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**MEMO**

**2007-09-13**

**To:** Professional Colleagues  
**From:** Marc H. Miller, President

**Re:** Labeling risk management statements

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**Background**

Current and projected growth rates for the medical device industry provide manufacturers with substantial opportunities for success. However, increased visibility has also raised the industry's risk profile, leading to a greater emphasis on risk management.

Evidence of the growing importance of medical device risk management is provided by the introduction of Underwriters Laboratories' formal ISO 14971 registration service. Additional evidence is the latest edition of IEC 60601 (standard for electrical medical devices), which includes a normative reference to ISO 14971. Product-specific changes, such as the EU's recent up-classification of total hip and shoulder replacements, provide added proof. Medical device labeling is a particular concern that is specifically referenced in ISO 14971, ISO 13485, and GHTF guidance.

**Risk Management Requirements for Multilingual Labeling**

Because of its risk management function in overseas markets, translated labeling and product information requires the same level of rigor as the English original. Following are key guidance statements on risk management for multilingual labeling from industry experts and regulators:

*Due to compliance implications for the essential requirements of the MDD and the IVDD, Notified Bodies consider translation to be an 'important outsourced service'...This makes translation providers subject to the outsourced vendor risk management considerations of ISO 13485:2003 and ISO 14971.*

- KEMA Notified Body

*Inaccurate translation of device labeling may jeopardize ISO 14971 compliance in overseas markets.*

- Oliver Christ, CEO, PROSYSTEMS (RAPS Annual Conference Panelist)

*Generating accurate translations for native language users helps to assure that devices are operated safely. This is especially true for those portions of the labeling that are themselves risk controls established by the manufacturer (information for safety). Also, there is no doubt that failures of labeling translation comprise postmarket information that the original device manufacturer needs to assess as part of its risk management process. Thus, Crimson must play a role in their clients' risk management process, and their efforts to improve and perfect the translation of labeling should be an integral part of any client's risk management system.*

- Dr. Harvey Rudolph, co-author of ISO 14971



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*Medical device labeling must convey to users critical safety information about the product while taking into account the language of both the user and the device documentation. Crimson Life Sciences is to be applauded for attaining this first-ever ISO 14971 certification for a risk management system capable of mitigating safety issues inherent to translation of medical device literature – an issue of great importance to the medical community.*

- Steve McRoberts, Principal Engineer, Medical Regulatory & Proprietary Compliance, UL

**ISO 14971:2000-Based Guidance for Multilingual Labeling**

On July 11 and 12, 2007, the risk management system of Crimson Life Sciences was audited to the requirements of ISO 14971:2000 under a newly-introduced registration service from Underwriters Laboratories (UL). One year previous, Crimson’s risk management system had been assessed by UL as part of an ISO 14971:2000 gap analysis. Based on implemented changes from the gap analysis, along with favorable audit results, Crimson became the first company, worldwide, to register a risk management system to ISO 14971:2000.

Both registration audit and gap analysis were conducted by Dr. Harvey Rudolph, former Global Program Manager with UL, 25-year FDA veteran (Deputy Director, Science and Technology; Chief of Medical Practices Section), Co-chair of the US Technical Advisory Group for Risk Management, and Distinguished Services Medal recipient (Public Health Service). Following is specific ISO 14971-based risk management guidance for multilingual labeling (as recommended by Dr. Rudolph).

Guidance Statement	Reference Standard	Sample Implementation
“The translation process itself is a one-time design activity, and therefore there is only one set of records associated with the design of the translation process...Since each project is of a reasonably similar nature, it would be expedient...to have a pro forma risk management plan, which would differ in only a few ways, project to project”	ISO 14971; Clause 3.2	Crimson has implemented pro forma plans (based on relative risk level) for, e.g., Class II and Class III devices, standard marketing material, non-labeling training material, and device UI/text string material.
“To claim conformity with ISO 14971...establish a risk management file for each project”	ISO 14971; Clause 3.6	Crimson has implemented a risk management file for each project that includes all relevant risk management records.
“Crimson has begun to implement the use of a risk estimator for each project...that uses all the characteristics of the translation job that could be construed as hazards” <i>Establish this estimator as part of the overall risk management procedure.</i>	ISO 14971; Clauses 4.4; 4.2; and 4.3	Crimson has implemented a risk management calculator that addresses all relevant labeling translation risks (e.g., project management risk, linguistic risk, technical risk, resource risk, scheduling risk, and product risk).
“ <i>Risk estimation:</i> The translation procedure is very much analogous to software development. It is a non-stochastic process and any errors (in translation) do not exhibit themselves unless they are exercised (read in an appropriate context). It is impossible to predict <i>a priori</i> the probability of an error in translation causing a harm, so, like software, trying to estimate a probability is to be discouraged. The company is entirely outcome driven in controlling risks.” <i>Residual risk evaluation: see above</i> <i>Risk/benefit analysis: see above</i> <i>Other generated hazards: see above</i>	ISO 14971; Clause 6	Crimson has implemented a Notified Body-approved adaptation of the SAE J2450 translation quality metric. This adaptation provides an objective basis for characterizing translation errors as either “Serious” or “Minor.” Crimson’s risk management policy and procedures are designed to mitigate the risk of serious translation error.



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“Because the hazards are the same for each project and because Crimson’s procedures always apply all risk controls to eliminate the risks from these hazards, the traceability required by ISO 14971 is essentially the same for each completed translation. This does not, however, imply that a risk management report is not necessary...reasons for the risk management report still apply, i.e. as a summary of what has been done and as documentation that the project is fit for release”	ISO 14971; Clause 8; Annex H	Crimson has implemented a risk management report that addresses the release requirements by documenting relevant risk control measures such as Project Quality Plan, Linguistic Risk Analysis, Project Hazard List, and Final Project Audit results.
“The manufacturer shall establish and maintain a systematic procedure to review post production information...The information shall be evaluated for possible relevance to safety, especially for the following: a) if previously unrecognized hazards are present...”	ISO 14971; Clause 9	Crimson has implemented a system so that “previously unrecognized hazards” are tracked and incorporated to a “Master Hazard List.”

Sources: Dr. Harvey Rudolph; ISO 14971 Gap Analysis; ISO 14971 Medical & Regulatory Audit Report

**Conclusion**

Both industry regulators and experts note the risk management importance of medical device labeling and product information (in general) and translated labeling and product information (in particular). In order to help clients meet these critical requirements, Crimson has registered the world’s first risk management system to ISO 14971:2000.

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