

Report on Standardisation “Electrical Equipment in Hospitals” – The Struggle for Standardised Solution

a report by

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Standardisation concerning electrical equipment in medical facilities is a difficult issue. A pertinacious conflict has been going on for years on a national and on international level to work out simplified solutions. This paper presents the results available so far. FKT is involved in three central subjects here:

- the activities of the Deutsche Elektrotechnische Kommission (DKE);
- the results of the Comité Européen de Normalisation Electrotechnique (CENELEC); and
- the standardisation concerning “Central Battery-buffered Power Supply Systems” (BSV) for safety functions in the supply of medically used areas.

When the first global standard (IEC 60364-7-710) was passed in 1996, DKE faced massive problems, realising that an agreement would be highly unlikely because of inconsistencies in the content. Since standardisation is currently only permitted on a European level, the necessary amendment in Germany could only be accomplished by special permit. For the last time now DIN VDE 0100-710:2002-11 reflects the national regulations on “Construction of low-voltage equipment – Requirements for facilities, premises and special equipment for medically used areas”. The DKE is restricted by a narrow timeframe to activities like processing requests and disputes and attending to European standardisation. It may be possible, however, to intensify work on national issues after finishing on the European context.

The Comité Européen de Normalisation Electrotechnique (CENELEC), as a workgroup to formulate European standards, has made considerable progress. The rapprochement of Germany and The Netherlands is an initial success, since the gap between both countries seemed nearly insurmountable for many years. And the active participation of Poland means a first step of harmonisation towards the East. Judging by the process within the last few years it is obvious that standardisation within Europe will require radical rethinking among experts: the standard again concentrates on the definition of security objectives rather than on the achievement of these objectives.

Hence, appropriate instructions will become necessary. Publications from other European countries should additionally support this process in the future. Talks on how to start these publications have already started.

The DKE will continue to work on the issue of “Central Battery-buffered Power Supply Systems” (BSV) for safety functions in the supply of medically used areas. The working committee AK 331.0.5 is preparing the requirements for DIN VDE 0558-507 that will include these stipulations. Agreement is unlikely to be reached this year. The participation of very hetero-geneous manufacturers and the fear on the facilities’ side that they might have to face excessive financial claims, based on exaggerated objectives, makes progress difficult. On the other hand, it is exactly this situation that has made it possible to nearly unanimously pass the proposal limiting these installations exclusively to special medical applications.

Standardisation for Facilities in Medical Use

Power supply for medical facilities is a sensitive issue in standardisation. Besides different conceptions and traditions within European countries the panel in charge, The CENELEC-WG 710, has taken its time to reach a common understanding, and to define itself as a brains trust beyond the issue of standardisation.

It is interesting that the leading members come from Denmark, Norway, The Netherlands, Spain, Italy, Austria, Poland and Germany. Apparently what we can expect is a common statement by the industrialised “Core-Europe”. This autumn will probably bring the final draft, followed by a survey on possible objections. Finally, in summer 2007, the new European Standard Electrical installations of buildings – medical locations – will be finished. This compilation will primarily cover safety objectives – a compromise we will have to get used to in this European context. But the European standardisation panel is already making efforts to issue a handbook which will make it easier to work with the new standard. ■