOR reports; however it is the responsibility of the appropriate Manager to advise the Health and Safety Advisor when absence from work has occurred as a result of a work-based accident. Incidents of this nature must be reported to the (Incident Contact Centre) within 10 days of the incident occurring, making the Health and Safety Advisor aware of any relevant incident at the earliest possible time is therefore essential.
- All Accident/Incident Report forms are forwarded to the Health & Safety Advisor at Connaught House. These are checked and recorded on a computer database. Any forms that may require further action or investigation are copied to the Chief Executive. If it is suspected that a significant risk still remains, it may be necessary for the Health & Safety Advisor or another nominated person to carry out a further investigation to ensure that an appropriate risk management strategy is in place.

**The Health and Safety Advisor** will submit a report to the HSE for any accident that meets the RIDDOR criteria.

From the computer data base the Health & Safety Advisor prepares a quarterly accident report for DRH Board of Directors, the Chief Executive, the Health and Safety Committee, Managers and Safety Representatives for the purpose of showing analysis, trends, etc.

Accident reports are retained for a minimum of 7 years.

## **7. ACCIDENTS DUE TO DEFECTS IN SUPPLIES OR EQUIPMENT**

- Any defects or potential hazards found by staff should be reported to the Manager and an incident form completed. Full details should be given of the incident and nature of the defect. A record should be made of any relevant information, e.g. equipment, manufacturer's name, serial number, batch number of medicinal products, etc.
- Defective healthcare equipment should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) Refer to Appendix C of this policy.
- Defective supplies or equipment should be immediately taken out of use, but not interfered with except for safety reasons or to prevent loss of samples. Items must be kept for inspection.
- Any material evidence should be kept by the Manager and where appropriate settings and control positions should be recorded at the time of the incident.
- In the event of equipment failure, or an incident involving injury from equipment, the equipment should be quarantined until such times a full examination has been carried out.
- Defective items of equipment or medical products may only be inspected by the manufacturers in the presence of a responsible officer after a technical assessment by an authorised member of DRH or an independent technical officer.
- In the case of defective or suspect medication, the Chief Executive or Deputy Chief Executive must be informed immediately. The Supplier of the drugs will also be informed.
- Offers to exchange a suspect or defective item must not be accepted. Samples or equipment must not be interfered with or removed by an outside agent without the prior approval of the Manager.
- Unless it is obvious that the defect is isolated and has no implications for other users, it should be reported by the Manager to the Chief Executive or Deputy Chief Executive.
- If an incident involving faulty equipment or supplies is reportable under the RIDDOR regulations, a copy of the RIDDOR form should be sent to the Health & Safety Executive.

## **8. ACCIDENTS DUE TO FAILURE OF SYSTEMS OR PROCEDURES**

Accidents can be caused by failures of systems or procedures. When evaluation of accidents takes place, care should be taken to check:

- Whether the correct procedure was being used at the time
- Whether the procedure being used could have contributed to the accident
- If the procedure being used requires adjusting

**Adjustments in systems can be necessary due to the:**

- Change in the service users needs
- Changes in the environment
- Changes in materials/equipment being used
- Changes in working practices
- Changes in technology

**Reference to Care/Support Plans should be made during the evaluation**

## **9. NEAR MISS**

*An accident is commonly defined as “an unplanned event, which may or may not result in injury or damage.”*

It is clear from this definition that it is not essential for an injury to have been sustained or for damage to have occurred for an accident to have happened. It should be regarded as a warning that a problem exists if the event had occurred under slightly different circumstances the outcome could have been different. This means that the same immediate and basic potential causes of the accident are in place but on this occasion the outcome is limited to the events occurrence without resultant injury or damage. Because of the potential for harm, the Manager should still investigate all these Incidents in the same way as accidents resulting in injury.

## **10. SERVICE USERS SUPPORT PLANS**

Following an Accident/incident involving a service user, an Adverse Incident report form should be completed and those details should also be entered on the service users Incident Report Card contained in the individuals support plan. Recording all incidents involving individual service users on one continuous form will provide a better picture of a service user’s incident history and should help staff to identify any emerging trends. A breakdown of incidents involving service users over any specified time scale can be supplied upon request by the Health and Safety Advisor. Quarterly breakdowns of all recorded incidents in all units will continue to be sent to all homes.

With all new referrals or homes involved in day care or respite care, every effort should be made to establish at the referral stage a history of accidents and incidents, along with current assessments. This will help provide a clearer indication as to any

potential areas of vulnerability and any effect this will have on other long term service users. These details provided should be recorded in the support plans along with known triggers, subsequent precautions, and safer working practices.

## **11. CRITICAL INCIDENT REPORTING**

The definition of a critical incidents any serious incident in which a service user member of the public or a member of staff comes to such harm that it is likely to result in medico-legal action and/or adverse media coverage. (See **Appendix B for full policy**)

## **12. PROPERTY/EQUIPMENT DAMAGE OR UNEXPLAINED LOSS**

Any property or equipment sustaining damage should be reported. Damage could be as a result of impact from moving objects, vandalism, fire, storm, collapse, etc. Unexplained loss of any equipment or personal belongings of any service user or staff member is also reportable.

## **13. INCIDENTS REPORTABLE UNDER THE REPORTING OF INJURIES, DISEASES AND DANGEROUS OCCURRENCES REGULATIONS 1995 (RIDDOR)**

**Employers are required to report to the Health & Safety Executive any adverse incident involving:**

- deaths or major injuries
- accidents resulting in over 3 day injury
- diseases
- dangerous occurrences
- Injury to members of the public
- Some work related diseases

Managers will ensure that the Health and Safety Advisor is advised promptly of any incident that may be reportable under RIDDOR. The Health and Safety Advisor will inform the Health & Safety Executive (see **copy of RIDDOR form at Appendix A**).

**Full details of RIDDOR reporting can be found at Appendix A**

**REPORTING OF INJURIES, DISEASES AND DANGEROUS  
OCCURRENCES REGULATIONS 1995  
(RIDDOR 95)**

**1. INTRODUCTION**

**RIDDOR 95** requires that work related accidents, diseases and dangerous occurrences are reported to the Health and Safety Executive or enforcing authority.

It applies to all work activities, but not to all incidents.

Reporting accidents and ill health at work is a legal requirement. The information enables the enforcing authorities to identify where and how risks arise and to investigate serious accidents.

**2. RESPONSIBLE PERSON**

The duty to notify and report these events rests with the responsible person. The responsible person within DRH is the Health and Safety Advisor. A space at the bottom of DRH Accident/Incident Report form queries whether RIDDOR reporting is necessary and it is essential that staff completing accident forms complete this section to avoid any incidents being missed.

**RIDDOR** applies to all places of work and controls the reporting of accidents, near misses and a range of diseases. The relevant authority requires a completed RIDDOR Form when appropriate within **10 days of the actual incident**.

In addition, any accidents which result in a major injury as listed in schedule 1 or any one of a series of Dangerous Occurrences (near misses) which are described in schedule 2 must be reported by the quickest practicable means. This is generally accepted as a telephone call or fax immediately and within 10 days followed up with a completed Form F.2508

**3. REPORTABLE EVENTS**

Whenever any of the following events arise out of or in connection with work, it must be reported to the enforcing authority in writing by the Health & Safety Advisor at Connaught House, who will keep a copy for reference. The incident will be brought to the attention of the Chief Executive or Deputy Chief Executive by the Health and Safety Advisor prior to sending the report.

**NOTE – A – B – C – D** are immediately reportable by telephone or fax. See also Policy for Reporting and Investigation of Critical Incidents (Appendix A)

- A. The death of an employee or service user whether or not they are at work, as a result of an accident arising out of or in connection with work.
- B. Any person suffering a specified major injury as a result of an accident arising out of or in connection with work. Specified major injuries are listed in Schedule 1 of Appendix 1.
- C. Someone who is not at work (eg member of the public) suffers an injury on a DRH site as a result of an accident and is taken from the scene to a hospital for treatment
- D. One of a list of specified dangerous occurrences takes place. Dangerous occurrences are events which do not necessarily result in a reportable injury, but have the potential to do significant harm. **(Listed in Schedule 2 of Appendix 1)**
- E. Someone at work is unable to do their normal work for more than 3 days as a result of an injury caused by an accident at work **(over 3-day injury)**
- F. The death of an employee or service user if this occurs some time after a reportable injury which led to that employee's or service user's death, but no more than one year afterwards.
- G. A person at work suffers one of a number of specified diseases, provided that the doctor diagnoses the disease and the person's job involves a specified work activity. The specified diseases and corresponding work activities are set out in **Appendix A schedule 3.**

## **SCHEDULE 1 – MAJOR INJURIES (Summary)**

- 1. Any fracture, other than to the fingers, thumbs or toes
- 2. Any amputations
- 3. Dislocations of the shoulder, hip, knee or spine
- 4. Loss of sight (whether temporary or permanent)
- 5. A chemical or hot metal burn to the eye or any penetrating injury to the eye.
- 6. Any injury resulting from an electric shock or electrical burn (including any electrical burn caused by arcing or arcing products) leading to unconsciousness or requiring resuscitation or admittance to hospital for more than 24 hours.
- 7. Any other injury:
  - a) leading to hypothermia, heat induced illness or to unconsciousness
  - b) requiring resuscitation, or
  - c) requiring admittance to hospital for more than 24 hours
- 8. Loss of consciousness caused by asphyxia or by exposure to a harmful substance or biological agent.

9. Either of the following conditions which result from the absorption of any substance by inhalation, ingestion or through the skin.
  - a) acute illness requiring medical treatment, or
  - b) loss of consciousness
  
10. Acute illness which requires medical treatment where there is reason to believe that this resulted from exposure to a biological agent or its toxins or infected material.

## **SCHEDULE 2 – DANGEROUS OCCURRENCES (Summary)**

Dangerous occurrences must be reported immediately

There is an extensive list of specified dangerous occurrences arising out of or in connection with work they include:

1. **Lifting machinery**  
The collapse of, the overturning of, or failure of any load bearing part, whether used for lifting goods, materials or passengers
2. **Pressure Systems**  
Explosion, collapse or bursting of any closed vessel, or associated pipe work, which might have caused death or major injury or resulted in stoppage of plant for more than 24 hours.
3. **Electric short circuit**  
Electrical short circuit or overload attended by fire or explosion which resulted in the stoppage of the plant involved for more than 24 hours and which may have been liable to cause death or major injury of any person
4. **Collapse of scaffolding**  
A collapse or partial collapse of any scaffold which is more than 5 meters high or (where scaffold is slung or suspended causes a working platform or cradle to fall more than 5 meters.)
5. **Collapse of building or structure**  
An unintended collapse or partial collapse of
  - a) Any building or structure under reconstruction, alteration or demolition involving a fall of more than 5 tonnes of material.
  - b) Any floor or wall of any building being used as a place of work.
6. **Explosion or fire**  
Any explosion/fire which resulted in stoppage of plant or suspension of normal work for more than 24 hours. Where the explosion or fire was due to the ignition of any material
7. **Escape of Substances**  
The accidental release or escape of any substance in a quantity sufficient to cause death, manor injury or any other damage to the health of any person

## **SCHEDULE 3 – REPORTABLE DISEASES**

### **Conditions due to Physical Agents and Physical Demands of Work**

1. Inflammation, ulceration etc. due to ionising radiation
2. Malignant disease of the bones due to ionising radiation
3. Blood dyscrasia due to ionising radiation
4. Cataract due to electromagnetic radiation

5. Decompression sickness
6. Barotrauma resulting in lung or other organ damage
7. Dysbaric osteonecrosis
8. Cramp of the hand or forearm due to repetitive movements
9. Subcutaneous cellulitis (beat hand)
10. Bursitis or subcutaneous cellulites (beat knee)
11. Bursitis or subcutaneous cellulitis (beat elbow)
12. Traumatic inflammation of the tendons
13. Carpal tunnel syndrome
14. Hand arm vibration syndrome

**Infections due to biological agents**

15. Anthrax
16. Brucellosis
17. Avian Chlamdiosis
18. Ovine Chlamdiosis
19. Hepatitis
20. Legionellosis
21. Leptospirosis
22. Lyme Disease
23. Q Fever
24. Rabies
25. Streptococcus Suis
26. Tetanus
27. Tuberculosis
28. Infections attributable to working with micro-organisms etc
29. Poisoning
30. Cancer of a bronchus of lung
31. Silicosis
32. Cancer of the urinary tract
33. Bladder cancer
34. Angiosarcoma of the liver
35. Peripheral neuropathy
36. Chrome ulceration of
  - a) the nose or throat or
  - b) the skin of the hands or forearm
37. Folliculitis
38. Acne – work involving exposure to mineral oil, tar, pitch or arsenic
39. Skin cancer
40. Pneumoconiosis (excluding asbestosis)
41. Byssinosis
42. Mesothelioma
43. Lung cancer
44. Asbestosis
45. Cancer of the nasal cavity or associated air sinuses
46. Occupational dermatitis
47. Extrinsic alveolitis (including farmers lung)
48. Occupational Asthma



## **POLICY FOR THE REPORTING AND INVESTIGATION OF CRITICAL INCIDENTS**

### **1. DEFINITION OF A CRITICAL INCIDENT**

“Any serious incident in which a service user, member of the public or a member of staff comes to such harm that it is likely to result in medico-legal action and/or adverse media coverage”. These include the following:-

- ❖ All cases of suicide or suspected suicide of service users
- ❖ All cases of suicide or suspected suicide of DRH staff while on duty
- ❖ All cases of homicide or suspected homicide involving service users and/or staff
- ❖ The death of any service user under the care of DRH which may be attributable to neglect, including self neglect
- ❖ Any incident resulting in serious injury for which DRH could be deemed liable or where DRH may be exposed to adverse media coverage
- ❖ Where there is a serious outbreak of an acquired infection.
- ❖ Any major incident involving HIV/AIDS
- ❖ Any serious incident or alleged incident involving sexual abuse
- ❖ Fire involving loss of life, injury or major damage to buildings or other property
- ❖ Serious acts of dishonesty or other serious offences

### **2. PROCEDURE FOR REPORTING A CRITICAL INCIDENT**

- ❖ As quickly as possible, and without compromising any remedial action being taken at the time a member of the Staff should be delegated to inform DRH Chief Executive or Deputy Chief Executive of the Critical Incident – out of hours the DRH “on call” system should be used.
- ❖ The senior person in charge of any DRH facility should have already taken immediate action to advise the Emergency Services, Police, Relatives, etc. as appropriate.
- ❖ The Manager, Deputy or senior person in charge should notify, by fax or telephone, any critical incident to regulatory bodies such as the CQC for Care Homes (Regulation 37) for care homes and (Regulation 28) for Fairfield & Elsadene – within 24 hours. Verbal reports should be followed up by a statutory notification form.
- ❖ The Mental Health Act Commission (found within CQC) should be advised if the incident involved the death of any service user subject to detention under a Section of the Mental Health Act 1983.

- ❖ The Chief Executive or Deputy Chief Executive should advise the appropriate purchaser of any critical incident within one working day.
- ❖ The appropriate Insurance Company should also be notified as soon as is practicable via DRH's insurance brokers.
- ❖ The Chief Executive or Deputy Chief Executive should also ensure that an appropriate management response to the critical incident has been instituted particularly the provision of support to other service users, relatives and staff that may have been affected.
- ❖ Staff should note that any press statements must only be given by the Chief Executive, the Deputy Chief Executive or DRH Chairman
- ❖ The Chief Executive will initiate an investigation to establish the details of the Incident and take any urgent action required as quickly as possible. Consideration may need to be given to the possible suspension of staff during the course of any investigation.
- ❖ The Chief Executive or Deputy Chief Executive will decide, following consultation with appropriate agencies, the nature and status of any additional review or inquiry.

### **3. PROCEDURE FOR INITIATING & CONDUCTING AN INTERNAL REVIEW**

- ❖ The terms of reference and membership of an internal review panel should be agreed with the relevant purchaser.
- ❖ It is the responsibility of the Chief Executive to initiate internal reviews following consultation with DRH Chairman.
- ❖ The function of an internal review is to identify inadequacies and/or failures in the provision of services and to make recommendations for corrective action. It is not meant to attribute blame but can make comments. Subject to agreement with the Purchaser, membership of an internal review panel would normally consist of the following but may vary according to the nature of the critical incident:-
  - A member of DRH Board of Directors
  - A senior manager directed by the Chief Executive
  - A nurse adviser
  - A medical adviser
- ❖ Any member of staff who has been directly responsible for the provision of care to any service user involved in the review shall not be included in the review panel.
- ❖ The conduct of the review should take account of the progress of any parallel disciplinary processes or police inquiries.
- ❖ In circumstances where an external inquiry is to be constituted, it may not be appropriate to include representatives of external agencies within the review panel.
- ❖ DRH should seek to consult with the appropriate purchaser during the course of the internal review in order to secure a joint approach with regard to the media and public confidence.
- ❖ DRH should endeavour to provide such training, guidance and support to members of the internal review panel as is practicable.
- ❖ Any internal review will be completed in as short a period as possible for the sake of individuals who are particularly concerned with the reviews outcome.

However, such consideration shall not compromise the integrity and thoroughness of the review.

#### **4. CRITICAL INCIDENTS REQUIRING AN EXTERNAL INQUIRY**

- ❖ The responsibility for initiating an external inquiry rests with the purchasing authority. The Chief Executive will ensure that the Purchaser is adequately briefed to implement the appropriate level of the inquiry.
- ❖ An external inquiry will normally be held in the following circumstances:
  - a) Where DRH's own internal inquiry of a critical incident reveals major deficiencies in practice, policy or procedures
  - b) Where there is evidence of a cluster of critical incidents which taken together suggest major deficiencies in practice, policy or procedures
  - c) All cases of suspected homicide which require clarification as to the manner in which DRH has discharged its responsibilities to service users, staff, visitors or the general public.

## Appendix C

### REPORTING ADVERSE INCIDENTS RELATING TO MEDICAL DEVICES

#### 1. INTRODUCTION

The Medicines and Healthcare Products Regulatory Agency (MHRA) investigates all adverse incidents reported to it concerning medical devices. Where the results of investigations may have implications for any service user, the MHRA issues a Hazard or Safety Notice, advising of hazardous products or unsafe procedures. Action taken as a result contributes to the safety of service users, users and others. The procedure detailed seeks to ensure that reports are submitted to the Adverse Incident Centre

#### 2. ADVERSE REPORTING PROCEDURES

DRH has put in place procedures to ensure that incidents related to medical devices are reported by:

- ❖ The completion of the normal DRH accident/incident form detailing the problem. The Health & Safety Advisor will pass this information to the MHRA.
- ❖ Devices involved in an adverse incident are kept in quarantine where practicable until MHRA's experts have been consulted. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation, with a photograph taken if possible
- ❖ Local action is taken as necessary to ensure the safety of service users, staff and others.
- ❖ All staff, including contractors are aware of their responsibilities and of the procedure to be used with regard to the reporting of incidents and the isolation and retention of defective items.
- ❖ All staff should be regularly reminded of these procedures and of their responsibilities with regard to adverse incident reporting. Managers should review, at regular intervals, the procedures in place to ensure that they are effective and being followed.

#### 3. HOW TO REPORT AN INCIDENT

- ❖ Incidents relating to medical devices must be reported to MHRA as soon as possible – normally by on-line reporting.
- ❖ The initial report of an incident should contain as much relevant detail as available, but should not be delayed. Serious cases must be reported to MHRA by the fastest means available.
- ❖ Further advice on reporting can be obtained from the Health & Safety Advisor at DRH.

#### 4. CONTACT POINT

MHRA prefers to receive incident reports on-line. Using these on-line systems to submit a completed report will prompt an automatic acknowledgement and the immediate electronic allocation of an MHRA Adverse Incident reference number.

The reference number will appear in the following format: **2005/002/014/401/047**

**If you do not automatically receive an MHRA reference number, please contact the AIC by other means ( i.e. e-mail, telephone or fax).**

##### **Alternative reporting methods**

**E-mail** - Download a **standard report forms** as an MS Word or rtf document, fill in the relevant sections as completely as you are able, and then e-mail it, preferably as an MS Word 97 attachment, to **[aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)**

**Fax/Mail** - Forms may also be downloaded as pdf documents. These can be completed and faxed to the Adverse Incident Centre on **020 7084 3109**, or mailed to the Adverse Incident Centre:

Adverse Incident Centre  
Medicines & Healthcare products Regulatory Agency  
2/2 G Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

**Telephone** - Telephone reports are only for incidents involving death, serious injury or serious public health concern. These must always be followed by a confirmatory written report. You can contact the **AIC Hotline** on **020 7084 3080**.

##### **Enquiries**

The **AIC Hotline, 020 7084 3080**, will also help with practical questions on reporting adverse incidents and can also provide updates on the progress of ongoing incident investigations.

For all technical enquiries concerning medical devices and to be put in contact with the relevant Medical Device Specialist please telephone the **Device Enquiry Line** on **020 7084 3100**.

##### **Out of Hours**

Outside of normal office hours, both the AIC Hotline and the Device Enquiry Line will connect to an answering machine. This machine carries a message that includes the telephone number of the Department of Health switchboard. In cases of urgency they are able to contact senior MHRA officials

## **5. WHAT IS AN ADVERSE INCIDENT**

An Adverse Incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including service users) or any other persons.

## **6. CAUSES OF ADVERSE INCIDENTS**

Adverse Incidents in medical devices may arise due to shortcomings in:

- ❖ The device itself
- ❖ Instructions for use
- ❖ Servicing and maintenance
- ❖ Locally initiated modifications or adjustments
- ❖ User practices, including training
- ❖ Management procedures

Conditions of use may also give rise to adverse incidents e.g.

- ❖ Environment conditions (e.g. electromagnetic interference)
- ❖ Location (e.g. devices designed for hospitals may not be suitable for use in Care Homes or supported housing)

## **7. REPORT THESE INCIDENTS**

An adverse incident involving a device must be reported to the MHRA if the incident has led to, or could have led to:

- ❖ A death
- ❖ Life threatening illness or injury
- ❖ Deterioration in health
- ❖ Temporary or permanent impairment of a body function or damage to a body structure
- ❖ The necessity for medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
- ❖ Unreliable test results leading to inappropriate diagnosis or therapy

Or where an incident was such that, were it to occur again, death or serious deterioration in the health of a service user might result

MHRA are also interested to learn of any other device related adverse incidents or minor faults and discrepancies, since they may take on a greater significance when aggregated with other similar events or may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

## **8. EXAMPLES OF MEDICAL DEVICES COVERED BY THIS PROCEDURE**

**Equipment used in the diagnosis or treatment of disease, or monitoring of service users e.g.**

- Syringes and needles
- Dressings
- Catheters (e.g. urinary, cardiac)
- Blood glucose measuring devices

**Equipment used in life support e.g.**

- Ventilators
- Defibrillators

**Equipment used in the provision of care and support e.g.**

- Orthotic and prosthetic appliances
- Wheelchairs
- Service users hoists, lifting and transfer equipment
- Pressure care prevention equipment
- Cotsides / bedrails
- Adjustable beds
- Bathing equipment

**Aids to daily living**

- Commodes
- Hearing Aids
- Urine drainage systems
- Domiciliary oxygen therapy systems
- Walking aids

MHRA are also interested in products which, although not themselves medical devices, are used closely in conjunction with these devices e.g.

- Sharps containers

## 9. DEFECTIVE OR CONTAMINATED ITEMS AND EVIDENCE

### EVIDENCE

All material evidence should be labelled and kept secure, under the charge of a responsible person. This includes the products themselves and, where appropriate, packaging material or other means of batch identification.

The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials gauges and indicators, together with any photographic evidence and eyewitness reports. In serious cases, this record should be witnessed and the witness should also make a personal written record.

If it is believed that an urgent examination of the defective item (or related items) is needed, then consideration should be given to sending the item(s) to MHRA's Adverse Incident Centre or inviting MHRA's experts to inspect them on site this option should only be carried out after full consultation with the Chief Executive.

### DEFECTIVE ITEMS

Defective items should not be allowed to be repaired (either in-house or by a third party), returned to the manufacturer/supplier or discarded before an investigation has been carried out. The manufacturer or supplier should be informed promptly, and may be allowed to inspect the items if accompanied by a responsible officer. In the case of a large batch it may be possible to provide a sample(s) for the manufacturer if this will facilitate the investigation. However, **the manufacturer must not be allowed to exchange, interfere with or remove any part of the product if this would prejudice MHRA's investigations, or those of other official bodies.**

If devices are required to be kept in use, it may be possible to remove defective part(s) so that the equipment may be required for re-use. MHRA's advice should be sought and, in all cases, the defective parts should be clearly identified and kept secure.

### CONTAMINATED ITEMS

Device Bulletin DB2006 (05) Managing Medical Devices contains advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard. **MHRA device specialists can provide additional advice where necessary, particularly where the item requires examination prior to decontamination.**

The Adverse Incident Centre will provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination. Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective contaminant, labelled and placed in quarantine. MHRA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

It is illegal to send contaminated items through the post.

## 10. OTHER ACTIONS AND RESPONSIBILITIES

The reporting system does not affect the statutory or other duty of staff locally to take appropriate actions as a result of an adverse incident. These include:

- To safeguard service users, staff and others.
- To prevent further use of a product which may be defective
- To follow DRH reporting system for incidents in the usual manner
- To report to the Health & Safety Executive when legally obliged to do so. A copy of any such notification should be sent to MHRA. A clear note should be attached showing that it is a report being made under this Safety Notice and that it is a copy of an official notification to the HSEL. Notification to MHRA does not count as, or substitute for, any other report which should be sent (e.g. in respect of an employee's industrial injury)
- To report the findings of HSE or Local Authority Inspectors to MHRA. Under their statutory powers, Health & Safety Executives or Local Authority Inspectors may identify inadequacies in a medical device's design, instructions for use or manner of use. They may also make recommendations. Any such observations or recommendations which may have implications for other users should be reported.
- To refer to the local Environmental Health Officer incidents or complaints relating to food. Incidents relating to foods involving contamination or potential contamination should be reported immediately to the local environmental health officer (EHO) who will decide on what, if any, further action will be taken.
- To refer to the coroner in the case of unexpected death. If a service user dies unexpectedly, the Manager should report the death to the coroner. Also, follow the normal reporting procedures to the Chief Executive or the Deputy Chief Executive and meet the Care Standards procedures. Pending the instructions of the coroner or his officer, any product implicated must not be interfered with in any way unless this is necessary for safety or to prevent loss of samples. Although the manufacturer of a suspect device should be informed immediately, neither he nor his agent should be allowed to inspect the device or remove any part of it without the Coroner's Society that, with the permission of the Coroner, MHRA's officers can examine suspect devices so as not to delay remedial action to protect others.
- To inform the manufacturer of a medical device which carries CE marking, to assist him in fulfilling this obligation under EC Directives. As a result of new UK regulations implementing the EC Directives concerning medical devices, manufacturers of medical devices will be required by law to report to the UK Competent Authority (Medical Devices Agency) certain incidents involving their products. This system is known as the "Vigilance System" and covers incidents which have led to, or which might have led to death or serious injury. The regulations implementing the first EC Directive apply to active implantable medical devices (for example implantable cardiac pacemakers) and came into force on 1 January 1993. The second set of

regulations, applying to a much wider range of medical devices, came into force on 1 January 1995.

Users should not rely solely upon the manufacturer making a Vigilance Report to MHRA, but additionally should follow the recommendations in the Procedure.

References:

Reporting of Injuries, Diseases and Dangerous Occurrences 1995  
(<http://www.hse.gov.uk/riddor/>)

Devices in Practice: a guide for health and social care professionals  
(MRHA 2001) [www.mhra.gov.uk/Publications/Safetyguidance](http://www.mhra.gov.uk/Publications/Safetyguidance)

November 2003

Reviewed September 2004; October 2005; August 2008

Next Review due August 2011

## APPENDIX D



### REPORTING ADVERSE INCIDENTS TO REGULATORY BODIES

#### **The Private and Voluntary Health Care (England) Regulations 2001**

**28.** - (1) The registered person shall give notice to the Commission of -

(a) the death of a patient -

(i) in an establishment;

(ii) during treatment provided by an establishment or agency; or

(iii) as a consequence of treatment provided by an establishment or agency within the period of seven days ending on the date of the death, and the circumstances of his death;

(b) any serious injury to a patient;

(c) the outbreak in an establishment of any infectious disease, which in the opinion of any medical practitioner employed in the establishment is sufficiently serious to be so notified;

(d) any allegation of misconduct resulting in actual or potential harm to a patient by the registered person, any person employed in or for the purposes of the establishment or for the purposes of the agency, or any medical practitioner with practising privileges.

(2) Notice under paragraph (1) shall be given within the period of 24 hours beginning with the event in question and, if given orally, shall be confirmed in writing as soon as practicable.

#### **The Care Homes Regulations 2001**

**37.** - (1) The registered person shall give notice to the Commission without delay of the occurrence of -

(a) the death of any service user, including the circumstances of his death;

(b) the outbreak in the care home of any infectious disease which in the opinion of any registered medical practitioner attending persons in the care home is sufficiently

serious to be so notified;

(c) any serious injury to a service user;

(d) serious illness of a service user at a care home at which nursing is not provided;

(e) any event in the care home which adversely affects the well-being or safety of any service user;

(f) any theft, burglary or accident in the care home;

(g) any allegation of misconduct by the registered person or any person who works at the care home.

(2) Any notification made in accordance with this regulation which is given orally shall be confirmed in writing

## APPENDIX E



<b>Health &amp; Safety Executive</b> <b>Priestly House</b> <b>Priestly Road</b> <b>Basingstoke</b> <b>RG24 9NW</b>	Tel No:  01256 404000	For General Health & Safety enquiries and information on regulations.
<b>Health &amp; Safety Executive</b> <b>14 Newfields</b> <b>Stinsford Road</b> <b>Nuffield Industrial Estate</b> <b>Poole – Dorset BH17 79F</b>	Tel No:  01202 667219	Local Office for urgent enquiries and inspectors visits
<b>Care Quality Commission (CQC)</b> <b>National Correspondence</b> <b>Citygate</b> <b>Gallowgate</b> <b>Newcastle upon Tyne</b> <b>NE1 4PA</b>	Tel: 03000 616161 e-mail: <a href="mailto:enquiries@cqc.org.uk">enquiries@cqc.org.uk</a>	For standards of care, information and reporting procedures (Independent Hospitals and Care Homes)
<b>Adverse Incident Centre</b> <b>Medicines &amp; Healthcare Products</b> <b>Regulatory Agency</b> <b>2/2 G Market Towers</b> <b>1 Nine Elms Lane</b> <b>London</b> <b>SW8 5NQ</b>	Tel No. & Fax 020 7084 3109  <a href="http://www.devices.mhra.gov.uk">www.devices.mhra.gov.uk</a>	For reporting incidents related to healthcare products
<b>Incident Contact Centre</b> <b>Caerphilly Business Park</b> <b>Caerphilly – CF83 3GG</b>	Tel No:  0845300 9923	RIDDOR Reports