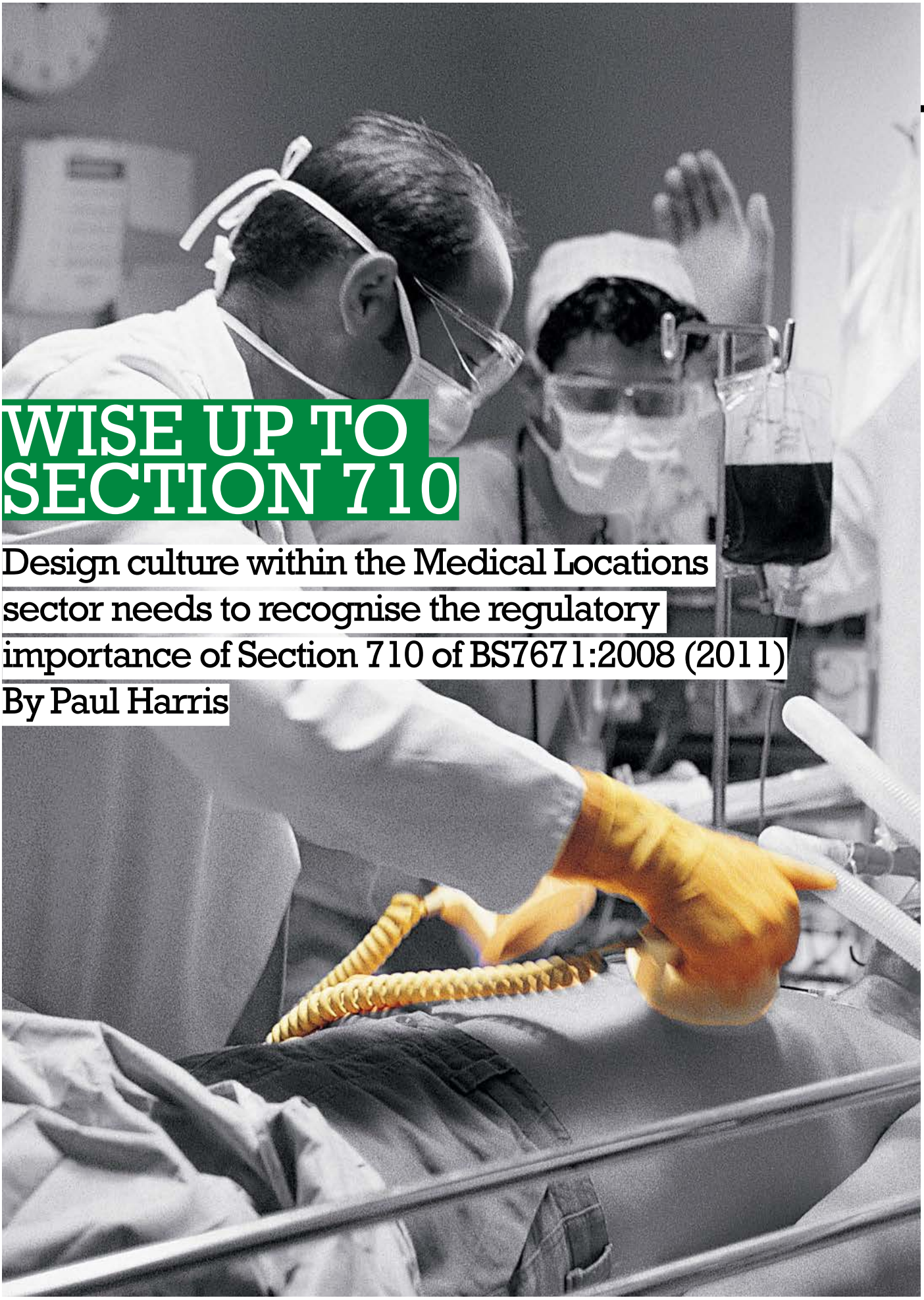


WISE UP TO SECTION 710

Design culture within the Medical Locations sector needs to recognise the regulatory importance of Section 710 of BS7671:2008 (2011)

By Paul Harris

IN JUNE 2005, the Medicines and Healthcare products Regulatory Agency (MHRA) published a guidance document, MEIGaN (Medical Electrical Installation Guidance Notes), to improve the quality and standard of workmanship in electrical imaging installations. This was followed by MEIGaN version 2 in 2007. The 2005 guidance document and its 2007 revision were designed specifically to deal with medical imaging installations.

Annex 1 to the 2005 guidance document, published later in 2005, was developed by the estates and facilities division of the Department of Health. This annex extended the scope of MEIGaN beyond imaging locations, and reflected the requirements of IEC 60364-7-710 2002, at the time the internationally agreed document for Medical Locations.

Available as a free download from the MHRA website, MEIGaN with its Annex 1, was considered 'best practice'. This best-practice status was reflected in the title of Annex 1: 'Healthcare interpretation of IEE Guidance Note 7 (Chapter 10) and IEC 60364-7-710 for Electrical Installations in Medical locations'. The publication of Section 710 within BS7671 2008 (2011), Guidance Note 7 (4th edition) and HD 60364-7-710 2012 overturned the best-practice status of MEIGaN and its Annex 1.

Dated guidance

The use of MEIGaN as a standard, as opposed to a guidance note, helped create a perception of approval, i.e. that of 'MEIGaN compliance', and gave the various stakeholders involved – clients, designers and installers – a label on which to place an expectancy of a certain level of skill, expertise and understanding.

Although MEIGaN has undoubtedly had a positive impact on electrical standards in medical locations, it has become apparent that certain requirements have become custom and practice, which appear to be different from the requirements of BS7671 (2011). In addition, as with all technical documents, a considerable level of upkeep and maintenance is required to prevent them becoming outdated as technologies and methods change. A review of MEIGaN indicates that its references and practice requirements have become outdated.

In addition to the MEIGaN documentation, BSEN 60601-1:2006: 'Medical electrical equipment Part 1: General requirements for basic safety and essential performance'; is available for designers, and covers the basic safety requirements for medical electrical equipment. This standard is an internationally agreed harmonised document and, as with other British and European normative information, is regularly reviewed to ensure the maintenance and upkeep of the standard.

Annex 1 was withdrawn by the MHRA in October and it is understood by the UK technical group working on Section 710 that MEiGaN (currently suspended) will eventually be superseded by Section 710 of BS7671 – a natural outcome given that CENELEC Document HD 60364-7-710, which forms the basis of Section 710, has been developed by technical experts in both the UK and across Europe.

HD 60364-7-710

The UK is a signatory to the Treaty of Rome for electro-technical matters and, as such, CENELEC Harmonised Documents have to be incorporated into our National Standard (BS7671) in terms of technical content, with very little room for manoeuvre in terms of the overall content. In the light of this requirement, the technical working group and JPEL 64 (the committee responsible for the production of BS7671) opted to incorporate the content of the draft standard, prHD 60364-7-710, into BS7671 2008 (2011). This act of foresight meant the wiring regulations (BS7671 2008 (2011)) incorporated the requirements later published as HD 60364-7-710:2012.

The resulting Section 710 divides all patient environments into three defined categories. These categories are defined in both Section 710 and HD 60364-7-710. Section 710 has empowered clients, healthcare providers and designers to make decisions based on internationally agreed regulatory requirements. However, what the regulations do not do, and are not intended to do, is to prescribe how particular performance criteria are to be achieved – this approach is in line with the general ethos of BS7671.

Current Industry Practice

A survey of the websites of manufacturers supplying medical equipment for medical locations I conducted in August 2012 exposed a widespread misunderstanding of the importance of Section 710. Different sectors of the industry, manufacturers, designers and installers, all seemed to be unaware that BS7671 2008 (2011) Section 710 Medical Locations applies, and continue to refer solely to MEIGaN, or its annexes. This apparent ignorance of Section 710 could have have significant consequences for those concerned in electrical installation work, in particular anyone who has to correctly certify electrical installations within Group 0, 1 or 2 Medical Location.

The document hierarchy

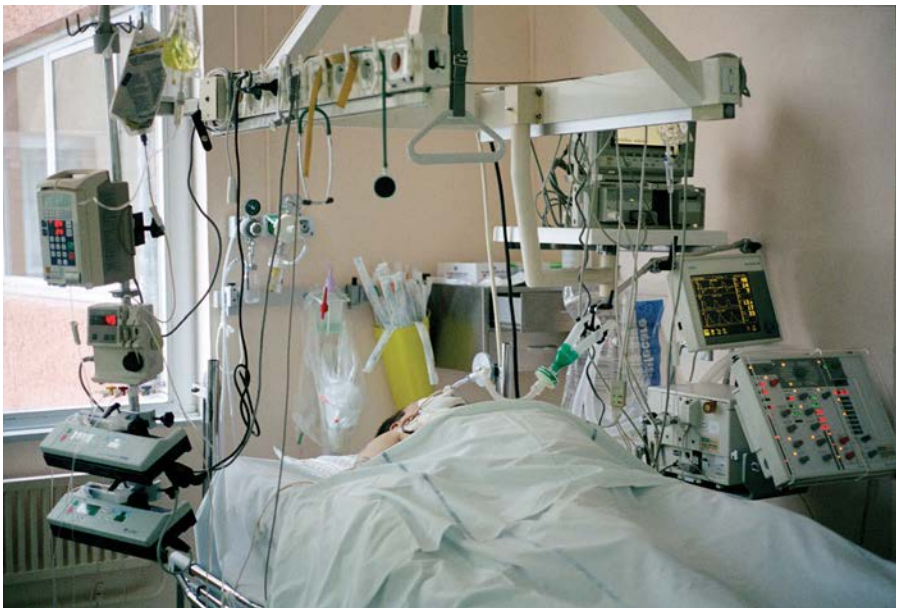
Most contracts and appointments will have as part of their requirements compliance with Health Technical Memoranda (HTMs), Health Building Notes (HBNs) and related healthcare guidance. The difficulty for the stakeholders and the client is to understand which documentation is applicable and, more importantly, the order of precedence within the hierarchy of documents. The diagram on p14 illustrates how precedence among documents operates: at a given level within the pyramid, a document has precedence over all documents lower down the pyramid.

For electrical installations the relevant documents, in order of decreasing precedence, are:

- Statute - Electricity at Work Regulations 1989
- Approved Code of Practice (ACOP) - HSR 25 Memorandum of Guidance on Electricity at Work Regulations 1989 published by the HSE
- British Standard/BSEN- BS76712008 (2011) Requirements for Electrical Installations
- Guidance Documentation- IET Guidance Notes, MEIGaN, HTM 06-01 etc.

In healthcare design, with the exception of the Firecode suite of documents, the HTMs and HBNs are deemed guidance and, as such, as with all informative documentation, a degree of interpretation is perfectly reasonable. Their guidance can be interpreted differently by different designers/ stakeholders, or even ignored completely. In contrast, British Standards and BS ENS are deemed to be generally best-practice and, in the case of BS7671, form the regulatory framework on which the wiring regulations for the UK are formed.

The other issue facing stakeholders is the age and clarity of the guidance. Whilst the principles of physics remain unchanged with the passage of time, any field of engineering will be subject >



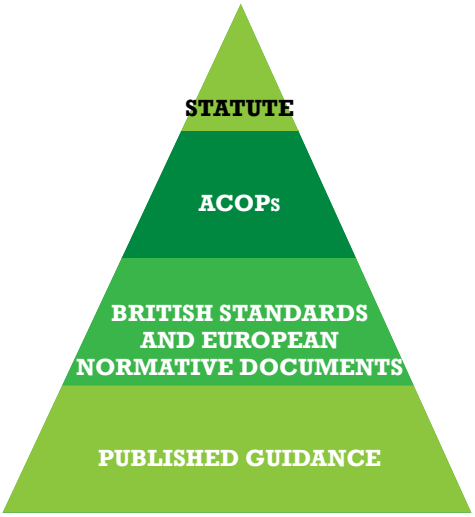


Fig 1: Document hierarchy

to advances in equipment/products and changes in practice, with important ramifications for different industry sectors, such as Medical Locations. HTM 06-01 illustrates the relatively infrequent revision programme within HTMs. It was last issued in 2006, having previously been issued in 1995. Given that the refresh rate of HTMs is far lower than is the case for the Wiring Regulations or supporting guidance, it is likely that HTMs are likely to be out of date when compared to BS767, or any of the supporting Guidance Notes.

A case in point

The potential for discrepancies between guidance and regulations can be illustrated by the example of a specific contradiction between BS7671 and HTM 0601. The contradiction arises from the difference in guidance offered by the HTM and the regulatory requirement stipulated by BS7671 (and HD 60364-7-710) in terms of UPS autonomy.

HTM 06-01 states in 10.9:

"….Where the UPS battery provides TPS to non operating-theatre low-power applications, the battery autonomy should provide clinical staff with enough time to start "hand bagging" or connecting supplementary equipment battery packs. Consequently, battery autonomy of 15–30 minutes may be appropriate…."

In contrast, Section 710, 710.560.6.1.1 Power supply sources with a changeover period less than or equal to 0.5s requires:

"In the event of a voltage failure on one or more line conductors at the distribution board, a safety power supply source shall be used and be capable of providing power for a period of at least 3h for the following:

i. Luminaires of operating theatre tables
ii. Medical electrical equipment containing light sources being essential for the application of the equipment, e.g. endoscopes, including associated essential equipment, e.g. monitors
iii. Life-supporting medical electrical equipment. The normal power supply shall be restored within a changeover period not exceeding 0.5s.

NOTE: The duration of 3h may be reduced to 1h if a power source meeting the requirements of Regulation 710.560.6.1.2 is installed.

There is an obvious discrepancy between Section 710 (which is HD 60364-7-710 2012 compliant) and the current HTM, written in 2006. If a contractor or consultant were to design to the HTM then there would be shortfall in autonomy of the UPS. This will have significant effects on the ability of the contractor and consultant to be able to sign compliance with BS7671.

Paul Harris is an independent consultant and a member of the UK Technical Working Group responsible for Section 710. He is planning to publish additional Section 710 technical articles, along with guidance documentation, during 2013

GROUPS

THREE-WAY CLASSIFICATION

BS7671 2008 (2011) categorises medical locations into three Groups (0, 1 and 2).

Group 0. Medical location where no applied parts are intended to be used and where discontinuity (failure) of the supply cannot cause danger to life.

Group 1. Medical location where discontinuity of the electrical supply does not represent a threat to the safety of the patient and applied parts are intended to be used: externally; invasively to any part of the body except where Group 2 applies.

Group 2. Medical location where applied parts are intended to be used, and where discontinuity (failure) of the supply can cause danger to life, in applications such as: intracardiac procedures; vital treatments and surgical operations.

In order to determine the classification and Group number of a medical location, it is necessary that the relevant medical staff indicate which medical procedures will take place within the patient environment. Guidance for the designer is provided by a list of typical medical locations and associated measures are indicated in Annex A710 of BS7671 2008 (2011). However, as the list is not exhaustive, in order to correctly determine the classification of a location, it is essential to understand if medical electrical equipment is connected to a patient, or if there can be contact between a patient and other persons touching parts of the medical electrical equipment/system and does failure of the mains supply have a detrimental effect on the medical procedure or patient's well-being.