GHTF

FINAL DOCUMENT

Title: Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative

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The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preface

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1.0 Introduction

The Global Harmonization Task Force (GHTF) Study Group 2 (SG2) developed a regulatory guidance document for manufacturers regarding adverse event reporting. This guidance is referenced as SG2 N21R8[1]. N21 includes guidance about reporting of adverse events that result in death or serious injury or certain types of near incidents. N21 also includes the consideration that certain types of failures may be exempt from reporting under regulatory vigilance procedures, but does not include a specific proposal on reporting of use errors. This document (N31) gives a proposal for reporting of use errors with medical devices by their manufacturer or authorized representative.

There is increased international focus on errors in the use of medical devices, and this document (N31) divides the broad category into two defined and distinct groups: use error and abnormal use. Both groups must be evaluated within the manufacturer's quality system and the results documented but only the use error group can be controlled by the manufacturer's quality system corrective and preventive action requirements, design validation, usability engineering, and risk management processes. By its nature the use error group usually involves a degree of uncertainty as to the root cause, but the risks can be managed by the manufacturer in conjunction with the national regulator and conformity assessment body. The risks involved with abnormal use must be managed between the healthcare facilities, national regulator or other responsible organization.

2.0 Scope

This document represents a global model, which provides guidance on the type of adverse events involving use errors, that should be reported by manufacturers or their authorized representatives to regulatory authorities.

The reporting of adverse events by the operator or user of medical devices is outside the scope of this document (N31), although some consideration for a user reporting scheme is given in Appendix B.

3.0 Definitions

3.1 Use error:

Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator.

Note Use error includes slips, lapses, mistakes and reasonably foreseeable misuse.

Definition taken from AAMI HE 74:2001[2] and IEC/CD2 60601-1-6:2002[3]. See also Appendix A for examples of potential use errors.

3.2 Abnormal use:

Act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer.

Note Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.

Definition taken from IEC/CD2 60601-1-6:2002[3]. See also Appendix A for examples of potential abnormal use.

3.3 Operator:
Person handling equipment.

Definition taken from IEC 60601-1, 2nd Ed.[4]

3.4 User:
Authority responsible for the use and maintenance of equipment.

Definition taken from IEC 60601-1, 2nd Ed.[4] GHTF-SG2 acknowledges that the term "user" might designate different persons under various regulatory systems.

4.0 Proposal for reporting of use errors

As with all reported device complaints, all potential use error events, (examples are given in Appendix A), and potential abnormal use events dealt with in paragraph 5.0, should be evaluated by the manufacturer. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes. Results should be available, upon request, to regulatory authorities and conformity assessment bodies.

4.1. Use error resulting in death or serious injury/ serious public health concern
Use error related to medical devices, which did result in death or serious injury or serious public health concern, should be reported by the manufacturer to the national competent authority.

4.2. Use error not resulting in death or serious injury / serious public health concern
Use error related to medical devices, which did not result in death or serious injury or serious public health concern, need not be reported by the manufacturer to the national competent authority. Such events should be handled within the manufacturer's quality and risk management system, as described in 6.0 below. A decision to not report must be justified and documented (see SG2 N21[1]).

4.3. Use errors becoming reportable
Use errors become reportable by the manufacturer to the national competent authority when a manufacturer:

- notes a change in trend (usually an increase in frequency), or a change in pattern (see SG2 N36[5]) of an issue that can potentially lead to death or serious injury or public health concern.); or
- initiates corrective action to prevent death or serious injury or serious public health concern.

5.0 Consideration for handling abnormal use

Abnormal use need not be reported by the manufacturer to the national competent authority under adverse event reporting procedures. Abnormal use should be handled by the health care facility and appropriate regulatory authorities under specific appropriate schemes not covered by this document (see Appendix B).

If manufacturers become aware of instances of abnormal use, they may bring this to the attention of other appropriate organizations and healthcare facility personnel.

6.0 How to reduce errors associated with medical devices

Errors associated with the use of medical devices have been reported in studies[6,7], in the range of 60-70%, as the cause of accidents with medical devices. Such errors have historically been called "user error", "operator error", and "human error". IEC 60601-1[4] Electrical medical equipment identifies human error as a hazard with medical devices, but remains silent under clause 46 in the 1988 edition, stating "under development".

Globally harmonized medical device regulation requires that medical devices be designed and manufactured in such a way that they will not compromise the clinical condition or the safety of the patient, or the safety and health of operators or other persons. In addition, risks must constitute acceptable risks when weighed against the benefits to the patient. This essential principle is being accepted globally. (SG1 N20R5: Essential principles of safety and performance of medical devices[8] and ISO 16142: Guide to the selection of standards in support of recognized essential principles[9]).

The risk reduction approach has resulted in European and International standards on risk analysis EN 1441[10] and ISO 14971-1[11]. The scope has been enlarged to cover risk management over the life cycle of the device. ISO 14971, Risk management[12] was formally accepted as an international standard in the year 2000. It requires that risk is analyzed and reduced to an acceptable level for the intended use or intended purpose, and also for the reasonably foreseeable misuse of a medical device. Consequently, errors relating to the use of medical devices have been designated "use errors" to avoid the connotation of blame on the operator or user or on the device and to differentiate them from abnormal use defined below. The term "use error" is defined in the IEC/CD2 60601-1-6[3] as an act which has a different result than intended by the manufacturer or different result than expected by the operator. Examples of potential use errors are given in Appendix A.

A process standard, IEC 60601-1-6: Usability[3], is being developed describing the usability engineering process, and provides guidance on how to implement and execute the process. This guidance was developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published as HE 74:2001[2]. AAMI also plans to revise AAMI HE 48:1993[13] which provides ergonomic data compilation. Guidance on operator and user training information to be provided by the manufacturer is also being developed.

IEC 60601-1-6, Usability[3], excludes abnormal use from its scope. Abnormal use is an act or an omission of an act by the user or the operator as result of conduct that is beyond any

reasonable means of risk control by the manufacturer of the medical device. Examples of potential abnormal use are given in Appendix A

ISO TC210 is revising ISO 13485: Quality System for Medical Devices[14], (EN 46001[15] equivalent), in line with the revision of ISO 9001:2000[16]. The revision of the quality system standard is scheduled for the year 2003. ISO 9001 contains elements of customer satisfaction in complaints or corrective action requirements. ISO TC210 will also revise ISO 14969:Guidance for quality systems[17], and enlarge on the feedback of use errors. This will be incorporated into several variables: into design considerations through the corrective and preventive action process, into design validation by using usability engineering, and into risk reduction and risk management processes over the life cycle of the medical device.

As discussed above, there is increased focus on use errors, and they have to be separated from abnormal use. This is being incorporated into quality system corrective and preventive action requirements, usability engineering, design validation, and risk management processes. For example, use errors will be evaluated by the manufacturers and documented, in places like design dossiers, and will be accessible to regulatory authorities and conformity assessment bodies.

7.0 References

1. GHTF -SG2 N21R8, *Adverse event reporting guidance for the medical device manufacturer or its authorized representative*, June 30, 1999
2. AAMI HE 74:2001, *Human factor design process for medical devices.*
3. IEC/CD2 60601-1-6:2002, *Medical electrical equipment – Part 1: General requirement for safety – Collateral standard: 6, Usability*
4. IEC 60601-1:1988, *Medical electrical equipment – Part 1-6: General requirements for safety*
5. GHTF-SG2 N36, *Manufacturer trend reporting of adverse events*, June 30, 2000
6. J. Cooper, R. Newbower, R. Kitz, *An analysis of major errors and equipment failures in anesthesia management: consideration for prevention and detection: anesthesiology*, 60:34-42,1984
7. S.Bleyer, *Medizinische technische Zwischenfälle in Krankenhäusern und ihre Verhinderung*, in: Anna W, Hartung C (Hrsg.) Miteilungen des Instituts für Biomedizinische Technik und Krankenhaustechnik der Medizinischen Hochschule Hannover, 1992.
8. SG1 N20R5, *Essential principles of safety and performance of medical devices*
9. ISO/TR 16142:1999-12, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices. Guide to the selection of standards in support of recognized essential principles.*
10. EN1441:1997-10, *Medical devices - Risk analysis* (Document being replaced by EN ISO 14971:2000-12 with three year transition to 2003-12)
11. ISO 14971-1:1988-10, *Medical devices - Risk management – Part 1: Application of risk analysis* (Document being replaced by ISO 14971:2000-12 with three year transition to 2003-12)
12. ISO 14971:2000-12, *Medical devices – Application of risk management to medical devices*

13. AAMI HE48:1993 *Human factors engineering guidelines and preferred practices for the design of medical devices*
14. ISO 13485:1996-12, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001.*
15. EN 46001:1996-08, *Quality systems - Particular requirements for the application of EN ISO 9001*
16. ISO 9001:2000-12, *Quality management systems – Requirements*
17. ISO 14969:1999-06, *Quality systems – Medical devices – Guidance on the application of ISO 13485 and ISO 13488*

APPENDIX A

EXAMPLES OF USE ERROR AND ABNORMAL USE

1. Potential use errors:

Complaint reports received of events occurring despite proper instructions and proper design according to manufacturer's analysis.

- Operator presses the wrong button.
- Operator misinterprets the icon and selects the wrong function.
- Operator enters incorrect sequence and fails to initiate infusion.
- Operator fails to detect a dangerous increase in heart rate because the alarm limit is set too high and operator is over-reliant on alarm system.
- Operator cracks catheter connector when tightening.
- A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labeling, marking, and product warnings provided with the pump. Some pumps are found to have cracked due to inadvertent cleaning with alcohol.
- Unintentional use of pipette out of calibration range.
- Analyzer placed in direct sunlight causing higher reaction temperature than specified.
- MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

2. Potential abnormal uses:

Complaint reports received of events occurring despite proper instructions, and proper design, and proper training according to manufacturer's analysis determined to be beyond any reasonable means of the manufacturer's risk control.

- Use of a medical device in installation prior to completing all initial performance checks as specified by the manufacturer.
- Failure to conduct device checks prior to each use as defined by the manufacturer.
- Continued use of a medical device beyond the manufacturer defined planned maintenance interval as a result of operator's or user's failure to arrange for maintenance.
- Contrary to the instructions for use, the device was not sterilized prior to implantation.
- Pacemaker showed no output after use of electrocautery device on the patient despite appropriate warnings.

Product analysis showed that the device was working in accordance to specifications, further investigation revealed that the operator was inadequately trained due to failure to obtain proper training.

- During placement of a pacemaker lead, an inexperienced physician or other non-qualified individual perforates the heart.

- The labeling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours in duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bled to death.
- Safety interlock on a medical laser removed by operator or user.
- Filter removed and intentionally not replaced resulting in particulate contamination and subsequent device failure.
- Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
- Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
- Pacemaker patient placed into MRI system with the knowledge of the physician.
- Ventilator alarm is disabled, preventing detection of risk condition.
- Patient's relative intentionally altered infusion pump to deliver a lethal overdose of the infusing drug to the patient.
- Home care worker uses bed rails and mattress to suffocate patient.

APPENDIX B

Considerations for Adverse Event Reporting by the Operator or User of Medical Devices (User Reporting)

Abnormal use, i.e. act or omission of an act by the operator or user of a medical device that is a result of conduct that is beyond any reasonable means of risk control by the manufacturer should be reported by the operator or user to the health care facility, following internal procedures based on anonymity and non-punity, for evaluation, feedback to the reporting person or facility and eventual corrective actions by the health care facility, in consultation with the manufacturer, if necessary, i.e., where a medical device may be involved.

If national authorities regulate the user reporting, it should follow the principle of anonymity and non-punity, evaluation, feedback to the reporting person or facility and eventual corrective action. In cases where a medical device is involved, the manufacturer should be informed about the adverse event by the Competent Authority upon receipt of such reports from the user.