

May 28, 2004

To: Marc H. Miller, CEO
Crimson Medical Translation

From: Jeff Schakenraad, PhD
Manager KEMA Medical, Notified Body

Re: Endorsement of the SAE J2450 Translation Quality Metric (as Utilized by Crimson Medical Translation) for Medical Translation Resource Evaluation and In-Process Translation QA

Dear Marc:

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

Identifying and preventing serious errors is the key translation risk management consideration (a serious error is one that may result in patient harm). In this regard, your adaptation and use of the SAE translation quality metric (SAE J2450) is supported by KEMA for the following purposes:

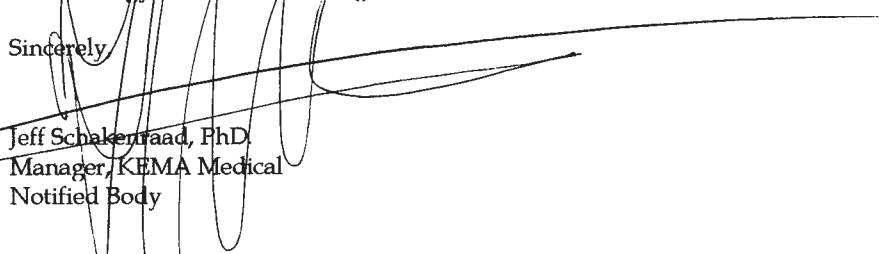
Evaluation of prospective translation resources - the SAE J2450 metric, as utilized by Crimson Medical Translation, ensures that prospective translation resources are measured according to an objective standard. Additionally, Crimson's Vendor Selection Maintenance and Audit SOP rejects any translation test that contains a serious error, as measured by the SAE metric.

In-process translation QA - Your use of the SAE J2450 metric (in combination with BackEditing™) for in-process QA ensures that persistent serious errors (after basic translation/edit) are identified and eliminated. The scoring system that you have developed based on SAE J2450 enables you to effectively audit your translation vendors and take corrective action - on a nearly continuous basis.

Audit of Existing Translated Materials - In combination with a linguistic QA check (such as your BackEditing™ process), your use of the SAE J2450 metric provides an objective methodology for inspection of translated material. It therefore provides an effective audit process for existing translations.

In your role as an "approved vendor" under ISO 13485:2003, KEMA supports your use of the SAE J2450 translation quality metric to screen translation resources and, in combination with your BackEditing™ process, to provide effective in-process translation QA. Your use of the SAE metric also provides an effective methodology for audit of existing translated material.

Sincerely,



Jeff Schakenraad, PhD
Manager, KEMA Medical
Notified Body

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