



COCIR Position Paper

13 February 2007

COCIR is raising awareness of risk of confusion on ISO classification of software

Currently ISO TC 215 is preparing two new documents on "*Guidance on risk evaluation and management in the deployment and use of health software*" and "*Application of risk management to the manufacture of health software*". COCIR is issuing a wake-up call to all medical device manufacturers and national standards developing organizations. These documents may lead to confusion and put an unreasonable burden on industry without improving the safety of patients.

COCIR and its member companies called on national standardization committees to vote against both of these ISO documents. Closing date at ISO for both votes was 13 February 2007.

ISO is introducing a new category called "health software" that is - roughly speaking - defined as software which is neither classified as a medical device, nor as part of a medical device – but which has a "possible influence" on patient health. According to this justification, software with influence on patient health may either be:

- software classified as a medical device (either as part of a medical device, controlling a medical device, or software which by itself is a medical device)
- software not classified as a medical device (covered by the proposed New Work Item Proposals - NWIPs)

The confusion starts with the new classification itself and will continue with the required implementation of new processes that will increase costs. Today, software used in healthcare is either classed as a medical device or not. As a medical device, there are comprehensive standards and regulations that apply. If considered a non-medical device it does not require standards that specify a separate process for the manufacture and testing of such software. Confusion will further increase because in detail, the rules that make software a medical device differ throughout the world. Software which is classified as a medical device in one country, may be classified as a non-medical device in other countries of the world.

The consequence for the software manufacturer is even worse: when selling the same software as a medical device in one country, they would have to follow medical device standards and regulations usually including IEC 60601 (Medical electrical equipment – General requirements for basic safety and essential performance), ISO 14971 (medical devices: application or risk management to medical devices), and in the future IEC 62304 (medical device software: software lifecycle processes). When selling exactly the same software as "health software" in another country, they will have to follow the requirements of the proposed NWIPs.

This will lead to contradictions and conflicts: manufacturers will have to implement two different processes for producing one software product, one will have to follow the requirements for medical devices and the other will have to follow the requirements for health software. What if these processes are different?

It is crucial that those NWIPs are closely monitored, in case they are accepted, so that:

- 1. confusion is avoided in classification of softwares,**
- 2. those future ISO standards will not contradict with existing standards and regulations for medical devices.**