Retrospective application of harmonized standards: an investigation

Peter Selvey, October 2011

While significant discussion continues around the content of EN 60601-1:2006 (IEC 60601-1:2005), it is generally understood that in Europe as of June 1, 2012[1], the previous edition will be withdrawn, leaving only the new edition to provide the legal "presumption of conformity" against essential requirements.

Notified Bodies have indicated that this situation is in effect *retrospective*: all older designs that are still being sold will have to be re-verified against the new standard. This is based on the interpretation that the "presumption of conformity" only exists at a point in time when each individual device is placed on the market. Thus, in order for manufacturers to maintain compliance, they must continuously update the design taking into account current harmonized standards.

Although standards are voluntary, it is still expected that manufacturers evaluate compliance on a clause by clause basis. This ensures the manufacturer is aware of specific non-conformities, and can then choose to redesign or provide an appropriate justification as to why alternate solutions still meet the essential requirements. Thus the voluntary nature of harmonized standards has little impact on the amount of work associated with updates in standards, and retrospective application to existing designs.

Despite the apparent unity in Notified Bodies on this interpretation, the MDD does contain text that calls this interpretation into question. Moreover, the implications of broad retrospective application may not have been fully considered by Notified Bodies.

The preliminary "whereas" section of the Medical Device Directive (MDD) includes the following paragraph:

> "Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk **must** be interpreted and applied in such a way as to take account of technology and practice existing **at the time of design** and of technical and economical considerations compatible with a high level of protection of health and safety;"

Later, in a paragraph associated with harmonized standards, this is repeated again:

> "… essential requirements should be applied **with discretion** to take account of the technological level existing **at the time of design** and of technical and **economic considerations** compatible with a high level of protection of health and safety"

These statements appear to indicate that the presumption of conformity may exist at the *time of design*, rather than the time of placing on the market. If so, this would remove the retrospective nature of standards, and conflict with the advice of Notified Bodies. While the "high level of protection" part is open to interpretation, it appears that the intention was to say that essential requirements, standards and risk should be considered to apply at the time of design, unless there are some serious concerns. For example, if incidents in the market led to changes in standards or state of the art, such changes could be considered reasonable even for old designs.

Unfortunately, this "time of design" statement lacks further legal support. In the core part of the directive (articles, annexes) the phrase is not repeated. It also appears that the "whereas" section has not been transposed into national law. The forward of EN ISO 14971 does repeat the above statement that "risk" must be assessed "at the time of design", and this is also clarified in again in Annex D.4 in the same standard. But since these references are hidden away from the

[1] The actual date will depend on particular standards

normative text, again they are often overlooked. So if the authors of the MDD really did intend the presumption of conformity to apply at the "time of design", there is considerable room for the EU to improve on implementation to provide greater legal certainty.

So, we are left with the task of finding out if retrospective application is feasible. An investigation finds that there are three key areas: the first looks at the unusually large number of standards that apply to medical devices; the second considers the case of “brand new” standards (without any transition period), and the third is the impact of requirements that apply to the manufacturer, as opposed to the device.

Notified bodies have tended to highlight the retrospective aspect on high profile product standards undergoing transition, such as the case with EN 60601-1. But they have been very weak in enforcing the retrospective rule for *all* harmonized standards.

This is not a reflection of poor quality work by Notified Bodies, but rather the impracticality of trying to verify retrospective application given the large number of products and standards. Both Notified Bodies and manufacturers struggle with the number of standards even for current designs, let alone having to consider retrospective application. Without pressure from Notified Bodies, most manufacturers naturally avoid spending large effort updating older designs to new standards.

The MDD is perhaps unique in all the directives for the large number of standards that can apply to a single "product". For other directives that might apply to a washing machine or a toaster, only a few standards apply to limited aspects, which are incidental to the main function of the device. While these standards evolve, there are rarely a large volume of changes in new requirements. Thus retrospective application is feasible for manufacturers to achieve. It is worth noting that the phrase “at the time of design” appears to be unique to the MDD, and does not appear in other high profile CE marking directives.

In contrast, standards for medical devices apply to many areas of safety both incidental and directly associated with the main function of the device. These standards are constantly being updated and expanded. Typical medical electrical devices will have at least 10 harmonized standards, and Appendix 1 of this document lists some 26 harmonized standards that would apply to a typical full featured patient monitor.

Keeping on top of all these standards *retrospectively* is arguably beyond what can reasonably be expected of manufacturers. Adverse effects include diverting resources from development of new technology, and increasing costs of medical devices. Another less obvious effect is that it tends to make standards less effective: recognizing the heavy burden, third parties often allow simplifications to make the standards easier to apply retrospectively, but these simplifications set up precedents that can take many years to reverse.

Not only are there a large number of standards being regularly updated, there are also many “brand new” standards which are harmonized without any transition period. This poses a special case where retrospective application is impossible, since a manufacturer cannot know when a standard will be harmonized. In a sense, the standard becomes instantaneously effective on the day it is first published in the Official Journal.

In literature associated with EN 60601-1:2006 (IEC 60601-1:2005), it has been pointed out that the original standard has been around for many years, thus manufacturers have no excuse for further delays beyond June 2012. But this is again an example where only high profile standards are being considered, not the full range of both harmonized and non-harmonized standards.

The “no excuse” interpretation implies that manufacturers must watch IEC or ISO publications, anticipate and prepare for harmonization. But this is not only unfair since there are many IEC and ISO standards that never get harmonized, it is also logistically impossible.

There are many examples where the time from first publication as IEC or ISO to publication in the Official Journal is less than 18 months[2]; no reasonable law could expect implementation in such a short time, particularly in the context of retrospective application. Moreover, the simple logistics of CE marking (such as the declaration of conformity, technical file) would be impossible arrange in a single day when the standard first appears in the Official Journal.

The case of "brand new" standards alone provides simple, unarguable evidence that the presumption of conformity cannot apply at the time of placing on the market, without violating the principles of proportionality and legal certainty[3].

A more complex situation exists with *manufacturer requirements*, usually in the form of *management systems*. EN 60601-1:2006 highlights these problems as it has both product and manufacturer requirements in the same standard.

Historically, the new approach directives were based on *product* requirements, and it is arguable that areas of the directive have not been fortified to handle *manufacturer* requirements. Even the definition of a harmonized standard is "a specification contained in a document which lays down the **characteristics required of a product** …"[4], and thus appears not to have provision for manufacturer requirements.

Since the principles of free movement, essential requirements the presumption of conformity all apply to the *device*, it is obvious management systems alone cannot be used to provide a presumption of conformity; rather it is the design specifications, verification records and other product related documents output from the management system which provide the main evidence of conformity.

If a harmonized management system standard is updated, the question then arises about the validity of product related documents which were output from the old system. In other words, whether the older documents still provide a presumption of conformity. Moreover, if a "brand new" management system standard is harmonized, the question arises whether manufacturers are obligated to attempt to apply the management system in retrospect for older designs.

This is different to product requirements, since management systems are clearly written to apply at the time of design. Thus, application in retrospect can trigger a massive amount of rework, far beyond what is reasonable to achieve the objective of health and safety.

Consider for example, a manufacturer that has completed the design of an electronic device, but did not have in place documented system for problem resolution during verification and validation testing, as required by EN 60601-1:2006 and EN 62304. As such, the manufacturer cannot declare compliance with the standard, without completely re-testing the whole device. The absence of a controlled problem resolution process is the source of many incidents in the market. On the other hand, repeat testing may take months or years for a single device, if applied to all medical devices would be a huge cost to the industry and clearly out of proportion, considering the relatively rare nature of serious adverse events.

What makes the difference here is that the costs associated with management systems are relatively small if applied at the time of design, whereas as the implementation *after* the design is complete can be incredibly high.

Thus, while less straightforward, management systems also provide a fairly strong argument that the presumption of conformity applies at the time of design.

In practice, most Notified Bodies take a flexible view on retrospective application of management systems, taking into account the amount of work required, and focusing on high

[2] See EN 62366 (Usability Engineering) which has only 13 months from publication as IEC to listing in the Official Journal.
[3] As required by the "Treaty of the European Union"
[4] See directive 98/34/EC

level documents associated with high profile standards.

Also with respect to "brand new" standards, Notified Bodies often apply an informal transition period of 3 years from the time a standard first harmonized, recognizing that immediate application is impractical.

While these relaxations are reasonable, they are not supported by the law. This is not a case where vagueness in the law requires Notified Body interpretation to fill in the details; this is in a sense a simple question of *when* the presumption of conformity applies. The answer, whatever it is, must then be universally applied.

With the current law, the only practical universal interpretation is that the presumption of conformity applies at the time of design, as indicated by the "whereas" section of the MDD.

It is worth to note that no official document endorsed by the EU commission indicates that retrospective application is required. This is unlikely to happen as documents issued by the EU are usually carefully vetted by the lawyers, a process which is likely to raise similar concerns as discussed above. In particular, the situation with "brand new" standards (standards without a transition period) will make the commission wary of formally declaring standards to be retrospective.

Also, it is a well established regulatory requirement (e.g. clinical data, EN ISO 13485, EN ISO 14971) that post market monitoring includes the review of new and revised standards. Thus, the "time of design" interpretation does not imply manufacturers can completely ignore new standards. But importantly, the flexibility in decisions to apply new standards to older designs is made by the manufacturer, not the Notified Body.

The "time of design" interpretation is not without problems. Designs may take many years to finalize, so the term "time of design" obviously requires clarification. It could also lead to products falling far behind state the art, or failing to implement critical new requirements quickly. Even using the "time of design" interpretation, "brand new" standards still pose a challenge to manufacturers, since it can be impractical to apply even to current designs. So, more work is required.

But in the context of EN 60601-1:2006, a "time of design" interpretation would act as a pressure relief valve not only for manufacturers, but for all parties involved who are struggling to apply such a large new standard retrospectively.

Appendix 1: Harmonized standards applicable to a patient monitor

The following is a list of harmonized standards which are currently applicable to a typical full featured patient monitor including accessories. Items shown in brackets are standards which are expected to replace the existing standard or are already in transition.

EN 980
EN 1041
EN 1060-1
EN 1060-3
EN 1060-4 (ISO 81060-2)
EN ISO 9919 (EN 80601-2-61)
EN ISO 10993-1
EN ISO 12470-1
EN ISO 12470-4 (EN 80601-2-56)
EN ISO 13485
EN ISO 14971
EN ISO 17664
EN ISO 21647
EN ISO 20594-1
EN 60601-1
EN 60601-1-2
EN 60601-1-4 (EN 60601-1/Clause 14)
EN 60601-1-6
EN 60601-1-8
EN 60601-2-27
EN 60601-2-30 (EN 80601-2-30)
EN 60601-2-34
EN 60601-2-49
EN 60601-2-51
EN 62366
EN 62304