Scottish Health Technical Memorandum 2014

(Part 1 of 4)

Overview and management responsibilities

Abatement of electrical interference

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Contents

1. Scope

General

1.1 Medical-electrical equipment in healthcare premises is liable to be susceptible to electrical interference from:

a. alternating magnetic fields;

b. alternating electric fields;

c. transient voltage changes.

Although distinct types, these interrelate and are generally known as Electromagnetic Interference (EMI). Electromagnetic Compatibility (EMC) is achieved when this interference is eliminated.

1.2 Earlier statutory regulations and British Standards Institution publications dealing with EMI were primarily concerned with preventing various types of electrical equipment (including medical-electrical equipment) from interfering with radio telecommunication services.

1.3 A requirement is in place for all electrical products, systems and installations not to cause, or be unduly affected by, EMI. The requirement is in the form of an EC Directive on EMC 89/336/EEC as amended by 91/263/EEC and 92/31/EEC. This Directive has been implemented in UK law by the Electromagnetic Compatibility Regulations 1992 (SI 2372) and amended by SI 3080: 1994 and SI 3180: 1995. Transitional arrangements, until 31 December 1995, were in situ so that member states could continue to allow to be placed on the market, or to be taken into service, apparatus which conforms to the national regulations in force in their territory on 30 June 1992.

1.4 The EMC Directive is not, however, all-inclusive. Apparatus wholly covered by other Directives (for example Telecommunication Terminal Equipment, which has its own specific Directive) is excluded, while medical devices, active implantable medical devices and in vitro diagnostic devices are covered by three specific Directives as follows:

a. Active Implantable Medical Devices - 90/385/EEC, UK legislation Active Implantable Medical Devices Regulations 1992 (SI 3146), effective 1 January 1993 and amended by the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 (SI 1671).

b. Medical Devices Regulations 1994 (SI 3017) implements Council Directive 93/42/EEC concerning medical devices. It lays down essential safety requirements which medical devices must satisfy.

c. The In Vitro Diagnostic Medical Devices Regulations 2000 (SI 1315) implements council directive 98/79/EC on in vitro diagnostic medical devices.

2. Management responsibilities

Statutory requirements

2.1 It is the responsibility of management to ensure that their premises comply with all statutes.

2.2 Managers of healthcare premises are obliged to ensure that medical electrical/electronic equipment, systems or installations comply with the requirements of the EC Directives on electromagnetic compatibility.

2.3 EC Directives contain specific requirements, to which products placed on the European market must conform. The EMC Directive applies to all electrical apparatus liable to cause electromagnetic disturbances, or whose performance is liable to be affected by such disturbances. The Directive does not specify the electromagnetic phenomena to be considered and does not specify the test methods nor the limits to be applied. It does require EC member states to recognise conformity in all apparatus which complies with certain standards which have been published in the Official Journal of the European Communities.

The EMC Directive has allowed the identification of a number of exclusions; for example apparatus covered by harmonised documents (HDs) in specific Directives is excluded, or will become excluded, when those specific Directives are implemented.

2.4 Apparatus excluded from the EMC Directive is as follows:

a. active implantable medical devices;
b. medical devices;
c. motor vehicles;
d. tractors and agricultural equipment;
e. non-automatic weighing equipment;
f. telecommunications terminal equipment.

2.5 The Active Implantable Medical Devices Directive 90/385/EEC has been adopted by the European Council. It contains full EMC provisions. The transition period (for conformance certification) ended on 31 December 1994.

2.6 Management is required to be aware of EC Directives for the procurement, installation and use in service of medical electrical/electronic equipment, systems and installations.

The EC Directive 89/336/EEC

2.7 The EMC Directive indicates essential equipment protection requirements, and devolves guidance to the International Electrotechnical Commission (IEC), European standards or national standards to define product characteristics in terms of electromagnetic compatibility between items of apparatus, within systems and in installations.

2.8 The EMC Directive applies to nearly all electrical and electronic apparatus placed on the market in the European Community on or after 1 January 1992 and thus affects manufacturers, distributors and in some cases end-users of electrical/electronic apparatus, systems and installations. Its main purpose is to remove technical barriers to trade, thus assisting in the completion of the single market. Behind this objective lies the genuine need to combat increasing levels of electromagnetic interference between electrical/electronic products, with effects ranging from those with simple nuisance value to major safety hazards. There are a limited number of specific exclusions from the Directive, such as electromagnetically benign apparatus (for example resistors and other passive circuit components) and equipment which is covered, or will be covered, in part or wholly, by other Directives for its EMC aspects, such as motor vehicles and medical devices. Where separate requirements exist but cover only certain electromagnetic phenomena, apparatus will still need to comply with the EMC Directive as regards the other EMI phenomena.

2.9 The scope of the EMC Directive is defined as:

"all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance".

2.10 Electromagnetic disturbance is defined as:

"any electromagnetic phenomenon which may degrade the performance of a device, unit of equipment or system. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself".

All electromagnetic frequencies are involved, as are all electromagnetic phenomena. The Directive therefore theoretically applies *a priori* to a vast range of equipment encompassing, as broadly as possible, all electrical/electronic appliances, equipment and installations. However, from the context and a study of the EMC Directive, it is possible to specify the scope more closely.

2.11 Components that are outside the scope of the Directive. This applies both to simple components and to complex items, so long as the item in question does not have an intrinsic function and its only purpose is to be incorporated inside the apparatus.

2.12 Systems must meet the requirements of the Directive. A system is defined as “several items of apparatus combined to fulfil a specific objective and intended to be placed on the market as a single functional unit”.

2.13 An installation is defined as several combined items of apparatus, or systems, put together in a given place to fulfil a specific objective but not intended to be placed on the market as a single functional unit. Each apparatus or system used in an installation is subject to the provisions of the Directive, and each apparatus of that system must comply with the installation conditions laid down by their manufacturer in order to ensure the proper operation of the installation itself.

2.14 The Directive applies to individual items of apparatus first placed on the European Community market, or first taken into service in the Community, on or after 1 January 1992 even if other items of the same design have been placed on the market or taken into service before that date. Transitional arrangements were agreed such that, until 31 December 1995, member states continued to allow to be placed on the market, or to be put into service, apparatus that conforms to the national regulations in force in their territory on 30 June 1992.

2.15 There are two basic protection requirements to be fulfilled:

a. apparatus must be so constructed that any disturbance it generates allows radio and telecommunication equipment and other apparatus to operate as intended;

b. apparatus must be constructed to provide an adequate level of protection against disturbances, that is, be immune.

2.16 In most cases the methods of satisfying the protection requirements are twofold. Manufacturers must:

a. manufacture in conformity with specified European standards, which will be published in the United Kingdom as identically worded British Standards; or

b. draw up a technical construction file which describes the apparatus, sets out the procedures used to ensure that the apparatus conforms with the protection requirements, and includes a technical report or certificate from a competent body.

2.17 The manufacturer, or his authorised representative established within the Community or, in the absence of either of the above, the person who places the apparatus on the Community market, must then hold that construction file at the disposal of the enforcement authorities in any member state for ten years.

2.18 An attestation must be given that the apparatus has met the protection requirements. The manufacturer, or his authorised representative established within the Community, must certify that the apparatus complies with the Directive by making a declaration of conformity. He must keep the

declaration available to enforcement authorities for ten years following the placing of the apparatus on the market. If the manufacturer is not established within the Community and he has no representative so established, the person who places the apparatus on the market has to hold the declaration.

2.19 The manufacturer or his authorised representative established within the Community must also affix the CE mark to the apparatus, or else to the packaging, the instructions for use or the guarantee certificate. The mark is in this form:

2.20 The CE mark is to be accompanied by the figures of the year in which it is affixed and, where appropriate, the distinctive letters of the approved body that issued the EC type-examination certificate. The mark also indicates that the apparatus complies with other Directives relevant to the product and requiring the CE mark.

2.21 Member states must take all appropriate measures to ensure that apparatus is placed on the market or taken into service only if it complies with the Directive when it is properly installed and maintained, and used for its intended purpose.

2.22 Unless there is evidence to the contrary, member states must presume that apparatus, which conforms to relevant, specified European standards or to relevant approved national standards, or for which a technical construction file exists, and which bears a CE mark, complies with the protection requirements.

2.23 Failure to comply with these requirements will be made a criminal offence within the EC.

2.24 Safeguard procedures are in place such that each member state is required to take all appropriate measures to withdraw from the market, or restrict the free movement of, apparatus bearing a CE mark but not complying with the protection requirements. The member state must immediately inform the European Commission of its action, giving reasons. The Commission must consult the parties concerned as soon as possible and, where it finds the action justified, is to inform member states forthwith.

2.25 Member states may take special measures concerning the taking into service and use of apparatus for a specific site in order to:

a. overcome an existing or predicted EMC problem; or

b. with regard to the installation of the apparatus, protect the public telecommunications network or stations used for safety purposes.

Member states are required to inform the European Commission and the other member states of such special measures, and the Commission is to give notice of special measures that have been recognised as justified in the Official Journal of the European Communities.

EC Directives for medical devices

2.26 The Directive 90/385/EEC for Active Implantable Medical Devices was first adopted by the European Council in June 1990. The implementation date was 1 January 1993, with the transition period ending on 31 December 1994. The scope of this Directive covers all powered implants including powered partial implants that are left in the human body. This Directive is to cover all EMC aspects and the EMC Directive 89/336/EEC will not apply.

2.27 The Directive 93/42/EEC Medical Devices lays down the essential safety requirements which medical devices must satisfy. The EMC Directive 89/336/EEC will not apply to the devices under this Directive.

2.28 The In-Vitro Diagnostic Medical Devices Directive 98/79/EC broadly applies to a device that is intended for the examination of substances derived from the human body. This includes:

- reagents, calibrators and control materials, whether supplied alone or as part of a kit;
- analyser systems, analytical instruments, apparatus or equipment;
- near-patient testing or self-testing devices;
- specimen receptacles (including blood collection tubes) specifically intended by their manufacturer for the primary containment and preservation of specimens derived from the human body for the purposes of in vitro diagnostic examination;
- accessories to in vitro diagnostic medical devices.

2.29 All other apparatus pertinent to healthcare premises is subject to the EMC Directive 89/336/EEC. Telecommunications Terminal Equipment (TTE) is subject to a specific Directive 91/263/EEC which covers dedicated telecommunications EMC requirements. EMC provisions not covered a specific Directive must be subjected to the EMC Directive 89/336/EEC.

Definitions

2.30 The following definitions apply throughout this document:

2.31 **Management:** is the owner, occupier, employer, general manger, chief executive, or other person who is accountable for the premises and is responsible for issuing or implementing a general policy statement under the Health and Safety at Work etc. Act 1974.

2.32 **Employer:** any person or body who:

a. employs one or more individuals under a contract of employment or apprenticeship;

b. provides training under the schemes to which the Health and Safety (Training for Employment) Regulations 1990 (SI 1380) apply.

2.33 **Department:** an abbreviation of the generic term "Scottish Executive Health Department".

2.34 **Duty holder:** a person on whom the Electricity at Work Regulations 1989 impose a duty in connection with safety.

2.35 **Electrical/Electronic equipment:** includes anything used, intended to be used or installed for use to generate, provide, transmit, transform, conduct, distribute, control, measure or use electrical energy.

2.36 **Equipment:** abbreviation of electrical/electronic equipment.

2.37 **System:** a system in which all the electrical equipment is, or may be, electrically connected to a common source of electrical energy, including such source and such equipment.

2.38 **High voltage (HV):** the existence of a potential difference (rms value for ac) normally exceeding 1000 volts ac between circuit conductors or 600 volts between circuit conductors and earth.

2.39 **Low voltage (LV):** the existence of a potential difference (rms. value for ac) not exceeding 1000 volts ac or 1500 volts dc between circuit conductors or 600 volts ac or 900 volts dc between circuit conductors and earth.

2.40 **Ambient level:** those levels of radiated and conducted signal noise existing at a specified test location and time when the test sample is inoperative. Atmospherics, interference from other sources, circuit noise, or other interference generated within the measuring set comprise the "ambient level".

2.41 **Antenna-induced voltage:** the voltage that is measured or calculated to exist across the open-circuited antenna terminals.

2.42 **Broadband emission:** emission which has a spectral energy distribution sufficiently broad, uniform and continuous so that the response of the measuring receiver in use does not vary significantly when tuned over a specified number of receiver impulse bandwidths.

2.43 **Conducted emission:** desired or undesired electromagnetic energy which is propagated along a conductor. Such an emission is called “conducted interference” if it is undesired.

2.44 **Cross coupling:** the coupling of a signal from one channel, circuit or conductor to another, where it becomes an undesired signal.

2.45 **Cross modulation:** modulation of a desired signal by an undesired signal. This is a special case of intermodulation.

2.46 **Crosstalk:** an electromagnetic disturbance introduced by cross coupling.

2.47 **Electromagnetic compatibility:** capability of electronic equipment or systems to be operated with a defined margin of safety, in the intended operational environment, at designed levels of efficiency, without degradation due to interference.

2.48 **Emission:** electromagnetic energy propagated from a source by radiation or conduction. This may be intentional or unintentional emission.

2.49 **Field strength:** the term “field strength” should be applied only to measurements made in the far field. The measurement may be of either the electric or the magnetic component of the field, and may be expressed as volts per metre, amperes per metre, or watts per square metre; any one of these may be mathematically converted to the others.

2.50 **Earth plane:** a metal sheet or plate used as a common reference point for circuit returns and electrical or signal potentials.

2.51 **Impulse:** an electromagnetic pulse of short duration relative to a cycle at the highest frequency being considered. Regularly repeated impulses of uniform level will generate a uniform spectrum of discrete frequencies (Fourier components), separated in frequency by an amount equal to the repetition frequency.

2.52 **Impulse bandwidth:** the peak value divided by the area of the impulse response envelope.

2.53 **Impulse emission:** emission produced by impulses having a repetition frequency not exceeding the impulse bandwidth of the receiver in use.

2.54 **Interference emission:** any undesirable electromagnetic emission.

2.55 **Intermodulation:** mixing of two or more signals in a non-linear element, producing signals at frequencies equal to the sums and differences of integral multiples of the original signals.

2.56 **Narrowband emission:** that which has its principal spectral energy lying within the bandpass of the measuring receiver in use.

2.57 **NAMAS:** a specialist NPL test executive approved under the auspices of the National Measurement Accreditation Scheme to accredit test laboratories to undertake EMC testing.

2.58 **Open area:** a site for radiated electromagnetic interference measurements which consists of open flat terrain at a distance far enough away from buildings, electric lines, fences, trees, underground cables and pipelines so that effects due to these are negligible. This site should have a sufficiently low level of ambient interference to permit testing to the required limits.

2.59 **Radiated emission:** radiation and induction field components in space.

2.60 **Spurious emission:** any electromagnetic emission from the intended output terminal of an electronic device, but outside the designed emission bandwidth.

2.61 **Spurious response:** any response of an electronic device to energy outside its designed reception bandwidth through its intended input terminal.

2.62 **Standard reference output:** a condition for a particular test sample that defines normal operation and is used in measuring any deviation from standard performance that occurs during susceptibility testing. Thus value should be indicated in the individual equipment specification.

2.63 **Susceptibility:** the characteristic of electronic equipment that permits undesirable responses when subjected to electromagnetic energy.

2.64 **Test antenna:** an antenna of specified characteristics designed for use under specified conditions in performing tests.

3. Organisation of statutory requirements

3.1 The worldwide organisation for standards is the International Electrotechnical Commission (IEC). The IEC is comprised of representatives from over 40 national electrotechnical committees. The International Special Committee on Radio Interference (CISPR) was formed in 1934 as a committee of the IEC. The CISPR has six subcommittees which prepare and manage the various standards and regulations.

3.2 CENELEC, the European electrotechnical standardisation body, has been given a mandate by the European Commission to draw up standards to be used for compliance with the EMC Directive. A number of generic and product-specific standards are currently being drawn up, and the first of these are already in place. See Table 1.

3.3 There are three types of standard for the EMC Directive:

a. product standard relating to a specific product;

b. product family standard, relating to a specific product group;

c. generic standard, relating to a particular location of operation.

3.4 Where a product standard exists, it will take precedence over a generic standard, but it is expected that most apparatus will be governed by generic standards because the number of product standards is likely to be small.

3.5 ETSI, the European Telecommunications Standards Institute, formulate standards which relate to EMC for radio telecommunications apparatus.

National standards

3.6 British Standards are produced by the British Standards Institution (BSI). It has a common structure to that of the IEC committees in the UK. The British member body of the IEC and CENELEC is the British Electrotechnical Committee (BEC). When dealing with international documents, commenting or voting, the BSI electrical committees do so on behalf of the BEC. The BSI Technical Committee GEL/110 is responsible for international documents and for British Standards relating to electromagnetic interference in connection with the EC Directives.

Statutory Instruments

3.7 In order to protect radio services, internationally agreed statutory limits are enforced for the field strength of radiated interfering signals at radio designated frequencies and for the magnitude of supply mains terminal

transient voltages. Special frequencies are allocated for industrial, scientific and medical purposes (ISM frequencies) and unlimited radiation energy is permitted on these frequencies. Data processing equipment is also included in the ISM range of frequencies.

3.8 The regulations concerning radio interference have hitherto been published in the United Kingdom as Statutory Instruments (SI) under the direction of the Department of Trade and Industry (DTI). See References for current Statutory Instruments.

4. Applicable standards

Household and commercial appliances

4.1 These appliances form one category of the wide-ranging items which cause radio or supply inferences. Unscreened interferences usually emanate from small motors/switching devices and regulating controls containing semiconductors. The CISPR has produced Publication 14 as a guidance document.

4.2 Reference should be made to BS EN 55014-1: 2001, 'Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission. Product family standard'.

4.3 The limitation of disturbances in electricity supply networks caused by domestic or similar appliances, equipped with electronic devices is referred to in BS EN 61000: 1995.

Fluorescent lighting

4.4 Specification for radio interference states limits and measurements for luminaires using tubular fluorescent lamps fitted with starters. BS 5394 has been superseded by BS EN 55015: 2001 'Limits and methods of measurement of radio interference characteristics of electrical lighting and similar equipment'.

Industrial, scientific and medical (ISM)

4.5 This equipment is permitted to produce intentional radio frequency signals as part of the function of the equipment, that is, inductive heating, arc welding and surgical diathermy.

4.6 There is considerable debate and disagreement, in relation to CISPR Publication No 11, between ISM manufacturers, communication and navigational operators. Data transmission and communications equipment using digital techniques, and therefore having a wide bandwidth susceptibility, is subject to encroachment from healthcare surgical diathermy equipment interference. In the UK there is one Statutory Instrument concerning electro-medical equipment (SI 1895: 1963).

Electro-medical equipment

4.7 Special frequencies are allocated for industrial, scientific and medical (ISM) purposes and unlimited radiation is permitted at certain frequencies. In the special case of surgical diathermy, there is no restriction for either frequency or power output.

4.8 The interference limits specified in the Wireless Telegraphy (Control of Interference from electro-medical apparatus) Regulations (SI 1895: 1963) are given in Table 1.

Data processing equipment/information technology equipment

4.9 The British Electro-technical Committee (BEC) produced BS 6527: 1988, 'Specifications for limits and measurements of spurious signals generated in data processing and electronic office equipment'. This standard has been replaced by BS EN 55022: 1998 and has sufficient technical content to be used internationally. The standard specifies terminal voltage limits at the mains terminals in the 0.15-30 MHz frequency range, and limits radiated frequency field strength in the 30-300 MHz frequency range for domestic and commercial users. Other relevant harmonised documents are HD 481 series, equivalent to BS 6667, which has been subsequently replaced by BS EN 61000-4-1.

TV and sound broadcast receivers

4.10 Sub-committee E of CISPR is responsible for limits of interference caused by TV and sound broadcast receivers and, uniquely within CISPR, is also responsible for immunity. Publication 13 specifies limits of interfering signals and has some limits for immunity over the 150-1605 kHz range.

4.11 BS 905: 1985, 'Limits of radio frequency and immunity', which was revised in 1991 and published in two parts, was replaced by BS EN 55013 and BS EN 55020. Part 1 (BS EN 55013) specifies limits of radio interference over a frequency range of 0.15-1000 MHz, some being expressed as voltage limits measured at the mains terminals, some as limits at the antenna and other limits for local oscillator radiation. Part 2 (BS EN 55020) specifies immunity limits of receivers and associated equipment in the 26-30 MHz range, and of TV receivers to tuned frequency interference or "ghosting". Part 2 in particular contains much new work, and was derived from CISPR sub-committee E.

Internal-combustion engine ignition

4.12 Once a great source of annoyance, the internal-combustion engine's problems are largely solved as far as broadcast reception is concerned. CISPR sub-committee D has produced Publication 12; and, upon joining the Common Market, the UK inherited a 1972 EC Directive 72/45/EEC. This is implemented in the UK by a Statutory Instrument 1217: 1973, which in turn referred to BS 833. The latter specifies limits of radiation over the 40-250 MHz frequency band. Reference should now be made to BS CISPR 12: 1997.

Public supply mains

4.13 BS EN 61000-4-11: 1994, IEC 61000-4-11: 1994 Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations and immunity tests. It defines the methods and range of preferred test levels for voltage interruptions and voltage variations for equipment connected to low voltage power networks.

Table 1 ISM Frequency bands

Frequency range	Max field strength microvolts per metre at 30 metres	Max Mains terminal Voltage in microvolts
150KHz-40MHz (excluding ISM frequencies)	30	1500
40 MHz –118 MHZ	15	750
118MHz – 223 MHz	30	1500
13.56 MHz± 0.05% (ISM frequency)	Unlimited	Unlimited
27.12 MHz ± 0.6% (ISM frequency)	Unlimited	Unlimited

Limits for the field strength and terminal voltage of harmonics of 13.56 MHz are also given.

5. Electromagnetic interference

5.1 The increased use of sophisticated technology in healthcare premises has resulted in a need to combat increasing levels of electromagnetic interference (EMI) between electrical/electronic products, with effects ranging from simple acceptable nuisance value to major safety hazards. Unacceptable nuisance effects and potential hazards due to EMI have resulted in the demand for a higher degree of reliability in all electronic/electrical apparatus including battery and/or mains voltage-driven electronic equipment, with the special requirement that all apparatus, systems and installations operate free from externally or internally generated electromagnetic interference.

Physical aspects

5.2 The source of interference, and its relationship to other susceptible equipment, divides naturally into three separate components as follows:

a. the source of the interference – the aggressor;

b. the equipment which is affected – the victim or susceptible equipment;

c. the path by which the source of interference is coupled to the affected equipment.

The source of interference

5.3 This is the aggressor device. It generates extraneous electromagnetic fields or produces undesired mains transient energy. This energy may be expressed in terms of watts and may be evaluated in volts and amps for conducted interference, or as volts per metre or amperes per metre for radiated field distribution pattern.

The susceptible equipment

5.4 This is the susceptible device. It has produced an undesired response to an interference signal.

The coupling path

5.5 This is the medium through which the energy of interference is transferred from the source to the victim. It is passive but it may be linear or non-linear electrically in its characteristic behaviour to that interference signal.

5.6 The transfer of an interference signal may be conducted electrically by wire, field induced magnetically as a near field effect, or electric field radiated as a far field effect.

5.7 Low frequency magnetic field interference is predominantly inductively transferred, whereas high frequency electric field interference is predominantly capacitively coupled between source and victim.

5.8 Electromagnetic field radiation is transferred in the form of a travelling wave, emanating from the energy source (for example radio transmitting antenna). The characteristic impedance of the medium through which the wave travels determines the speed of wave travel.

For free space, the characteristic impedance is:

$Z_o = \sqrt{(\mu_o / C_o)} = 377$ ohms.

For free space the velocity of a wave is given by:

$V_o = \sqrt{(\mu_o C_o)} = 3 \times 10^6 ms^{-1}$ (the velocity of light).

Where: μ_o = permeability of free space.

C_o = permittivity of free space.

Psychological requirement and tolerance

5.9 The level of tolerance to any interference signal seen or heard from an item of equipment depends upon the sensitivity or response of the victim equipment, and the skill by which the victim can clearly and accurately separate the desired signal information from the sum of the observed signal. The ratio of “desired signal strength” to “interference strength” is defined as “signal-to-noise” ratio (S_n):

$$S_n = \frac{\text{Signal strength in watts}}{\text{Interference strength in watts}}$$

5.10 There is no absolute requirement to remove all interference from the information signal in every situation. The need to obtain a higher level of information signal purity becomes progressively more costly.

5.11 It is essential that all equipment continue to function in a safe and reliable manner. Each item of equipment, system or installation will have its own tolerance level for safe performance and this level of minimum acceptable performance should not be breached. Reciprocally, no equipment, system or installation should cause the malfunction of any other equipment, system or installation. Exceptions to the rule are closely governed: details are given in section 2.0 of this document.

6. Management action

6.1 Managers of healthcare premises are required to be aware of, and understand, the basic concepts of electromagnetic interference and to provide an overview of managerial responsibility, guidance and expectations with regard to existing Statutory Instruments.

6.2 Managers of healthcare premises are required to be aware of the implications of the EMC Directive 89/360/EEC for the procurement of medical-electrical apparatus and systems, and the installation requirements stipulated by the manufacturer for proper operation of the installation.

6.3 Medical and technical staff who are to operate medical electronic and electrical equipment in healthcare premises should be given support knowledge to understand the effects of mains-borne and electromagnetic interference upon the equipment.

6.4 Engineers who are responsible for the design, preparation of specifications and purchase of all types of electrical equipment for healthcare premises should make suppliers fully aware of their requirements and ensure that performance guarantees and test certificates are provided by the manufacturer of the equipment within the contract terms.

6.5 Architects who are responsible for the layout and structural planning of healthcare premises should consult with design engineers on the spatial layout required for equipment, particularly those spaces where large active sources of electromagnetic interference will be generated.

6.6 Manufacturers providing general and medical electronic and electrical equipment should develop an understanding of healthcare premises requirements and of the various types of equipment therein.

References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	***Title***	***Publisher***	***Date***	***Notes***
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc. Act	HMSO	1974	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 1671	Active Implantable Medical Devices Regulations	HMSO	1995	
SI 1315	In Vitro Diagnostic Medical Devices Regulations	HMSO	2000	
SI 3017	Medical Devices Regulations	HMSO	1994	
SI 2179	Building Standards (Scotland) Regulations	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations	HMSO	1998	
SI 2372	Electromagnetic Compatibility Regulations	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	

Publication ID	Title	Publisher	Date	Notes
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
SI 1895	Wireless Telegraphy (Control of Interference from Electro-medical Apparatus) Regulations 1963	HMSO	1963	
SI 1675	Wireless Telegraphy (Control of Interference from Radio Frequency Heating Apparatus) Regulations 1971	HMSO	1971	
SI 1217	Wireless Telegraphy (Control of Interference from Ignition Apparatus) Regulations 1973	HMSO	1973	
SI 1267	Wireless Telegraphy (Control of Interference from Household Appliances, Portable Tools, etc.) Regulations 1978 (as amended)	HMSO	1978	

Publication ID	Title	Publisher	Date	Notes
SI 1268	Wireless Telegraphy (Control of Interference from Fluorescent Lighting Apparatus) Regulations 1978 (as amended)	HMSO	1978	
89/336/EEC	Electromagnetic Compatibility (EMC) Directive	HMSO	1992	
90/385/EEC	Active Implantable Medical Devices Directive	HMSO	1990	
91/236/EEC	Telecommunications Terminal Equipment Directive	HMSO	1991	
93/42/EEC	Medical Devices Directive	HMSO	1993	
98/79/EC	In Vitro Diagnostic Medical Devices Directive	HMSO	1998	
British Standards				
BS 5049-1	Radio interference characteristics of overhead power lines and high-voltage equipment. Description of phenomena	BSI Standards	1994	
BS 5049-2	Radio interference characteristics of overhead power lines and high-voltage equipment. Methods of measurement and procedure for determining limits	BSI Standards	1994	
BS 5049-3	Radio interference characteristics of overhead power lines and high-voltage equipment. Code of practice for minimising the generation of radio noise	BSI Standards	1994	
BS 5260	Code of Practice for Radio Interference Suppression on Marine Installations	BSI Standards	1975	
BS 6299	Methods of measurement of the suppression characteristics of passive radio interference filters and suppression components	BSI Standards	1982	
BS 6345	Method for Measurement of Radio Interference Terminal Voltage of Lighting Equipment (based on BS CISPR 15)	BSI Standards	1983	
BS 6626	Code of practice for the maintenance of electrical switchgear and control gear voltages above 1 kV and up to and including 36 kV	BSI Standards	1985	
BS 6667: Part 1	Electromagnetic compatibility for industrial-process measurement and control equipment: General introduction	BSI Standards	1985	
BS 6667: Part 2	Electromagnetic compatibility for industrial-process measurement and control equipment: Method of evaluating susceptibility to electrostatic charge	BSI Standards	1985	

Publication ID	Title	Publisher	Date	Notes
BS 6902-1	Cardiac Pacemakers: Specification for implantable cardiac pacemakers	BSI Standards	1990	
BS 6902-1: supplement No.1	Cardiac Pacemakers: Specification for implantable cardiac pacemakers. Electromagnetic compatibility	BSI Standards	1996	
BS 727	Specification for Radio-Interference Measuring Apparatus (based on BS CISPR 16)	BSI Standards	1983	
BS 7671	Requirements for electrical installations. IEE wiring regulations	HMSO	1992	16th edition
BS 833	Specification for Radio Interference Limits and Measurements for the Electrical Ignition Systems of Internal Combustion Engines (based on BS CISPR 12 and BS CISPR 21)	BSI Standards	1970	
BS CISPR 12	Vehicles, motorboats and spark-ignited engine-driven devices. Radio disturbance characteristics. Limits and methods of measurement	BSI Standards	1997	
BS CISPR 16-1	Specification for radio disturbance and immunity measuring apparatus and methods. Radio disturbance and immunity measuring apparatus	BSI Standards	1999	
BS CISPR 16-2	Specification for radio disturbance and immunity measuring apparatus and methods. Methods of measurement of disturbances and immunity	BSI Standards	1996	
BS CISPR 16-3	Specification for radio disturbance and immunity measuring apparatus and methods. Reports and recommendations of CISPR	BSI Standards	2000	
BS EN 50065-1	Specification for signalling on low-voltage electrical installations in the frequency range 3 kHz to 148.5 kHz. General requirements, frequency bands and elecromagnetic disturbances	BSI Standards	1992	
BS EN 50081-1	Electromagnetic compatibility. Generic emission standard: Residential, commercial and light industry	BSI Standards	1992	
BS EN 50082-1	Electromagnetic compatibility. Generic immunity standard: Residential, commercial and light industry	BSI Standards	1992	
BS EN 50083-2	Cabled distribution systems for television and sound signals. Part 2: Electromagnetic compatibility for equipment	BSI Standards	1995	

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BS EN 50098-1	Customer premises cabling for information technology. ISDN basic access	BSI Standards	1999	
BS EN 50098-2	Customer premises cabling for information technology. 2048 k/bit/s ISDN primary access and leased line network interface	BSI Standards	1996	
BS EN 55011	Specification for limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	BSI Standards	1998	
BS EN 55013	Limits and methods of measurement of radio disturbance characteristics of broadcast receivers and associated equipment.	BSI Standards	1997	
BS EN 55014 -1	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission. Product family standard	BSI Standards	2001	
BS EN 55014 -2	Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard	BSI Standards	2001	
BS EN 55015	Limits and methods of measurement of radio interference characteristics of electrical lighting and similar equipment	BSI Standards	2001	
BS EN 55020	Electromagnetic immunity of broadcast receivers and associated equipment	BSI Standards	1995	
BS EN 55022	Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement	BSI Standards	1998	
BS EN 55024	Information technology equipment. Immunity characteristics: Limits and methods of measurement	BSI Standards	1998	
BS EN 60601-1	Medical electrical equipment. General requirements for safety	BSI Standards	1990	
BS EN 60601-1-1	Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems	BSI Standards	1993	
BS EN 60801-2	Electromagnetic compatibility for industrial-process measurement and control equipment. Electrostatic discharge requirements	BSI Standards	1993	

Publication ID	Title	Publisher	Date	Notes
BS EN 61000-3-2	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	BSI Standards	1995	
BS EN 61000-3-3	Electromagnetic compatibility (EMC). Limits. Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 16A	BSI Standards	1995	
BS EN 61000-4-1	Electromagnetic compatibility (EMC). Testing and measurement techniques. Overview of immunity tests. Basic EMC publication	BSI Standards	1995	
BS EN 61000-4-3	Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test	BSI Standards	1997	
BS EN 61000-4-4	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test. Basic EMC publication. Based on IEC 1000 4-8	BSI Standards	1995	
BS EN 61000-4-7	Electromagnetic compatibility (EMC). General guide on harmonics, interharmonics measurements and instrumentation, for power supply systems and equipment connected thereto. Based on: IEC 1000 4-7	BSI Standards	1993	
BS EN 61000-4-9	Electromagnetic compatibility (EMC). Testing and measurement techniques. Pulse magnetic field immunity test. Basic EMC publication	BSI Standards	1994	
BS EN 61000-4-10	Electromagnetic compatibility (EMC). Testing and measurement techniques. Damped oscillatory magnetic field immunity test. Basic EMC publication	BSI Standards	1994	
BS EN 61000-4-11	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips short interruptions and voltage variations immunity tests	BSI Standards	1994	

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Scottish Health Technical Guidance				
SHTM 2007	Electrical services supply and distribution	PEF	2001	CD-ROM
SHTM 2011	Emergency electrical services	PEF	2001	CD-ROM
SHTM 2020	Electrical safety code for LV systems (Escode – LV)	PEF	2001	CD-ROM
SHTM 2021	Electrical safety code for high voltage systems (Escode – HV)	PEF	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 4	General Purposes States and Functions Model Safety Permit-to-Work Systems	PEF	1997	
	NHS in Scotland – Procode	PEF	2001	
NHS in Scotland Fire Safety Management				
SHTM 81	Fire precautions in new hospitals	PEF	1999	CD-ROM
SHTM 82	Alarm and detection systems	PEF	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	PEF	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	PEF	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	PEF	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	PEF	1999	CD-ROM
SHTM 87	Textiles and furniture	PEF	1999	CD-ROM
SFPN 3	Escape bed lifts	PEF	1999	CD-ROM
SFPN 4	Hospital main kitchens	PEF	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	PEF	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	PEF	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	PEF	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	PEF	1999	CD-ROM
	Scottish Executive Health Department 'Fire Safety Policy'	PEF	1999	
	Fire Safety Documentation Reference Guide	PEF	1999	
	A Model Management Structure for Fire Safety	PEF	1999	

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
UK Health Technical Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
MES	Model Engineering Specifications	NHS Estates	1997	As required
HTM 2020	Electrical safety code for low voltage systems (Escode – LV): Volume 2	HMSO		
Department of Health Publications				
	Management of medical equipment and devices (Health Equipment Information 98). Medical Devices Agency	Dept. of Health	1991	
	First aid at work. Health and safety (First Aid) regulations 1981. Approved code of practice and guidance (L 74)	HSE	1997	