Scottish Health Technical Memorandum 2014

(Part 3 of 4)

Validation and verification

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.

Definitions

1.5 The following definitions apply throughout this document.

1.6 **Management:** is the owner, occupier, employer, general manager, 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.

1.7 **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.

1.8 **Department:** an abbreviation of the term “Scottish Executive Health Department”.

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

1.10 **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.

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

1.12 **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.

1.13 **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.

1.14 **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.

1.15 **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”.

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

1.17 **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.

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

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

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

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

1.22 **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.

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

1.24 **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.

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

1.26 **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.

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

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

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

1.30 **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.

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

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

1.33 **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.

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

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

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

1.37 **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. This value should be indicated in the individual equipment specification.

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

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

2. Commissioning

2.1 EMC testing can be carried out at three levels of assembly:

a. component - which includes black box testing, switches, relays;

b. sub-system - electronic or electrical equipment that performs a specific function, within an overall system;

c. system - the overall equipment, to ensure that the whole assembly complies with the specification, and that no interrelated or cross-interferences exist between the equipment and/or the environment.

Works testing

2.2 The electronic and/or electrical equipment should be tested and demonstrated as a complete operational unit where possible. RF emission from any electrical equipment should be determined, and at the same time its level of susceptibility to any external influences that may be generated around the works.

2.3 At the time of contract the operational use and the location of use of the equipment must be made known by the purchaser to the manufacturer. A certificate of guaranteed electromagnetic compatibility must be obtained for the electrical equipment either as per the EC Directive on EMC (89/336/EEC) or the Directive concerning Medical Devices 93/42/EEC.

2.4 The EMC test environment should simulate the environment/location in which the equipment will be required to operate, and may also include transmitting stations, vehicular devices, mobile communication units and diathermy apparatus.

Site testing

2.5 Before in situ operational tests or demonstrations are carried out on the electrical equipment to be installed, it is essential that two phases of a 3-phase supply are available. The test equipment and the monitoring equipment must not be on the same phase of supply or else suitable arrangements must be made to isolate this equipment. The screening of the location from outside RF sources of emission must be in place.

2.6 Aggressive electromagnetic radiation and power supply interference must be measured to determine the suitability of the location for the electrical equipment, or whether radiation screening or electrical supply filtering may be necessary.

2.7 Where screening or filtering may be necessary the cost of such requirements must be assessed and carefully balanced against the cost of a new location.

2.8 A basic list of electromagnetically compatible location requirements may include the following:

a. power ring main and lighting supply wires screened and enclosed in isolated metal conduit which is earthed at point of entry to the location;
b. socket boxes are metal enclosed;
c. fluorescent light fittings metal screened. Incandescent lighting is interference free;
d. power and lighting supply mains filtered;
e. a dedicated protective earth system of low impedance should be available.

RF radiation screening

2.9 The following methods can be adopted:

a. the walls and ceiling can be covered with screening material;
b. window openings can be covered by a screen mesh;
c. resonant frequency of the room can be determined, with and without electrical equipment installed;
d. ventilation duct openings can be covered by honeycomb screens;
e. the use of radio frequency absorbent materials should be considered.

Legal test requirements

2.10 As per the EC Directives, all items of equipment are to be electromagnetically compatible both in terms of emissions (generation of undesired electromagnetic energy) and immunity (adverse reaction to the presence of undesired electromagnetic energy).

2.11 The range of electrical apparatus found in healthcare premises means that, in order to meet the requirements of the EMC Directive, a number of harmonised standards will apply. For example, refrigerators and microwave ovens will be required to meet the appropriate product specific standards or, in the absence of these, the generic standards for domestic, commercial and light industry.

2.12 Diathermy apparatus will be required to meet the product standards for industrial, scientific and medical equipment.

2.13 Computing devices will require to be manufactured to the product specific standards required for information technology equipment.

2.14 Achieving conformity with the EMC Directive presents a number of technical and commercial problems. The technical problems include identification of the appropriate standard and deciding the route to conformity. Commercial problems include the cost of meeting the requirements and the timing of actions leading to conformity.

2.15 The use of harmonised standards in full enables the manufacturer to demonstrate conformity with the protection requirements of the EMC Directive.

2.16 Where the manufacturer has not fully applied a harmonised standard, or where such standards do not exist, the manufacturer must draw up a technical construction file which enables the conformity of the product to be assessed. This file is verified by a NAMAS or an EC accredited laboratory of the manufacturer's choice.

3. EMC test objectives and plan

3.1 In order to achieve EMC effectively and economically it is essential that the EMI threat is considered fully at all stages of design, development, manufacture, installation and maintenance. The implementation of curative measures at a late stage, or retrospectively, will almost inevitably result in considerable extra effort and cost, and, not least, inconvenience to both supplier and user.

3.2 It is therefore essential that the EMC design goals are established at an early stage preferably before the contract, and an EMC plan is agreed and implemented for all stages. For a fairly simple item of equipment this may involve minimal effort whereas for a large sophisticated system all EMC related aspects must be documented.

Procurement requirement

3.3 The following questions are relevant:

a. Is the requirement clearly understood?
b. Is the equipment to be installed in a defined/controlled area?
c. Does the minimum EMC Directive requirement apply?
d. What is the defined purpose of the equipment?
e. What levels of interference exist in the equipment's external environment?
f. What levels of interference are being created by co-sited equipment?
g. How much allowable interference can be generated by the equipment without threatening co-sited equipment?

These questions will give a prediction of the vulnerability and annoyance factors of the equipment to be procured and will allow the designer to choose the correct technology components and design for optimum performance of the equipment.

Specification

3.4 Is the classification of the equipment correctly stated so that the correct set of EMC specifications and tests can be applied?

Control plan

3.5 The following questions are relevant:

a. Are the lines of responsibility for the implementation of EMC established?
b. Are the definitions and relevant documents identified and available?
c. Have all the relevant mechanical design aspects been considered?
d. Have all the electrical design aspects been covered?
e. Have all the installation practices been identified?
f. Has the test strategy been established?
g. Are the production and maintenance controls in place?
h. During production has sample testing been carried out?

Test plan

3.6 The test plan is the most accurate way of agreeing the requirements applicable to the equipment. The test plan may include one or more of the representative procedures:

a. a description of equipment for test;
b. a statement of test objectives;
c. the criteria for determining the equipment or parts to be monitored;
d. test requirements which should include frequency ranges, test equipment to be used, exact points of measurement and the various modes of operation;
e. test procedure to be followed;
f. chain of command;
g. type of test report;
h. any methods required to evaluate the test results.

3.7 The involvement of the above procedures will be dependent upon the importance placed upon the assembly level, and the sensitivity of the equipment under test.

Test report

3.8 This should accurately detail all the test results and measurement uncertainties and link across to the test plan.

Interference simulation tests

3.9 Interference voltages and electromagnetic fields at desired frequencies can be superimposed upon input signals, power supplies or equipment bodies. Special equipment is required for these tests and the tests are preferably carried out at a third party test house or the manufacturer's works in the presence of the management's approved representative.

3.10 The range of tests required must be specified in the contract document and a certificate of satisfactory performance provided, stating type test and routine test before delivery can be accepted and authorised by the management representative. Depending on the classification of the equipment, all apparatus must be endorsed with the EC conformity 'CE' mark as described in SHTM 2014 – 'Overview and management responsibilities', paragraph 2.20.

3.11 The test equipment must be sufficiently flexible to demonstrate that the equipment under test is immune to interference for the use intended. Certain critical parameters should be chosen on which to monitor equipment susceptibility.

3.12 The test equipment will be required to simulate one or more of the following tests:

a. power failures or interruptions originating within the switching system, or supply over or under voltage changes;
b. interference pulses on power lines - high energy and slow risetime (300 nanoseconds (ns)) generated when switching large inductive or capacitive loads, medium energy and medium risetimes (35 ns) generated by the operation of fast power switching devices. Low energy and fast risetime (5 ns) generated through switches and relays;
c. simulation of electrostatic discharge to the equipment;
d. high voltage for insulation soundness and determination of insulation leakage current;
e. electromagnetic fields to simulate hostile radiated interference.

3.13 The EMI emissions generated within the equipment must also be measured to assess the degree of interference generated by the equipment:

a. measurement of electromagnetic voltage and current, and power on power and signal lines;
b. measurement of the electric and magnetic components of the electromagnetic energy generated by the equipment.

Radiated emissions measurements

3.14 For some types of electrical equipment, such as diathermy, RF emissions can only be effectively assessed on the basis of the radiated field.

3.15 To assess the degree of interference, an open test site should be chosen, with the aggressor equipment transmitting to the susceptible receiving equipment from known distances. The open site may be a special site where secondary reflection/transmission emissions are eliminated or a practical site where reflection may be present off the site infrastructure.

3.16 The second test measurements should be repeated with and without the aggressor equipment in the actual location of operation.

3.17 The RF measurements are generally made using two methods. Up to 30 MHz the RF voltage at the mains terminal is measured as a conducted interference test and above 30 MHz generally up to 1000 MHz, by measurement of the radiated energy in field strength in V/m.

3.18 Care should be taken when making on-site measurements of radiated fields in rooms that are not “damped” with radio absorbent material. The room, whether screened or not, may have a resonant frequency dependent upon the physical dimensions and the equipment within the room. Tests should be made to ensure that this frequency is not within the susceptibility range of the equipment under test or the same range of other victim equipment in another location. The tests should be carried out firstly with the room empty in order to characterise the ambient condition and afterwards with the room occupied by equipment.

3.19 The resonant frequency may be damped by the use of RF energy absorbent cones suitably placed around the sides and ceiling of the room.

Electrostatic discharge

3.20 The incidence is very much increased, firstly by the excessive dryness in the air, that is, a more resistive path for an electron charge to dissipate, and secondly the ease in which charge may be induced by man-made fibres, as opposed to the more moisture absorbent natural fibres.

3.21 The tests have now been described in BS EN 61000-4-1. A high voltage probe tester designed for simulating an electrostatic discharge is applied to the various parts of an item of equipment. The voltage control range for tests recommended is between 2 and 15 kV with risetimes of normally five nanoseconds ±30% depending on the specification applied. Equipment is now available which can apply test voltages with less than one nanosecond risetime up to 8 kV.

4. Test equipment standards

4.1 A range of equipment is available to carry out the whole range of simulated interference tests covered in this SHTM. Each item of test equipment is a specialised and complex design, and will therefore lie beyond the economical or practical requirements of healthcare premises. Investigation of EMI problems involve the measurement of complex waveforms. The instruments for emissions test purposes, operate in the frequency domain and are based on radio receiver designs where the peak, quasi-peak and average interference values can be measured.

4.2 Full details of performance and design parameters for radio interference measuring receivers are given in BS727: 1983 and BS CISPR 16-1: 1998 and BS CISPR 16-2: 1996.

Test site

4.3 An open field site or screened room with RF absorbers, that is, anechoic chamber, may be used for testing the susceptibility of an item of equipment under test to electromagnetic transmission. In an open field site the distance between the test antenna and the equipment under test may range from 2 m to 30 m. The site is arranged to precise elliptical dimensions with a uniform earth plane. A suitable site should be able to operate over a frequency range 25 MHz to 1000 MHz.

Spectrum analysers

4.4 Spectrum analysers are used in a variety of EMC investigatory tests principally for detection of the harmonics generated from non-sinusoidal waveform generators and digital signals. The instruments can be manually operated or have automatic sweep scan control over the operating frequency range. They are not as accurate as radio receivers designed for the accurate measurement of electromagnetic phenomena.

Measuring receiver equipment (MRE)

4.5 The MRE may be semi-automatic or manual with display equipment and an X-Y plot recorder. MRE are generally super-heterodyne receivers which are more suited for accurate measurements than for investigatory testing (spectrum analysers are more versatile but generally not as accurate).

Power line impedance stabilising networks

4.6 A Line Impedance Stabilisation Network (LISN) of suitable impedance (50 ohms/50 µH) should be provided for presenting a known constant impedance between the supply and the equipment. The equipment under test and the test equipment must be fed from different single phases of a common 3-phase supply, or suitably isolated from each other.

Signal generators

4.7 The signal generator must possess sufficient output in conjunction with power amplifiers to provide the required field strength meter reading for immunity testing over the required frequency range.

Antennae

4.8 The antennae are generally dipoles arranged in horizontal or vertical configuration or looped antennae for magnetic fields.

Current injection probes

4.9 This is generally a portable instrument that injects a representative interference signal into any connecting power cable of electronic equipment under test thus providing an instant assessment of the vulnerability of the equipment under test to RF. This instrument generally operates over a wide spectrum with amplitude and frequency modulated signals at an output of 50 mW, 100 mA. This is a basic instrument which simulates the interference current flow in a conductor thus highlighting a potentially susceptible defect.

Mains supply interference simulators

4.10 The adaptability of these simulators can vary in the range of tests they are designed to perform. The unit may comprise a central control unit, plus an additional feature of plug-in mainframe units, to control the simulation of mains failures and interference pulses generated in system operations normal/abnormal behaviour as follows:

a. pulses: medium to fast 5/100 ns to 35/3000 ns;

b. dropout times, within $\frac{\lambda}{2}$ wave;

c. dropout time within a wave train and phase delay;

d. voltage wave amplitude variation;

e. repetitive bursts of pulses, less than 2000 V, 0.1 Hz up to 10 kHz, or greater than 2000 V, 0.1 Hz up to 5 kHz;

f. standardised lightning voltage pulse and surge current, 1.2/50 microseconds and 8/20 microseconds respectively;

g. high voltage test range 100/5000 V ac, 100/1000 V dc and equipment leakage current.

Magnetic field meter

4.11 The magnetic field meter is an instrument to measure low frequency magnetic fields. The main features of the instrument are:

a. orthogonal coils, independent of field direction;

b. frequency range (5 - 1000 Hz) for all low frequency magnetic fields;

c. wide dynamic range 0.01 - 1000 microTesla with auto-ranging;

d. true rms flux with dominant frequency measurement;

e. polarisation measurement and presentation;

f. flexible data logging functions with the possibility to transfer stored results to printer or computer;

g. battery powered to avoid any power supply interferences.

5. Supervision

5.1 EMC tests to equipment are not usually carried out on site. Every endeavour should be made to ensure that the items of equipment are tested initially in the manufacturer's works or at an accredited NAMAS or EC test laboratory to ensure the representative environmental conditions for test are met. "CE" conformity labels and manufacturers' installation procedures must be supplied.

5.2 In cases where equipment is large and requires building on site into fixed positions then the highest standard of test equipment must be used. Management representatives, with the best understanding and knowledge of the required test procedures and test routines, must be witnesses. A manufacturer must be fully informed of the purpose and the function of the equipment under test, and given a full specification of the operating expectations of the equipment at the specification stage.

5.3 A written guarantee must be part of the acceptance for completion of works. For tests to be smoothly and quickly carried out to a satisfactory conclusion, electrical services and other piped systems must be completed and in place, as allocated by the project management. Extra test services required must be stated by the manufacturer, as part of his tender for the contract, not at the time of arrival on site to carry out tests.

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	

Publication ID	Title	Publisher	Date	Notes
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	
BS EN 61000-3-2	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	BSI Standards	1995	

Publication ID	Title	Publisher	Date	Notes
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	

Publication ID	Title	Publisher	Date	Notes
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	