



**NEPHROLOGY PROGRAM
DEPARTMENT POLICIES AND PROCEDURES**

**Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-16
Incidents Involving Medical Devices within the Nephrology Program
No.: 01549 (TOH Standardized Policy Number)**

ISSUED BY: Nephrology Technical Practice Committee
DATE OF APPROVAL: 2015/11

APPROVED BY: Program Clinical Director and Division Head
LAST REVIEW/REVISION DATE: 2017/01

CATEGORY: Equipment Maintenance
IMPLEMENTATION DATE: 2015/12

POLICY STATEMENT:

The Nephrology Biomedical Technical Services shall be contacted when incidents involve medical devices used within the Hemodialysis Units, Hemodialysis Satellite Units, Home Dialysis Unit as well as in patient homes in order to perform the appropriate investigations, report its findings as part of The Ottawa Hospital (TOH) Medical Device Incidents [policy # 00348](#)

Incidents involving non-dialysis related equipment shall be reported to the appropriate department i.e. Corporate Biomedical Engineering or Facilities Management

DEFINITION(S):

1. A **reportable incident** is defined as any unusual occurrence that is inconsistent with the routine care and adversely affects a patient (unexpected negative treatment outcome)
2. A **Medical Device** is defined as any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings. Included are single and multiple use supplies. Drugs are **NOT** included

ALERTS: N/A

PROCEDURE (in-center/satellite):

1. Clinical staff shall undertake emergency measures to stabilize the patient, staff and/or individual(s) affected
2. All staff involved shall undertake appropriate action to minimize damage to equipment and the environment when and if possible
3. First staff involved in incident shall ensure that:
 - All equipment, including disposables, attached to, or involved in the incident in the same room or area remains as is, except where contra-indicative to patient, staff, and/or individual safety
 - Label equipment as: "NOT TO BE USED/UNDER INVESTIGATION"
 - Initiate PSLS report
4. Contact Nephrology Biomedical Technical Manager and Unit Clinical Manager.
5. If possible, have pictures taken of the device(s), including damage, dial settings, digital readings, etc...
6. DO NOT disconnect or change the relative physical position of equipment or interconnecting cables, except where absolutely necessary to avoid further injury or damage
7. Note all relevant settings (volume settings, equipment set points, water treatment system values, etc...) of the equipment in use at the time the incident occurred, and include this information on the incident report
8. Unit staff (Aides/Nursing) shall perform external cleaning of the equipment once it is ready to be removed from service
9. If the device is a Hemodialysis machine do not initiate any cleaning programs without consulting with the Technical Manager
10. If the equipment has a black box type of recording device, the data shall be downloaded by the Nephrology Biomedical Technologist to a storing device before any other operations take place
11. Retain and preserve any and all disposable products that may have been involved, including packaging material (i.e. wrapping with model and lot numbers, etc...)
12. Document, and report, any incident, accident or unusual occurrence on the incident report (PSLS) form following The Ottawa Hospital standards of practice
13. DO NOT release any equipment, or disposable products implicated in the incident to non-hospital staff or external agency. Only TOH Medical Affairs or the Technical Manager may authorize the release
14. The Unit Clinical Manager and the Technical Manager shall be responsible to inform the Program Clinical Director and Division Head

ADDENDUM (Home Dialysis Unit):

Follow same procedure as in-centre/satellite plus:

If an outside organization has been involved during the incident i.e. paramedic, police, fire, coroner, family member, etc..., the Clinical Manager of the Home Dialysis Unit and the Technical Manager shall be informed immediately. Requests for additional information if required must be directed to the Clinical Manager of the Home Dialysis Unit so these can be directed to Medical Affairs

RELATED POLICIES / LEGISLATION:

1. [Corporate Policy and Procedures - Security and unusual Occurrences - No.: 00348 - Medical Device Incidents](#)

REFERENCES: N/A

COMMENTS / SIGNIFICANT REVISIONS: N/A