Glia
June 13, 2015
London, ON

Problem Reporting and Investigation Protocol [PRIP]

1.0 Purpose

The Problem Reporting and Investigation Protocol [PRIP] outlines Glia's system for conducting problem report investigations, and complies with the requirements outlined in Health Canada's **Medical Device Regulations (SOR/98-282).** This document is also informed by Health Canada's **Guidance on Investigation of Reported Medical Device Problems (GUI-0054).** The PRIP is a guidance and resource document which outlines steps to identify, investigate, manage, and correct reported risks involving Glia's medical devices.

2.0 Scope

Due to Glia's position as a manufacturer and distributer of medical devices, the PRIP was developed to aid in the investigation, recording, tracking, and resolution of reported problems regarding Glia's medical devices.

The PRIP ensures that the requirements outlined in Health Canada's **Medical Device Regulations (SOR/98-282)** are met within a system that is customized to address the needs of both Glia and users of Glia's medical devices.

3.0 Definitions

Definitions in the PRIP are adopted from Health Canada's **Guidance on Investigation of Reported Medical Device Problems (GUI-0054).** Definitions in the **Guidance on Investigation of Reported Medical Device Problems (GUI-0054)** are based on the **ISO 14971** and **ISO 13485** documents**.**

Corrective Action: Action to eliminate the cause of a detected problem with Glia's medical devices, or other undesirable situation relating to Glia's medical devices.

Correction: Action to eliminate a detected problem with Glia's medical devices, including repair, modification, adjustment, relabelling, or inspection of a device without its physical removal from the market (recall).[1]

Distributor: A person who sells a device in Canada for the purpose of resale, sale, or use. Glia is a distributor of medical devices.

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[1]There is a distinction between Corrective Action and Correction. A correction eliminates the detected problem and prevents an occurrence, a corrective action is taken to prevent recurrence. Correction and Corrective Action can be made in conjunction with each other (**Guidance on Investigation of Reported Medical Device Problems (GUI-0054) P. 5)**.

Harm: Physical injury or damage to the health of people, or damage to property or the environment.
Health Care Facility: A facility that provides diagnostic or therapeutic services to patients.

Manufacturer: A person or company who sells a medical device under their own name, or under a trade-mark, design, trade name, or other name to mark owned or controlled by the person. The manufacturer is responsible for manufacturing, designing, assembling, processing, labelling, packaging, refurbishing, or modifying the device. Glia is a manufacturer of medical devices.

Medical Device: A device within the meaning of the Act except any device that is intended for use in relation to animals.

Preventative Action: Action to eliminate the cause of a potential nonconformity or other undesirable situation. It is taken to prevent occurrence.

Recall: Any action taken by Glia to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness after becoming aware that the device:

(a) may be hazardous to health
(b) man fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics of safety
(c) may not meet the requirements of the Medical Devices Regulations [MDR]

note: Recall does not refer to regular updates of Glia products.

Record: A document stating results achieved or providing evidence of activities performed.

Reported problem: For the purposes of Glia's QPID, a communication from any source (email, phone, fax, or other) on a medical device that has been released for sale which indicates an actual or potential deficiency that may impact the performance or safety of the device.

Risk: Combination of the probability of occurrence of harm and the severity of that harm. Glia has a separate document related to "risk".

Risk Assessment: Overall process comprising of risk analysis and risk evaluation.

Risk Evaluation: Judgement, on the basis of risk assessment and estimation, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.

3.1 Abbreviations

ISO: International Standards Association

PRIP: Glia's "Problem Reporting and Investigation Protocol"

SRF: Standard Reporting Form

4.0 Protocol

Adopted from Health Canada's **Guidance on Investigation of Reported Medical Device Problems (GUI-0054)** the stages in Glia's PRIP involve recording the initial complaint, filing a preliminary risk assessment and then escalating the issue if necessary based on the estimated risk. The timeframe for completion of the investigation and (if necessary) corrective or preventative action (including recall) is determined on a case by case basis, and is also influenced by the estimated level of risk.[2] Though there are no specific guidelines for time to completion, the PRIP provides a goal time for completing each activity.

4.1 Instructions

1) Once aware of potential problems with a medical device, it is the responsibility of Glia to document the issue. Problems that may require investigation include but are not limited to:

The specific device
Packaging and labelling
Compliance with regulatory requirements
Direct or indirect consumer complaints
Problems reported through other sources (returned goods, service calls, requests for repairs, etc…)

2) When a potential problem is received, the "Standard Reporting Form"[3] [SRF] is to be completed. The SRF can be filled out for the complainant (either orally or in writing via email or messaging service) with a Glia employee, or can be sent to the complainant to complete alone.

Timeframe for completion: Within two business days [48 hours] of receipt of the initial communication regarding the problem with the medical device.

3) Upon completion of the SRF, the information is to be delivered immediately to Dr. Tarek Loubani via email, mail, or in person.

Timeframe for completion: Immediately upon completion of the SRF.

4) Once the SRF is received by Dr. Tarek Loubani, Dr. Loubani is to complete a "Preliminary Risk Assessment" [PRA][4] based on the information collected through the SRF. If Dr. Loubani is unable to complete the PRA, the task may then be delegated to

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[2] For a comprehensive guideline on Risk Estimation, please see Glia's "Risk" document located in Appendix 1.

[3] For the "Standard Reporting Form" see Appendix 2.

[4] For the "Preliminary Risk Assessment" see Appendix 3.

an alternate staff member. However, upon completion of the qualified staff member, Dr. Loubani must review and sign the PRA.

Timeframe for completion: Within two business days [48 hours] of receipt of the SCF.

5) Upon completion of the PRA, Dr. Loubani is to estimate the risk of the problem. Based on the level of perceived risk (Type I, Type II, or Type III) Dr. Loubani will then initiate no action, or some form of preventative, corrective, and/or recall action.[5] Dr. Loubani will also determine whether the problem meets criteria for mandatory problem reporting as defined by Health Canada.[6]

Timeframe for completion: Within two business days [48 hours] of completion of the PRA.

6) If no corrective, preventative, or recall action is recommended, the file is to be closed and stored in a secure file managed on a secure computer by Dr. Loubani. If requested by the original complainant, an update on the progress and finding of the original complaint will be disclosed orally or through writing. The SRF and PRA will then be kept by Dr. Loubani in a secure, password protected digital file folder for the life of the applicable medical device, plus one year.

7) If Corrective or Recall action is recommended, please see Glia's protocol and outline for "Corrective and Recall Action".[7]

5.0 Document References

Health Canada: Medical Devices Regulations (SOR/98-282). (2011). Retrieved from: http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-12.html#h-40

Health Canada: Guide to Recall of Medical Devices (GUI-0054). (2011). Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php#sec5256_42

[5] For the "Preventative, Corrective, and Recall" document, see Appendix 4.

[6] For the "Mandatory Problem Reporting" document, see Appendix 5.

[7] For the "Preventative, Corrective, and Recall" document, see Appendix 4.