

Proposal for Reporting of Use Errors with Medical Devices

1. Scope

The Global Harmonization Task Force (GHTF) Study Group 2 (SG2) has developed a regulatory guidance document for manufacturers regarding adverse event reporting. This guidance is referenced as SG2 N21R8. It includes guidance for the regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents. It 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 gives an overview on emerging process standards which are streamlining the handling of use errors by industry and makes a proposal to regulatory authorities on how to handle use errors under adverse event reporting procedures. Comments are invited.

2. Background

Errors in the use of medical devices have been reported in studies (1, 2), in the range of 60-70%, as the cause of accidents with medical devices. Such errors have been called "user error", "operator error", and "human error". IEC 60601-1 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".

The European Medical Devices Directive 93/42/EU requires that 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 users 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 (see SG1 N20R4: Essential Principle, and ISO/DIS 16142: Guide to the selection of standards in support of recognized essential principles).

The risk reduction approach has resulted in European and International standards on risk analysis EN 1441 and ISO 14971-1. The scope has been enlarged to cover risk management over the life cycle of the device. A draft ISO/IEC standard- DIS 14971: Risk management- has been developed under a draft mandate of the European Commission. ISO 14971 is expected to be formally accepted 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 user or on the device. The term "use error" is defined as- an act which has a different result than intended by the manufacturer or different result than expected by the operator. Use error may result from a mismatch between variables including: the operator, the device, the task, or the environment.

A process standard, IEC 60601-1: Human Factor Engineering, is being developed describing the human factors engineering process, and providing guidance on how to implement and execute the process. This guidance is being developed by the Association for the Advancement of Medical Instrumentation (AAMI). AAMI also plans to revise AAMI HE 48:1993 which provides ergonomic data compilation. Guidance on user training information to be provided to the manufacturer is also being developed.

ISO TC210 is going to revise ISO 13485: Quality System for Medical Devices, (EN 46001 equivalent), in line with the revision of ISO 9001:2000. The revision of the quality system standard is scheduled for the year 2000. ISO 9001 contains elements of continuous improvements and customer satisfaction in complaints or corrective action requirements. ISO TC210 will also revise ISO 14969: Guidance for Quality Systems, 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 human

factors engineering, and into risk reduction and risk management processes over the life cycle of the medical device.

3. Proposal

As discussed above, there is increased focus on use error. It is being incorporated into quality system corrective and preventive action requirements, design validation, human factors engineering, 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.

Therefore:

- All use errors should be evaluated by the manufacturer- under risk management, human factor engineering, design validation, and corrective and preventive action processes- and should be available, upon request, to regulatory authorities and conformity assessment bodies.
- Adverse events involving use error related to medical devices, where there is death or serious injury, should be reported by manufacturers to the national competent authority.
- Adverse events involving use error, where there is no death or serious injury, should not be reported.

4. References

- (1) 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
- (2) 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.