



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

## General Conditions for the Certification of Management System

The National Standards Authority of Ireland, inc. (hereinafter referred to as NSAI) provides Management System Certification Services to client organizations in accordance with all relevant accreditation requirements. This document provides an overview of the certification process and details the Clients responsibilities to achieve and maintain certification.

### 1.0 PROJECT INITIATION

To initiate the Management System Certification process, the client organization must return a completed application and a signed copy of the quotation signifying agreement with the provided pricing and the following documents:

- General Requirements for the Certification of Management Systems.
- Terms and Conditions of NSAI.
- Condition for Use of NSAI Registration Marks

### 2.0 CERTIFICATION PROCESS OVERVIEW

#### Preliminary Assessment (Optional)

This is an optional value add activity involving an on-site assessment of the management system against the requirements of the standard. It is focused on identifying gaps in the system and depending on needs of the company the scope may be limited to specific areas of concern or encompass the entire system. A report is issued indicating the degree of compliance/non-compliance. Pre-assessment activities may be combined with on-site Stage 1 Audit activities.

#### Stage 1 Audit

This phase involves reviewing the clients understanding regarding the requirements of the standard and readiness to continue with the Management System Certification process. It is recommended that at least part of this visit be conducted at the client location and includes a review of the following:

- Management System Documentation
- Client location and site specific conditions.
- The scope of the management system and the associated processes.
- Status of the Internal Audit and Management Review activities.

The results of the Stage 1 Audit will be documented in an Audit Report and will include any areas of concern that could be classified as nonconformity during the Stage 2 Audit.



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

## Stage 2 Audit

This is the comprehensive, on-site assessment to evaluate the implementation, including effectiveness, of the client's management system against the requirements of the standard. Prior to the beginning of the Stage 2 Audit, the client will receive an audit plan detailing the activities that will be occurring during the audit. The audit team will analyze all information and audit evidence gathered during the Stage 1 and Stage 2 Audits and will determine the audit recommendation and communicate it to the client at the closing meeting. In the case of a positive audit conclusion, the information provided by the audit team will be reviewed by the relevant Operations Manager and, if satisfactory, certification will be granted. Any non-conformances detected are handled as outlined below.

## Re-audit

If the Stage 2 Audit resulted in significant findings, the audit team may recommend that an on-site re-audit be conducted to verify effective implementation of corrective actions prior to issuing the registration.

In the case of a re-audit, the client has up to six months from the Stage 2 Audit date to implement the necessary corrective action and have the re-audit conducted. If the re-audit does not occur within the 6 months, a new Stage 2 Audit may be required.

## Surveillance Audits

This is the ongoing assessment of the Management System including on-site audits carried out at defined intervals. The interval is dependent on the company size, complexity, degree of compliance and system maturity. The total number of surveillance days per annum is fixed regardless of the interval. After achieving certification, the first surveillance is conducted within 6 months of the certification decision.

## Special Audits

If the client decides to expand or reduce their scope of certification with respect to activities or faculties, a Special Audit may be scheduled to evaluate the changes and the continued effectiveness of the Management System. Special Audits may also be conducted in conjunction with normal surveillance activities.

## 3-Year Re-assessment

At 3-year intervals, a recertification audit will be conducted to evaluate the continued fulfillment of all of the requirements of the relevant management system standard. Consideration will also be given to the performance of the management system over time and will include a review of previous surveillance audit reports. In the case of a positive audit recommendation, the information



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

provided by the audit team will be reviewed by the relevant Operations Manager and, if satisfactory, continued certification will be granted.

### Short Notice Audits

It may be necessary for NSAI to conduct audits of certified clients at short notice to investigate complaints, review significant changes or to follow up with suspended clients. Under such conditions, NSAI will make every effort to accommodate the clients scheduling and operational circumstances.

### Non-Conformances

A nonconformity is the absence of, or the failure to implement and maintain, one or more required management system elements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the capability of the management system to achieve the policies and objectives of the organization.

All nonconformities must be verified as being effectively corrected within the time agreed. The time allowed to implement corrective action will be consistent with the severity of the nonconformity. At a registration assessment or reassessment, a Category 1 Audit Finding will not allow a positive recommendation to be made until effective closure is confirmed. The client must analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken to eliminate detected nonconformities.

### Suspension Of Certification

If the registration is placed on suspension, the client's management system certificate is temporarily invalid. The client must refrain from further promotion of its certification until such time as the registration is re-instated.

Certification may be suspended under the following conditions:

- the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
- any other reasons which result specifically from failure to meet conditions agreed to formally between NSAI and the client.
- the client does not provide the necessary arrangements outlined in Section 3.

### Withdrawal of Certification

If the registration is withdrawn, the client must discontinue its use of all advertising matter that contains any reference to a certified status.

Certification may be withdrawn under the following conditions:



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

- failure to resolve issues that have resulted in the suspension of certification in the time established by NSAI
- the certificate or registration is improperly used
- the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
- any other reasons which result specifically from failure meet conditions agreed to formally between NSAI and the client.
- the certificate holder ceases to supply a product, process or service for an extended period of time;
- the certificate holder requests the cancellation.

### Reduction in the Scope of Certification

NSAI will reduce the client's scope if the certificate holder ceases to supply a product, process or service for an extended period of time or when the client has persistently or seriously failed to meet the certification requirements for those parts of the scope.

## **3.0 CLIENT RESPONSIBILITIES**

### Management System Documentation

The client's current management system documents including :

- Quality Manual.
- Relevant Procedures and Work Instructions.
- Internal Audit and Management Review Schedule.
- Copy of last 3 Audit Reports and Current Certificate (Transfer Only)

are reviewed by an audit team member as a part of the Stage 1 Audit. If conducted off-site, the client shall submit these documents for review 6 weeks prior to the Stage 2 Audit date.

### Management Review and Internal Audits

Prior to the Stage 2 Audit, the client must conduct one complete internal audit of the management system. All elements of the applicable standard are to be audited and the results presented to management for discussion during their management review.



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

## Management Representative

The client will identify an audit representative who will act as the main point of contact for all certification related activities.

## Audit Team Selection

At a time prior to the audit the client will be informed about the audit team member(s). It will be ensured that the auditors were not involved in consulting activities for the client in the two years preceding the planned audit (five years for Medical Device Clients). The client has the right to reject, with reason, any audit team members. If rejected, alternate auditors will be offered. If specific technical issues must be addressed in order to assess the management system, an appropriate technical expert will be included on the audit team.

## Necessary Arrangements

The client will make all necessary arrangements for the conduct of audits including provisions for examining documentation and access to all process areas, records and personnel for the purpose of initial certification, surveillance, recertification and resolution of complaints. In addition, the client will make provisions and accommodate the presence of observers from associated accreditation bodies and trainee auditors. In the case of a transfer of registration from another CB, the client authorizes NSAI to contact them as required.

## Notice Of Changes

The client must inform NSAI, without delay, of matters that may affect the capability of the management system to continue to fulfill the requirements of the standard used for certification. These include changes relating to:

- legal, commercial, organizational status or ownership.
- organization and management
- contact address and sites
- scope of operations under the certified management system
- major changes to the management system and processes
- significant increases or decreases in the number of employees

## Use Of Certification and Accreditation Marks

The client may use the NSAI certification marks and the accreditation marks for advertising and marketing purposes. The requirements for use these marks are specified in "Conditions for use of the NSAI Registered Marks" - MK-00-01. The requirements and/or conditions for the use of any Accreditation Mark shall refer to the latest requirements published by the respective Accreditation Body. NSAI shall be contacted if there is any further question regarding the use of Marks / Logos.

## **4.0 NSAI RESPONSIBILITIES**



# NSAI

National Standards Authority of Ireland  
Údarás Um Chaighdeán Náisiúnta na hÉireann

## Confidentiality

NSAI will treat in confidence all the client's data that is made available and will use it only for the agreed purpose. Documents made available will not be provided to third parties. Exceptions to this are:

- the submission of detailed reports to the Certification Oversight Committee in the case of concerns raised regarding impartiality.
- access to client's file by the Competent Authorities and Accreditation Bodies shown on the certificate(s) issued to the client.
- the client provides NSAI, Inc. with written authorization to release certain information.
- a legal or accreditation requirement to release this information.

## Complaints and Appeals

It is the policy of NSAI to handle and resolve all complaints and appeals in a timely and effective manner.

Complaints and Appeals are asked to be submitted through [feedback@nsai.ie](mailto:feedback@nsai.ie). The submittal will be assigned to the appropriate NSAI staff member for review and appropriate correction and corrective action. If the appeal was unsuccessful the Operations Manager shall inform the appellant that they are also free to raise the appeal process further by writing directly to one or more of NSAI's Accreditation Bodies and/or related Regulatory Bodies.

If the complainant is not satisfied with the results of the investigation and NSAI's resolution, the complainant may escalate to higher levels of NSAI management or NSAI's Accreditation Bodies and/or related Regulatory Bodies.

## Changes In The Certification Process

NSAI will inform its clients of changes to the certification process including transition plans and time frames for the implementation of such changes.

## List of Registered, Suspended and Withdrawn Companies

NSAI is required to maintain a list of registered, suspended and withdrawn clients stating the name, location and scope of registration and will make this available to the public upon request.