

Documents useful to **Independent Safety Assurance**



Change History

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Cover Images (clockwise from top left)

- Nuclear power plant
- Euro fighter
- Oil and natural gas offshore platform
- London Underground

About the supporting organisations

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1. Safety or Safety Related Legislation and Standards

General Safety Related UK Legislation and Standards

- Health and Safety at Work Act etc. 1974
- Electricity at Work Regulations 1989, Statutory Instrument No. 635
- Electrical Equipment (Safety) Regulations 1994, Statutory Instrument No. 3260
- Supply of Machinery (Safety) Regulations 1998, Statutory Instrument No. 3073
- Provision and Use of Work Equipment Regulations 1998, Statutory Instrument No. 3163
- Control of Major Accident Hazards (COMAH) Regulations 1999, Statutory Instrument No. 743
- Planning - Control of Major Accident Hazards Regulations 1999, Statutory Instrument No. 981
- Management of Health & Safety at Work Regulations 1999 with amendment, Statutory Instrument No. 3242
- Ionising Radiations Regulations 1999, Statutory Instrument No. 3232
- Pressure Equipment Regulations 1999, Statutory Instrument No. 2001
- Pressure Systems Safety Regulations 2000, Statutory Instrument No. 128
- Control of Substances Hazardous to Health Regulations 2002, Statutory Instrument No. 2027
- Dangerous Substances and Explosives Atmospheres Regulations 2002, Statutory Instrument No. 2776
- Health and Safety - Control of Major Accident Hazards Regulations 2005 with amendment, Statutory Instrument No. 1088
- General Product Safety Regulations 2005, Statutory Instrument No. 1803
- Liability for Defective Products 1985 (85/374/EEC) as implemented by Consumer Protection Act 1987
- Electromagnetic Compatibility Regulations 2006 with amendment, Statutory Instrument No. 3418
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, Statutory Instrument No. 1348
- Construction (Design & Management) Regulations 2015, Statutory Instrument No. 51

Generic Safety Standards and Guidance

- BS EN 61508, Functional Safety of Electrical/Electronic/Programmable Electronic Safety Related Systems, 2010
- PAS 754:2014, Software Trustworthiness. Governance and management specification, British Standards Institution, 2014
- Data Safety Guide, Safety Critical Systems Club Data Safety Initiative Working Group, January 2015, http://data-safety.scs.org.uk/doku/dswig:doc_main

Military Safety Related Standards

- Interim Def Stan 00-55, Requirements for safety of programmable elements in defence systems, UK Ministry of Defence, Issue 3, December 2014
- Def Stan 00-56, Safety management requirements for defence systems, UK Ministry of Defence, Issue 6, April 2015
- Def Stan 00-25, Human factors for designers of equipment Part 14. Military land vehicle design, UK Ministry of Defence, Issue 1, August 2000
- Def Stan 00-250, Human factors for designers of systems - Human factors integration, in 5 parts, UK Ministry of Defence, May 2008
- Def Stan 00-970, Design & airworthiness requirements for service aircraft, UK Ministry of Defence, July 2015
- MIL-STD-882E, Standard practice for system safety, US Department of Defence, May 2012

UK Defence Safety Regulatory Publications

- Acquisition Safety and Environmental Management System (ASEMS), Defence Equipment and Support, UK Ministry of Defence
- Project Orientated Safety Management System (POSMS), Defence Equipment and Support, UK Ministry of Defence
- Joint Services Publication 309: Fuel and gas safety assurance
- Joint Services Publication 375: Management of health and safety in defence, January 2015
- Joint Services Publication 392: Management of radiation protection in defence, April 2011
- Joint Services Publication 403: Handbook of defence land ranges safety, May 2015
- Joint Services Publication 430: Management of ship safety and environmental protection, December 2013
- Joint Services Publication 454: Safety and environmental protection for defence, September 2014
- Joint Services Publication 482: Explosives regulations, May 2013

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- Joint Services Publication 498: Major accident control regulations
- Joint Services Publication 518: Regulation of the naval nuclear propulsion programme, April 2014
- Joint Services Publication 520: Defence, ordnance, munitions and explosives safety and environment management over the equipment acquisition cycle, April 2014
- Joint Services Publication 538: Regulation of the nuclear weapon programme, July 2014
- Joint Services Publication 815: Defence health, safety and environmental protection, December 2014
- Joint Services Publication 862: Explosives regulations part 1 surface ships, December 2013
- Joint Services Publication 862: Maritime explosives regulations part 2 submarines, December 2013
- Military Aviation Authority Regulatory policy, UK Ministry of Defence
- Military Aviation Authority Regulatory articles - 1000 to 5000 series, UK Ministry of Defence
- Manual of air safety, UK Military Aviation Authority
- Manual of military air traffic management, UK Military Aviation Authority
- Manual of maintenance and airworthiness process, UK Military Aviation Authority

Aviation Safety Related Legislation and Standards

- EC Regulation 216/2008, Common rules in the field of civil aviation and establishing a European Safety Agency, 2008
- EU Regulation 748/2012, Rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, 2012
- EU Regulation 2015/640, Additional airworthiness specifications for a given type of operations, 2015
- International Air Transport Association, Dangerous goods regulations manual, 57th Edition, 2016
- ARP4754/ED-79, Aerospace Recommended Practice (ARP), Guidelines for development of civil aircraft and systems, SAE International/EUROCAE, November 2011
- ARP4761/ED-135, Aerospace Recommended Practice (ARP) Guidelines and methods for conducting the safety assessment process on civil airborne systems and equipment, SAE International/EUROCAE, December 1996
- DO-178C/ED-12C, Software considerations in airborne system and equipment certification, RTCA/EUROCAE, January 2012 [also DO-178B/ED-12B which is still used]
- DO-254/ED-80 Design assurance guidance for airborne electronic hardware, RTCA/EUROCAE, April 2000
- DO-297/ED-124 Integrated Modular Avionics (IMA) Development guidance and certification considerations, RTCA/EUROCAE, December 2010
- CAP 722, Unmanned aircraft system operations in UK airspace, guidance, Civil Aviation Authority, May 2012
- STANAG 4671 UAV systems airworthiness requirements, Edition 1, September 2009
- IR-21 Certification procedures for aircraft and related products and parts, 2012
- CS-23 Certification specifications for normal, utility, aerobatic, and commuter category aeroplanes, European Aviation Safety Agency, July 2012
- CS-25 Certification specifications for large aeroplanes, European Aviation Safety Agency, July 2014
- CS-27 Certification specifications for small rotorcraft, European Aviation Safety Agency, November 2017
- CS-29 Certification specifications for large rotorcraft, European Aviation Safety Agency, November 2008

Air Traffic Management Related Legislation, Standards and Guidance

- EU Regulation 1034/2011, Safety oversight in air traffic management and air navigation service, 2011
- EC Regulation 482/2008, Establishing a software safety assurance system to be implemented by air navigation service providers, 2008
- CAP 670 SW 01, Regulatory objectives for software safety assurance in air traffic services equipment, May 2014
- Def Stan 00-972, Military Air Traffic Services Equipment safety and performance standards (Aerodrome, Terminal and Naval Air Traffic Services), UK Ministry of Defence, Issue 4, May 2013
- DO-278/ ED-109 Guidelines for communication, navigation, surveillance and air traffic management systems software integrity assurance, RTCA/EUROCAE, March 2002
- ESARR3, Use of safety management systems in air traffic management service providers, Edition 1.0, July 2000
- ESARR4, Risk Assessment and criteria in air traffic management, Edition 1.0, April 2001
- EUROCONTROL, Air navigation system safety assessment methodology, SAF.ET1.ST03.1000-MAN-01, Edition 2, April 2004
- EUROCONTROL, Safety Case Development Manual, Edition 2.2, November 2006

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Rail Related Legislation, Standards and Guidelines

- EU Regulation 402/2013, The Common Safety Method (CSM) for risk evaluation and assessment, European Commission, 2013
- Rail Safety and Standards Board, Rail industry guidance notes (GNs) on the management of change to the mainline railway system, GE/GN 8640 to GE/GN 8645
- The Railway and Other Guided Transport Systems (Safety) Regulations 2006 with amendment
- EU Directive 2008/57/EC, Railways Interoperability Directive, 2008 as amended by 2009/131/EC and 2011/18/EU
- The Railways (Interoperability) Regulations, 2011, Statutory Instrument No. 3066 as amended by The Railways (Interoperability) Regulations 2013 with amendment, Statutory Instrument No. 3023
- BS EN 50126, Railway Applications. The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS), 1999
- BS EN 50128, Railway Applications. Communications, signalling and processing systems. Software for railway control and protection systems, 2011
- BS EN 50129, Railway Applications. Communications, signalling and processing systems. Safety related electronic systems for signalling, 2003
- BS EN 50159, Railway applications. Communication, signalling and processing systems. Safety-related communication in transmission systems, 2010

Nuclear Safety Related Legislation, Standards and Guidance

- Nuclear Installations Act 1965 with amendment
- Radioactive Substances Act 1993
- BS EN 61513, Nuclear Power Plants. Instrumentation and control system important to safety - General requirements for systems, 2013
- BS EN 60880, Nuclear Power Plants. Instrumentation and control system important to safety. Software aspects for computer based systems performing category A functions, 2009
- BS EN 60987, Nuclear Power Plants. Instrumentation and control system important to safety. Hardware design requirements for computer based systems, 2015
- BS EN 62138, Nuclear Power Plants. Instrumentation and control system important to safety. Software aspects for computer based systems performing category B or C functions, 2009
- BS EN 62340, Nuclear Power Plants. Instrumentation and control system important to safety. Requirements for coping with common cause failure, 2010
- Office for Nuclear Regulation, Safety assessment principles Revision 0, 2014
- Office for Nuclear Regulation, Technical assessment guides
- International Atomic Energy Agency, Safety standards
- World Association of Nuclear Operators, Principles & Guidance, and good practices

Automotive Safety Related Legislation and Standards

- EC Regulation 661/2009, Type approval requirements for general safety of motor vehicles, their trailers and systems and components, 2009 as amended by EU regulation 407/2011
- ISO 26262, Road vehicles. Functional safety in 10 parts, 2011
- MISRA, Guidelines for safety analysis of vehicle based programmable systems, ISBN 0 9524156 5 7, November 2007
- MISRA, Development Guidelines for vehicle based software, ISBN 0 9524156 0 7, November 1994
- MISRA, Report 2, Integrity, February 1995
- MISRA, Report 8, Human factors in software development, February 1995

Petrochemical Safety Related Legislation and Standards

- EU Directive 2012/18, Control of major accident hazards involving dangerous substances, 1992, as amended by 2003/105/EC
- The Offshore Installations (Safety Case) Regulations 2005, Statutory Instrument No. 3117
- Safety Case Regulations adopted for the UK Offshore Industry (Petrochemical), 1992
- Pipelines Safety Regulations 1996, Statutory Instrument No. 825
- BS EN 61511, Functional Safety. Safety instrumented systems for the process industry sector, 2004

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Medical Safety Related Legislation and Standards

- EU Directive 90/385/EEC, Active implantable medical devices, 1990 with amendment
- EU Directive 93/42/EEC, Medical devices, 1993 with amendment
- EU Directive 98/79/EC, Vitro diagnostic medical devices, 1998 with amendment
- BS EN 14971, Medical Devices - Application of risk management to medical devices, 2001
- BS EN 60601-1, Medical electrical equipment - General requirements for safety, 1990
- BS EN 60601-1-1, Medical electrical equipment - Safety requirements for medical electrical systems, 2001
- BS EN 60601-1-4, Medical electrical equipment - General requirements for programmable electrical medical system, 1997
- BS EN 60601-2-X, Medical electrical equipment - Particular requirements for safety - Specification for device X

2. Other Useful Development Standards and Guidance

- ISO/IEC 12207, Systems and software engineering. Software life cycle processes, 2008
- ISO/IEC 15288, Systems and software engineering. System life cycle processes, 2008
- BS ISO 17776, Petroleum and natural gas industries, Offshore production installations. Guidelines on tools and techniques for hazard identification and risk assessment
- BS EN 31010, Risk management. Risk assessment techniques, 2010
- BS IEC 60300-3-9, Risk management - Guide to risk analysis of technological systems, 1995
- BS IEC 60812, Analysis techniques for system reliability - Procedure for failure mode and effects analysis, 1985
- BS IEC 61025, Fault tree analysis, 2007
- BS IEC 61882, Hazard and operability studies (HAZOP studies). Application guide, 2001
- PD ISO/IEC TS 15504-10 Information technology. Process assessment. Safety extension, 2011
- IEEE 1220, Application and Management of the Systems Engineering Process, 2005
- INCOSE, Systems engineering handbook Version 3.2.2, <http://www.incose.org>
- CASS, Conformity assessment of safety-related systems, <http://www.61508.org/cass>

3. Safety Competence

- IET/BCS, Competence Criteria for safety related systems practitioners, 2007, IET

4. Security Legislation and Standards Relating to Safety

- EU Directive 2013/0027 (COD), Measures to ensure a high common level of network and information security, commonly known as the Cybersecurity Directive, 2014
- NIST Special Publication 800-160, Systems security engineering. An integrated approach to building trustworthy resilient systems, May 2014
- ISO/IEC 27000 Series of Standards
- ISO/IEC 27001, Information technology. Security techniques. Information security management systems. Requirements, 2013
- ISO/IEC 27005, Information technology. Security techniques. Information security risk management, 2011
- ISO/IEC 27014, Information technology. Security techniques. Network security, 2013
- ISO/IEC 29147, Information technology. Security techniques. Vulnerability disclosure, 2014
- ISO/IEC 30111, Information technology. Security Techniques. Vulnerability handling processes, 2013
- BS IEC 62443-3, Industrial communication networks. Network and system security, 2013
- ISO/IEC 18045, Information technology. Security techniques. Methodology for IT security evaluation, 2008

5. Inspecting, Certifying, Conforming

- ISO/IEC 17000 Series of Standards
- ISO/IEC 17011, Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies, 2004
- ISO/IEC 17020, Conformity assessment. Requirements for the operation of various types of bodies performing inspection, 2012

- ISO/IEC 17021, Conformity Assessment. Requirements for bodies providing audit and certification of management systems, 2014
- ISO/IEC 17024, Conformity assessment. General requirements for bodies operating certification of persons, 2012
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, 2005
- ISO/IEC 17029, Conformity Assessment. Requirements for the operation of various types of bodies performing inspection, 2012
- ISO/IEC 17065, Conformity Assessment. Requirements for bodies certifying products, processes and services, 2012

This document lists key safety related regulations, standards and guides. The versions quoted were the most recent known at the publication date. This list is not to be considered as an exhaustive list. Therefore the use of this list assumes that it is the user's responsibility to define the relevant safety documents required by a project and to use the latest version or the version defined by a client, safety organisation or other approval body.

- Please send suggestions for improvements for consideration by the Independent Safety assurance Working Group to: isawg@theit.org