NSAI

CERTIFICATION GUIDE

NSAI Certification

As Ireland's national standards body, NSAI aims to inspire consumer confidence and create the infrastructure for products and services to be recognised and relied on, all over the world. NSAI treats all clients equally, no matter how big or small they are. The principles of impartiality, objectivity and confidentiality are cornerstones of NSAI's services.

NSAI host a biannual certificate presentation ceremony for newly certified organisations.

"It's not enough to do your best; you must know what to do & then do your best".

"Inspection with the aim of finding the bad ones and throwing them out is too late, ineffective, and costly. Quality comes not from inspection but from improvement of the process".

"A system is a network of interdependent components that work together to try to accomplish the aim of the system. A system must have an aim. Without the aim, there is no system".

"Eighty-five percent of the reasons for failure are deficiencies in the systems and process rather than the employee. The role of management is to change the process rather than badgering individuals to do better".

- the above quotes are attributed to Dr. W. Edwards Deming, considered by many to be the master of continual improvement of quality.

General management systems certification process:

- Application for registration which includes organisation specific quotation
- Optional gap assessment if unsure about whether to undergo assessment for registration
- Preliminary assessment – stage 1 involves inspection of documentation and general review
- Registration assessment – stage 2, a full review of your management system
- Certification decision and feedback
- Surveillance and reassessment to ensure maintenance of your management system including change management

Benefits of certification include:

- Bottom line improvements
- Customer satisfaction
- Employee engagement
- Global recognition
- Enhanced image of organisation

Table of Contents

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ISO 9001:2015
Quality Management

ISO 9001:2015 is the world's foremost quality management standard, used by hundreds of thousands of organisations in over 170 countries around the globe.

It sets out the essential requirements for a practical and effective quality management system (QMS) which is, in essence, a system for minimizing risk and maximizing opportunity. ISO 9001 is suitable for any organisation regardless of their size and industry. It can be used to focus on improving performance in a particular department, plant or site. However, it is most effective when implemented throughout an organisation at every level.

ISO 9001:2015 is part of a series of quality management system standards, sometimes referred to as ISO 9000. These comprise:

- ISO 9000:2015 – Fundamentals and Vocabulary, this standard describes the fundamental concepts and principles of quality management
- ISO 9001:2015 – Requirements, which specifies the criteria for certification
- ISO/TS 9002:2016 – Guidelines for the application of ISO 9001:2015
- ISO 9001:2015 for Small Enterprises - What to do? - This handbook was written by a group of experts from ISO/TC 176/SC 2, and features useful information on everything from how to get started right through to guidance for those who choose to seek certification.

ISO 9001 sets out 7 key principles:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

These key principles are not auditable but are fundamental attributes of any quality management system.

The key elements of ISO 9001:2015 are "PLAN - DO – CHECK - ACT". They consist of:

- Establishing the quality management system
- Using the quality management system
- Reviewing whether the results are satisfactory
- Improving the quality management system

It is most likely that an organisation already has an effective quality management system but it may be informal and not well documented. ISO 9001 provides a more systematic approach to achieving an organisation's objectives. It should not however result in excessive bureaucracy or paperwork or lack flexibility. Nor should it be a financial burden. Quality management systems should be considered an investment as the return on investment will be in terms of benefits and improvements throughout the whole organisation.

ISO 14001:2015
Environmental Management

With rising public awareness of the need to protect our environment, governments and businesses are under increasing pressure to minimize their environmental footprint and promote sustainable development. The ISO 14001 - Environmental Management Systems (EMS) - standard has been developed to help organisations identify, manage and control the activities that have an environmental impact.

Industrial companies, service organisations, utility and public bodies worldwide have embraced ISO 14001 as the preferred model for environmental management and improved performance. The standard is compatible with other management standards particularly the widely used ISO 9001 quality management standard.

ISO 14001 is flexible, as every organisation is different it sets out broad principles which can help organisations to:

- Establish good environmental performance as a strategic objective
- Sustain continual improvement of environmental performance
- Look at your products from 'cradle to grave'
- Reduce waste and pollution
- Analyse, plan, control and monitor all activities that may have an environmental impact
- Comply with legislative and regulatory requirements
- Demonstrate to regulators, stakeholders and other interested third parties that you have an efficient environmental management system

This can in return lead to:

- Strengthened stakeholder confidence
- Greater competitive advantage
- More secure long-term viability

ISO 14001:2015 Environmental management standard has the following companion standards:

- I.S. EN ISO 14004:2016: Environmental management systems - General guidelines on implementation
- I.S. EN ISO 14031:2013: Environmental management - Environmental performance evaluation - Guidelines
- I.S. EN ISO 14006:2011: Environmental management systems - Guidelines for incorporating ecodesign
- ISO 14001:2015 A practical guide for SMEs : It aims to help small businesses understand the requirements of an environmental management system and to help them implement ISO 14001 successfully.

The intention of ISO 14001:2015 is to provide a framework for a holistic, systematic and strategic approach to the organisation's environmental policy, plans and actions. An effective environmental management system based on ISO 14001 provides an organisation's top management with a road map. This roadmap then allows them manage environmental issues effectively by prevention and the identification of areas for cost savings in energy consumption, raw material usage and waste disposal.

ISO 45001:2018

Occupational Health & Safety Management

ISO 45001 was developed in response to customer demand for a recognisable occupational health and safety management system standard against which their OH&S management system can be assessed and verified.

ISO 45001 is compatible with ISO 9001:2015 (Quality) and ISO 14001:2015 (Environmental) management systems standards. This facilitates the integration of quality, environmental and occupational health and safety management systems by organisations should they wish to do so.

In a nutshell, ISO 45001 requires an organisation to:

- Determine OH&S hazards and assess the risks
- Establish control measures to manage risks identified
- Develop objectives to drive improvements
- Determine legal requirements and evaluate legal compliance
- Provide safety training and awareness
- Communicate safety measures and controls
- Maintain work related equipment
- Investigate incidents to prevent recurrence
- Develop and promote a positive safety culture within the organisation.

The advantages of an effective Occupational Health and Safety (OH&S) management system:

An ISO 45001 based OH&S management system will enable an organisation to improve its OH&S performance by :

- Implementing a structured approach for managing OH&S
- Developing and implementing an OH&S policy and OH&S objectives
- Establishing systematic processes which consider its “context” and which take into account its risks and opportunities, and its legal and other requirements
- Determining the hazards and OH&S risks associated with its activities; seeking to eliminate them, or putting in controls to minimise their potential effects
- Establishing operational controls to manage its OH&S risks and its legal and other requirements

Some of the key benefits realised as a result of the implementation of OH&S are:

- Reduced work related injury and ill-health
- Eliminate or reduce risk to tolerable risk level
- Motivate & empower staff through greater and better staff participation, consultation and communication
- Enhanced and improved engagement of top management
- A positive shift in culture and attitude
- Enhanced reputation

SSIP - Safety Systems in Procurement

NSAI certification to ISO 45001 & SSIP can allow your organisation to appear on the SSIP portal.
SSIP (Safety Schemes in Procurement) is a construction procurement regulator in the UK and N.I.
www.ssip.org.uk

ISO/IEC 27001:2017
Information Security Managment

ISO 27001 Information Technology - Security Techniques, provides requirements for establishing, implementing, maintaining and continually improving an information security management system (ISMS).

Benefits of implementing ISO/IEC 27001

1. Compliance
> reputational damage caused by ineffective security
> compliance with legislation and stakeholder needs and expectations
> enables secure exchange of information

2. Marketing
> win new business and retain existing clients
> increased credibility when tendering for contracts
> expand into global markets
> demonstrates best practice

3. Cost reduction
> reduce risk of suffering a data breach
> avoid fines
> implement proportionate security controls

4. Structure your business
> define responsibilities
> improved management processes and risk strategy

5. GDPR - EU General Data Protection Regulation (GDPR)
> Is your organisation compliant under the EU GDPR? ISO 27001 can be used to provide a basis for evidence of compliance with the I.T. security aspects the GDPR.
For more information on the GDPR see www.gdprandyou.ie

ISO/IEC 27001 Implementation Methodology

> Get top management support
> Construct business case and Project Plan
> Define scope of system
> Conduct risk assessment and plan risk treatment
> Agree effective monitoring methodology and applicable KPI's
> Train personnel
> Implement controls
> Operate and maintain ISMS
> Conduct audit of system and policies
> Management review
> Implement corrective actions and repeat as necessary

ISO 22301:2012
Business Continuity Management

Business Continuity Management (BCM) is a holistic management process that identifies potential threats to an organisation and the impacts to business operations that those threats, if realised, might cause. ISO 22301 provides a framework for building organisational resilience with the capability for an effective response that safeguards the interests of its key stakeholders, reputation, brand and value-creating activities.

Business Continuity Management provides processes (activities) and resources that ensure the continued achievement of the critical objectives of an organisation.

The primary objective of a BCM is to allow the executive of an organisation to continue to manage their business under adverse conditions by the introduction of appropriate resilience strategies, recovery objectives, business continuity and crisis management plans. This is achieved in collaboration with, or as a key component of, an integrated risk management initiative.

ISO 22301:2012 specifies requirements to plan, establish, implement, operate, monitor, review, maintain and continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise.

The goal of a BCM initiative is to provide answers to the following questions:

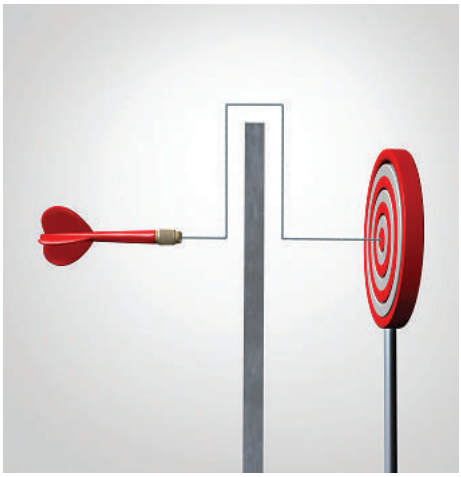
- How would the business continue to service its customers?
- How would the business continue to operate?
- How long can the business be sustained or survive during the disaster (if non-operational)?
- How to minimize the losses and impact?
- How to recover and resume?
- How to achieve cost-effective resumption following an interruption?
- How to effectively manage and respond during a crisis?

The requirements specified in ISO 22301:2012 are generic and intended to be applicable to all organisations, or parts thereof, regardless of type, size and nature of the organization. The extent of application of these requirements depends on the organisation's operating environment and complexity.

Demonstrate Agility & Resilience

How resilient is your organisation to the impact of rapid change and how agile is its leadership in responding to both planning for change and responding to it?

For an organisation to sustain its operations in rapidly changing times reliance on certification to comply with tender requirements and or customer expectations may no longer be enough.



For an organisation to weather the changes brought about by actions, often wholly outside their control, they must not only build an entity that complies with both customer and regulatory expectation such as environmental compliance, occupational health & safety and quality best practice but also over the horizon disruptive changes. These might include:

- the impact of Brexit
- new customer requirements, and/or products, and/or service requirements
- new tougher environmental requirements resulting from the Paris agreement on Climate change
- the General Data Protection Regulation (GDPR) requirement on customer data effective from May 2018.

There are other risks to business activity such as interdependence on a supplier or overreliance on a small customer base. Speed to market, turn-around times, back up and support are becoming ever more demanding.

Lean six sigma can help in reducing waste; waste of product, time, process steps, and storage of raw materials but can leave an organisation exposed if a vital supplier lets them down. A buffer that would normally see the organisation through may well have been eliminated in a 'lean' drive some time back.

ISO 22316:2017 defines organisational resilience as the *'ability of an organisation to absorb and adapt in a changing environment' while, agility can be defined as 'the capability of a company to rapidly change or adapt in response to changes in the market. A high degree of organisational agility can help a company to react successfully to the emergence of new competitors, the development of new industry-changing technologies, or sudden shifts in overall market conditions'.*

Demonstrate Agility & Resilience

A holistic integrated response to business pressures can offer the opportunity for an organisation to be both resilient and agile. The following checklist demonstrates how an organisation can employ a robust buffer to test how well equipped they are to meet any changes by using international best practice as a bench mark:

Review the Organisations direction	International best practice	Focus
Product or service quality - enhance customer satisfaction Keep customers Open new markets	Quality ISO 9001	The customer, the output, product or service. Risks and opportunities embedded in the organisational strategy. Business plans reviewed and updated regularly
Become part of the green economy Attract new customers Opens new markets Comply with regulations More sustainable, long term	Environment ISO 14001	Cleaner production Save on waste Reduce costs Projects an image of a caring organisation Enthuses staff and stakeholders in what the organisation does.
Leadership and People management Learning & Development Communication and engagement	Human Resource Management ETP 1000	It's all about the employee - an organisations biggest assest.
Reducing energy costs Move to renewable supplies of energy Cut CO_2 emissions Direct saving of costs	Energy ISO 50001	Monitor and measure target energy use per production unit Visualise energy consumption throughout the organisation Create energy reduction champions Switch to renewable sources, solar, wind, photovoltaics and biomass
How safe is the workplace and how healthy are the employees	Occupational Health & Safety ISO 45001	Staff Your organisation Others you interact with
How secure is the data you hold from accidental loss or hacking	I.T. Security ISO 27001	Comply with GDPR, data protection Provide against virus attack Phishing protection
Will your organisation survive sudden change from: Your market Regulations International challenges such as Brexit	Business Continuity ISO 22301	Business Continuity tests your preparedness for both planned and unexpected change.
Test how resilient your organisation is	Security and Resilience ISO 22316	Security and Resilience - Set out a framework to test your organisations sustainability

ISO 50001:2011
Energy Management System

World energy consumption is on the rise. It has more than doubled in the last 40 years and is projected to increase by up to 30 % by 2030. Energy production and use account for roughly two-thirds of the world's greenhouse gas (GHG) emissions, which are the predominant cause of climate change. Reducing our energy use is one of the surest ways of lowering GHG emissions, thus reducing our impact on the climate while sustaining the growth of the world economy and boosting energy security for all. The development and deployment of technologies and policies for new and renewable energy sources will help, but it can take time and changes need to be implemented now. Individual organisations have an important role to play in achieving future sustainability and this can be done by improving their energy management. [ISO publication - ISO 50001 Energy Managment Systems)*

** International Energy Agency (IEA), Energy and Climate Change: World Energy Outlook, Special report, 2015.*

ISO 50001:2011 Energy Management Standard is compatible with the widely used ISO 9001:2015 Quality Management Standard and ISO 14001:2015 Environmental Management Standard. It has international recognition and is considered the benchmark standard worldwide for Energy Management.

ISO 50001 Energy Management System requires organisations to:

- Develop a policy for more efficient use of energy
- Fix targets and objectives to meet the policy
- Use data to better understand and make decisions about energy use
- Measure the results
- Review how well the policy works
- Continually improve energy management

The benefits include:

- Reduced carbon emissions
- Improved compliance with energy legislation
- Identifying opportunities for improvement
- Ensuring a greater level of control
- Satisfy the expectations of stakeholders
- Reduced costs and improved business performance
- Demonstrating transparency and commitment
- Enhanced image

ISO 50001 is suitable for all businesses regardless of their size, geography or industry. It is particularly effective though if the business operates in an energy intensive industry or one that faces green house gas (GHG) emissions regulation or legislation. ISO 50001 formalises energy policies and objectives and embeds them into energy efficient thinking throughout the organisation.

ISO 22000:2005
Food Safety Management System

Many diverse organisations are involved in the chain of primary production, manufacturing, packaging, storage, distribution and preparation and sale of our food. The management of food safety and quality risk throughout these industries is of paramount importance with failure resulting in incidents ranging from loss of customer trust through to consumer morbidity and mortality. Individual businesses, industry sectors, governments and indeed economies have been ravaged by food scares. With customers and consumers becoming ever more aware of the importance of high quality, nutritious, safe food the demands continue to build.

The establishment of shared, common high-quality standards across the food industry, backed by sector specific pre-requisite requirements, is fundamental to ensuring cross-sectoral understanding and communication and delivering safe food. To support the food industry in achieving these goals ISO have developed ISO 22000 as a Food Safety Management Standard that is relevant to any business involved in the food chain.

The Standard complies with HACCP principles, is compatible with other ISO standards, and can help to:

> Plan, implement, operate, maintain and update your food safety management system
> Demonstrate compliance with applicable laws and regulations governing food safety
> Assess and meet customer expectations related to food safety
> Communicate food safety information to suppliers, customers and other relevant parties
> Demonstrate to all interested parties that you meet the terms of your stated food policy
> Gain food safety management system certification/registration to the key global benchmark

To complement the core management system standard and support intra- and cross-sectoral transparency and understanding, ISO has developed pre-requisite standards in the ISO 22002 series that define the key infrastructural and operational hygiene requirements within each sector.

The combination of ISO 22000 with sectoral pre-requisite standards defines a food safety management system that is based on the most advanced technological, managerial and scientific expertise that aims to create a level playing field across regional, continental and global markets by replacing divergent local standards with harmonised food safety management systems, benchmarked against best practices.

FSSC 22000
GFSI Food Safety Management

The food industry is continuously met with rapidly evolving and ever more challenging food safety, security, ethical, nutritional, legislative, customer and consumer requirements. To assist in meeting these challenges, food safety system standards must themselves be capable of rapidly assessing industrial needs, achieving consensus and supporting implementation, harnessing the expertise of food professionals and representative bodies from across the world. This multi-disciplinary approach is now seen as the cornerstone of food safety management systems and has led to the development of FSSC 22000.

FSSC 22000

FSSC 22000 (www.fssc22000.com) is an ISO 22000 based food safety management system that leverages the best practices of ISO 22000, sector specific pre-requisites programs and current industrial themes defined within specific additional FSSC 22000 requirements. This multi-component approach ensures the rapid inclusion of real, current food safety challenges within a robust, structured food safety management system and has resulted in the standard achieving GFSI benchmarking, and wide acceptance of FSSC 22000 across the industry.

Key components of FSSC 22000

Globally accepted ISO 22000
- > Risk based approach
- > HACCP based
- > Communication
- > Continuous improvement

Clearly defined sector specific PRPs
- > Structural hygiene
- > Operational hygiene
- > Personnel requirement

Additional FSSC requirements
- > Auditor competency
- > Food defence and Food fraud
- > Allergen control
- > Environmental monitoring

A key to the success of FSSC has been encouragement of the development of technical standards that specify relevant pre-requisite programmes for each sector. The ISO/TS 22002 series e.g. ISO/TS 22002-1 for food manufacturing, ISO/TS 22002-4 for food packaging and national standards e.g. NEN/NTA 8059 (Transport & Storage) remove historical uncertainty through provision of definitive requirements for their specific sectors.

These standards, when coupled with ISO 22000, the additional FSSC requirements and oversight, have resulted in GFSI recognition for FSSC 22000 and its rapid proliferation and implementation in leading Irish and global food businesses.

ISO 55001:2014
Asset Management

A new international suite of standards has been created to give guidance in asset management best practice. ISO 55001 focuses on helping you develop a proactive lifecycle asset management system. This supports optimisation of assets and reduces the overall cost of ownership while helping you to meet the necessary performance and safety requirements.

ISO 55001 'Asset management - management systems - requirements', accompanied by ISO 55000 'Overview, principles and terminology' and ISO 55002 'Guidelines for the application of ISO 55001' will support businesses in achieving the best possible net return from assets while reducing the cost of ownership.

ISO 55001 is a framework for an asset management system that will help your business to pro-actively manage the lifecycle of your assets, from acquisition to decommission. An asset management system provides a structured, best practice approach to managing the lifecycle of assets. This system helps you to manage the risks and costs associated with owning assets, in a structured, efficient manner that supports continual improvement and on-going value creation.

The benefits of ISO 55001

- Reduced risks associated with ownership of assets – anything from unnecessary maintenance costs and inefficiency to accident prevention (explosions at gas plants for example)
- Improved quality assurance for customers/regulators – where assets play a key role in the provision and quality of products and services
- New business acquisition - stakeholders gain confidence from the knowledge that a strategy is in place to ensure assets meet the necessary safety and performance requirements
- Supports international business growth – demonstrating that the requirements of an internationally recognised asset management system are being met
- Alignment of processes, resources and functional contributions (instead of departmental silos and competing short-term priorities)
- Creating a transparent audit trail for what is done, when and why
- Better understanding and usage of data and information to provide informed and consistent decisions
- Improved planning (especially capital expenditure)
- Consistent, prioritised and auditable risk management
- Alignment and coordination of existing initiatives, including competency development
- Greater engagement of the workforce, including leadership, communications and cross-disciplinary teamwork

This standard is primarily intended for use by:

- Those involved in the establishment, implementation, maintenance and improvement of an asset management system such as: utilities, transport, mining, process and manufacturing industries worldwide. Those involved in delivering asset management activities and service providers.
- Internal and external parties to assess the organisation's ability to meet legal, regulatory and contractual requirements and the organisation's own requirements.
- Is intended to be used for managing physical assets in particular, but it can also be applied to all other types of asset and by all types and sizes of organisations. The standard does not specify financial, accounting or technical requirements for managing specific asset types.

High Level Structure - HLS

ISO has completed work to provide identical structure, text and common terms and definitions for management system standards of the future. This will ensure consistency among future and revised management system standards and make integrated use simpler. It will also make the standards easier to read and, in so doing, understood by users.

Why?

ISO has over the years published many management system standards for topics ranging from quality and environment to information security, business continuity management and records management. Despite sharing common elements, ISO management system standards come in many different shapes and structures. This, in turn, results in some confusion and difficulties at the implementation stage.

From theory to practice

All technical committees developing management system standards have to follow the HLS in the new consolidated ISO Supplement. The HLS harmonises structure, text and terms and definitions, while leaving the standards developers with the flexibility to integrate their specific technical topics and requirements.

Example of the HLS

Clause 1 - Scope
Clause 2 - Normative references
Clause 3 - Terms and definitions
Clause 4 - Context of the organization
Clause 5 - Leadership
Clause 6 - Planning
Clause 7 - Support
Clause 8 - Operation
Clause 9 - Performance evaluation
Clause 10 - Improvement

Examples of identical definitions:

Organisation, interested party, policy, objective, competence, conformity.

New requirements

There are subtle language issues such as the change from document and records to documented information, to the use of IT and other tools to illustrate what is being done. The new text recognises the use of the broad concept of risk and the need to understand risk in the context of the management system. It also encourages everyone to view preventive action as a broader concept than simply preventing an incident from re-occurring.

Currently more than 38 management systems standards comply to the HLS - these include ISO 9001, ISO 14001, ISO 45001, ISO 27001, ISO 22301, ISO 50001 and ISO 55001. ISO 22000 is also joining the HLS.

ISO 13485
Medical Devices Management System

ISO 13485 is an internationally recognized standard that sets out requirements for a comprehensive management system for the design, development, manufacture, installation and servicing of medical devices. It is often seen as the first step towards achieving compliance with European, Canadian and other regulatory requirements for medical device manufacturers. ISO 13485 is essential for any organisation operating at any tier in the medical device supply chain.

ISO 13485 key differences:

Although ISO 13485 is based on ISO 9001, a manufacturer that is compliant with ISO 9001 cannot also claim compliance with ISO 13485 due to the significant differences between those two standards. ISO 13485 was written to meet the regulatory requirements of the medical devices industry and places additional emphasis on documented procedures and processes, along with evidence of compliance to product design specifications and statutory requirements.

ISO 13485 adds specific requirements relating to:

> Design control and risk management
> Product technical documentation
> Environmental control
> Traceability and inspection
> Documentation and validation of processes
> Special processes and their control
> Awareness of regulatory requirements and relevant actions
> Record keeping

Companies that produce products with both medical and non-medical applications can be certified to both ISO 13485 and ISO 9001.

The benefits of ISO 13485 include:

> Increased probability of making safe and effective medical devices
> Legal compliance, meeting regulatory requirements
> Improved risk management and quality assurance
> Improved ability to respond to customer requirements
> Increased efficiency and cost savings
> Improved ability to win more business through proven business credentials
> Help to maintain the quality of supply chain

MDSAP - Medical Device Single Audit Program

NSAI is an authorised AO (Auditing Organisation) to conduct single audit of a medical device manufacturer that will be accepted by all five regulatory authorities participating in the program:

- Therapeutic Goods Administration of Australia (TGA)
- Brazilian Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada
- United States Food and Drug Administration (US FDA)
- Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)

CMDCAS

NSAI is a fully accredited CMDCAS registrar allowing you gain entry to the Canadian market. However please note the CMDCAS system will be superceded by MDSAP from 31st December 2018.

Accreditation

NSAI has a subsidiary office in the USA (NSAI Inc.) and is accredited by ANAB (ANSI-ASQ National Accreditation Board) and SCC (Standards Council Canada).

Contact: **medical.devices@nsai.ie**

Medical Device Approval

NSAI is a leading Notified Body and world renowned certification provider - and has the experience, resources and accreditations to help accelerate the successful entry of medical devices into the market place.

NSAI will perform your device certifications in a timely, professional and courteous manner.

> One to one customer relationship where quality, regulatory and clinical guidance facilitate fast project management timelines.
> Pre-submission meetings provide regulatory and clinical discussions in preparation for CE mark technical file and dossier
> Fast-Track options available for expedited CE mark scheduling to support business needs
> NSAIs submission scheduling process ensures you always know exactly when your product review begins

CE Marking of Medical Devices

NSAI is Notified by the HPRA as an EU Notified Body for the following European Medical Directives:

Medical Devices Directive - 93/42/EEC (MDD)

- Annex II, V and VI

Active Implantable Medical Device Directive - 90/385/EEC (AIMDD)

- Annex II and V

In-Vitro Diagnostic Directive - 98/79/EEC (IVDD)

- List B: all products
- Self-test products

TSE Regulation - 722/2012

Human Blood Directive - 2000/70/EC

Contact: **medical.devices@nsai.ie**

ETP 1000:2017
Excellence Through People

Excellence Through People is offered in cooperation with CIPD, The professional body for human resource and people development, and IITD - The Irish Institute of Training & Development.

Success as a business owner or manager largely depends on the ability to improve business performance through people. Excellence Through People (ETP) provides a business improvement model for organisations to enhance performance and realise strategies through the management and development of their people.

The focus of ETP is to get organisations to look at their people as a key source of competitive advantage.

The model helps you achieve business improvement by:

> Putting the right human resource systems in place to maximise employee contribution
> Aligning people practises with the goals of your organisation
> Maximising the investment in human resource management

The scheme is used by many of Ireland's most successful organisations in becoming more efficient, productive, flexible, competitive and innovative.

Benefits for your organisation include:

> Bottom-line improvements
> Customer satisfaction
> Employee engagement
> Workforce organisation
> Quality improvement
> Succession planning
> Innovation

The process for business improvement takes you through five core sections and shows you the criteria required to attain Excellence Through People certification:

1. Business planning and continuous improvement

   The organisation plans where it is going and continuously improves its approach to quality.

2. Effective communication and people engagement

   The organisation communicates with and encourages its people in an effective manner.

3. Leadership and people management

   The organisation leads and manages its people and their performance to predetermined objectives in a competent and effective manner.

4. Learning and development

   The organisation plans and evaluates the development of its people in support of the achievement of its business goals.

5. HR systems and employee wellbeing

   The organisation provides for the health, safety and wellbeing of all its people in a fair and nondiscriminatory manner.

Product Certification

Before a product can be certified, it must first undergo a process of inspection and testing to ensure it meets:

> Minimum quality assurance standards
> Any relevant legal requirements

Certification procedure

The stringency of the inspection and testing procedure varies depending on the nature of the product and its intended use. Components used in aerospace, for example, must undergo rigorous safety testing before being certified fit for purpose.

In the Republic of Ireland, NSAI is the main body responsible for product certification where a certifiable standard exists.

Our product certification services can be divided into two broad categories:

> CE Marking, which is now a legal requirement for many products sold in the European Union. NSAI has been appointed Notified Body in respect of the following EU Directives only:

- Construction products regulation
- Non-automatic weighing instruments
- Medical devices
- Active implantable medical devices
- In vitro diagnostic medical devices

> Irish Standard Mark (ISM), a system of quality control supervised by NSAI. This allows NSAI to grant an ISM licence to organisations where applicable under a certifiable Irish Standard (I.S.).

In addition to our general certification services, NSAI operates individual certification schemes for specific product and service groups. These include:

> Security Systems – based on I.S. EN 50131-1, which covers alarm and intrusion systems and I.S. EN 50132 which covers CCTV systems
> Electrical Products – with plugs, sockets and leads in Ireland different from the rest of Europe, NSAI has developed additional standards for electrical products
> Timber Certification – NSAI supports the timber industry through a range of timber certification and inspection schemes
> Ready Mix Concrete – based on I.S. EN 206-1, which obliges producers to conform to a range of requirements designed to improve quality and consistency.
> SQAS Transporting Dangerous Chemicals – NSAI provides an inspection service developed by the European Chemical Industry Council (Cefic)

Motor Vehicle Type Approval - NSAI is the Irish Approval Authority as defined in:

> 2007/46/EC - Motor vehicles and their trailers
> (EU) No 168/2013 - Two or three wheel vehicles and quadricycles
> (EU) No 167/2013 - Agricultural and forestry vehicles

These directives/regulations provide the safety and environmental requirements for vehicles on the road in Ireland and Europe.

Other Certification

Ecolabel certification

The European Ecolabel is a voluntary scheme, established in 1992 to encourage businesses to market products and services that are kinder to the environment. Products and services awarded the Ecolabel carry the flower logo, allowing consumers - including public and private purchasers - to identify them easily.

The voluntary nature of the scheme means that it does not create barriers to trade. On the contrary - many producers find that it gives them a competitive advantage.

The EU Ecolabel is a rapidly growing brand. Many producers wanting to sell their products across Europe have realised the benefits that the European Ecolabel brings. Products bearing the Flower logo can be marketed throughout the European Union and the EEA countries (Norway, Iceland and Liechtenstein).

Today the EU Ecolabel covers a wide range of products and services, with further groups being continuously added. Product groups include cleaning products, personal care products, paper products, household appliances & items, electronic products, home and garden products, lubricants and services such as tourist accommodation.

W: ecolabel.eu

PEFC Forest Management and Chain of Custody

NSAI are offering certification to PEFC so that organisations who use wood products from sustainable sources can declare this to their customers and the public. This certification ensures confidence that, in the many process stages between forest and consumer ("tree to me"), sustainable products can be identified and managed. Copies of the standards and further information can be found on the PEFC website.

W: PEFC.ie / PEFC.org

(For PEFC Forest Management it is important that you download the standard from the PEFC.ie website as there are national differences)

Business Working Responsibly Mark

The Business Working Responsibly mark is Irelands only certified standard for CSR (Corporate Social Responsibility) and is offered by BiTC (Business in the Community) and audited by NSAI.

The Business Working Responsibly Mark's framework is based on the pillars of CSR: Community, Workplace, Marketplace, Communications and Environment. It underpins every service we offer so we can provide you with a pathway towards achieving this standard.

For further information on BiTC and the Business Working Responsibly Mark please contact BiTC direct at W: bitc.ie or T: 01 874 7232.

IQNet

IQNet - The International Certification Network

NSAI is a member of IQNet which gives your NSAI certification worldwide recognition.

IQNet is an international network of partner Certification Bodies with a Head Office in Bern, Switzerland.

Active since 1990, IQNet has almost 40 partner certification bodies with more than 200 subsidiaries worldwide. Each of these IQNet partners is a leader in their region; and collectively through IQNet, this represents the most extensive and reputable network of Certification Bodies worldwide.

IQNet members mutually recognise ISO9001, ISO14001, ISO 50001, OHSAS 18001, ISO 22000 & FSSC 22000, ISO 27001, ISO 22301 and various other certifications of all IQNet partners as being equivalent to their own. An IQNet certificate is provided to all certifed customers of these standards by their member Certification Body. Confidence in certificate equivalence is founded on regular and rigorous peer evaluations across the Network.

IQNet supports the work of international organisations by its membership and involvement in:

- IAF Internation Accreditation Forum (www.iaf.nu)
- EA European cooperation for Accreditation (www.european-accreditation.org)
- ISO/CASCO Conformity Assessment (www.iso.org/casco)
- ISO/TC 176 - ISO 9001 (www.iso.org/iso/home/standards_development.htm)
- ISO/TC 207 - ISO 14001 (www.iso.org/iso/home/standards_development.htm)
- The Consumer Goods Forum (www.theconsumergoodsforum.com)
- GFSI Global Food Safety Initiative (www.mygfsi.com)

IQNet's Mission

IQNet Partners

- To have strongly commited IQNet partners who can demonstrate their recognition and reputation of excellence in the marketplace
- To provide tools and services to partners to advance competence and competitiveness

Market / Products

- Through its Network, offering innovative assessment and certification services, help clients to improve enterprise quality aimed at sustainable success
- Be, through its Network, the leading local and global service provider in the field of non-financial assessments

Certification community

- Actively contribute to the development of effective, efficient and user-friendly conformity assessment processes ensuring credible output.

For more information on IQNet and a full list of services provided please visit: www.IQNet-Certification.com

NOTES

Additional Links:

The Irish National Accreditation Board
www.inab.ie

ISO website
www.iso.org

Request for Quotation

Name of Organisation			
Address			
Contact Name		**Function:**	
Telephone number		**e-mail:**	
Direct dial number		**Web address:**	

STANDARD / SCHEME *(please indicate):*

ISO 9001 - Quality ☐	ISO 14001 - Environment ☐	ISO 45001 - Health & Safety ☐			
ISO 50001 - Energy ☐	ISO 27001 - IT Security ☐	ISO 45001 & SSIP ☐			
ISO 22000 - Food Safety ☐	ISO 55001 - Asset Management ☐	ISO 15489 - Records Management ☐			
ISO 22000 & FSSC ☐	ISO 22301 - Business Continuity ☐	EN 15838 - Customer Contact Centres ☐			
Excellence Through People (ETP) ☐	CE Marking under CPR[1] ☐	I.S. EN 1090 - Structural Steel ☐			
I.S. EN 50131 - Intruder Alarms ☐	I.S. 228 - Monitoring Schemes ☐	S.R. 40 ☐	S.R. 41 ☐		
I.S. EN 50132 - CCTV ☐	I.S. EN 50133 - Access Control ☐	I.S. 998 - C.I.T. ☐			
PEFC Chain of Custody (CoC) ☐	PEFC Forrest Management (FM) ☐	Other (please state #):			

Please contact medical.devices@nsai.ie for request for quotation forms for the following:

- ISO 13485 Medical Devices
- MDSAP
- 93/42/EEC Medical devices
- 90/385/EEC Active implantable medical devices
- 98/79/EC In vitro diagnostic medical devices

INFORMATION FOR QUOTATION PURPOSES all fields must be addressed

Transfer from other accredited Certification Body	Yes ☐	No ☐	If yes please attach copy of current certificate of registration	
Integrated Management System	Yes ☐	No ☐	Level of integration *(please specify %)*:	
Nature of Business / Scope of Certification				
If you outsource any process(s) please specify				
Company products / services **excluded** from application if any				
Number of people involved in the above business (include sub-contractors):				
Breakdown of Employees by Department/Function (an organisation chart or additional page may be added)				
Number in Design / Development / Research		Number deployed in field / site activities:		
Shift times (if applicable)		Relevant Regulatory / Statutory Requirements		
Location(s) for Assessment: ***If more than one location a list of all locations with staff numbers at each is essential*** – an additional page may be added)				
Name of Consultant (if any)				
Additional information:		Date request submitted to NSAI:		

Completed forms may be posted to Certification, NSAI, 1 Swift Square, Northwood, Santry, Dublin 9 or Email to: certification@nsai.ie

OFFICE USE ONLY	IAF:	EMS/EnMS/OHSAS Complexity:

[1] ***Applications must be accompanied with a list all relevant hEN and AoC***

NSAI
Certification
1 Swift Square, Northwood
Santry, Dublin 9

T: 01 807 3800
E: certification@nsai.ie

W: nsai.ie

NSAI Standard Sales

T: 01 857 6730
E: info@standards.ie

W: standards.ie