Irish Engineering Services Certification Services

Certification of QA Systems and Products (ISO 17065 & ISO 17021)

OVERVIEW

Irish Engineering Services Limited are accredited by INAB to offer numerous certification services under ISO/IEC 17065 and 17021:

- PE(S)R / PED: Modules A2, B, C2, D, D1, E1, F, G and H1 (CE)
- PE(S)R / PED: Module H (CE)

Details of the QA and Product Certification Processes are given below.

QA Only Certification Process

Following the successful review of the application from the client the initial certification assessment of **a management system** is decided into two stages - Stage 1 and Stage 2 .

Stage 1 visits

In a Stage 1 visit the following elements are assessed:

- the design and definition of the management system to confirm conformity with certification requirements including the assessment standard and certification scope
- the self governance undertaken including internal audits and management review
- confirmation of the contractual arrangements, including definition of approval scope, and identifying the planning, logistics, sampling etc. that will be used during the Stage 2 visit.

Normally our assessment team perform the Stage 1 visit of a client's management system on-site. Please note that performing the Stage 1 visit off-site creates additional risk for the Stage 2 visit.

Note: For most management systems, it is recommended that at least part of the Stage 1 is carried out at your premises to achieve the objectives.

Stage 2 visit

Parts of the management system that were assessed during the Stage 1 visit and were determined to be fully implemented, effective, and in conformity with requirements, may not need to be re-assessed during the Stage 2 visit. However, our assessor must confirm that those parts of the management system already assessed continue to conform to certification requirements. If so, our assessor will include a statement to this effect in the Stage 2 visit report. Our assessor will state that conformity was established during the Stage 1 visit. Stage 2 visits must have a visit plan. The plan follows the requirements in ISO/IEC 17021 and takes into account the information obtained during the Stage 1 visit.

The Stage 2 visit:

- takes place at the site(s) of your organization
- evaluates the implementation and effectiveness of your management system.

Our assessment team:

- conducts the Stage 2 visit to gather objective evidence that your management system conforms to the assessment standard and other certification requirements

- assesses a sufficient number of examples of your activities in relation to the management system to get a sound appraisal of the implementation, including effectiveness, of the management system
- addresses a sufficient number of your staff, include g senior management and operational personnel, of the assessed facility, to provide assurance of the implementation and understanding of the system throughout your organization
- analyses all information and objective evidence gathered during the Stage 1 and Stage 2 visits to determine the extent of fulfilment with all certification requirements and decide on any nonconformity • may propose opportunities for improvement but shall not recommend specific solutions.

The Stage 2 visit includes an examination of your management system including at least the following:

a) information and evidence about conformity to all requirements of the applicable normative document
b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets
c) your management system and performance as regards legal compliance
d) operational control
e) internal auditing and management review
f) management responsibility for your policies
g) links between the normative requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, personnel competence, operations, procedures, performance data, and internal audit results.

Granting Certification

On completion of the agreed corrective actions and verification by the Audit Team Leader the completed audit report and closed out findings sheets are forwarded to the Scheme Leader along with a recommendation whether or not to issue the certification and whether any conditions, restrictions or limitations should apply.

Registration

The Scheme Leader grants the registration Certificate on behalf of Irish Engineering Services Limited Management based on an evaluation of the audit reports and conclusions and the recommendations of the Audit Team Leader.

- The certification document issued to the client shall identify the following:
- Name of the client and location assessed
- Date of granting, extending or renewing certification
- Expiry date of the certificate
- Date of granting initial certification
- Unique number of the certificate
- The EU Directive and module used for assessment
- The scope of the certification with respect to product, process etc.
- The name and address of Irish Engineering Certification Services
- Any other pertinent information required by the standard or directive

Maintenance of Certification and Surveillance

During the first and second year of certification the client will be subject to surveillance activities. Surveillance shall be an on site audits conducted to assess the continued implementation of the quality management system.

Surveillance audits shall be at approximately twelve month intervals with the first audit being no later than twelve months from the end of the Assessment audit. Surveillance audits need not cover the full quality system at each visit.

The objective of surveillance is to:
• verify that your approved management system:
• meet the needs and expectations of the users of the certification
• delivers continual improvement
• consider the implications of changes initiated because of any change in your system, activities, processes and / or products
• confirm continued conformity with certification requirements.

Certificate renewal

Planning for the certificate renewal

We conduct certificate renewals on a three-yearly basis, planned at the previous surveillance visit and agreed with you.

Conducting certificate renewal visits

We conduct the Certificate renewal visit similarly to a Stage 2 assessment. In addition, we include a review of your system documentation to ensure that it:
• continues to suit your company, and
• complies with the certification requirements and the scope of certification, including continual improvement.

Changes to your approval

For any increase or decrease (e.g Expanding or reducing the scope of Certification) in your certificate of approval, please submit a formal request for the change. Irish Engineering Services Certification Services will review the request to consider:
• additions or changes to competency requirements for the visit team(s)
• additions or reductions in visit duration requirements

You will be notified of any changes by an amended contract. We will undertake a separate document review visit (Stage 1) if the change requested has meant a major change or addition to your documented system.

The change to approval visit will be performed in line with our process for Stage 2 assessment visits, although a formal visit plan is not normally produced. If no document review (Stage 1) has been undertaken, time will be allowed during the visit for the team leader to review relevant documentation and to agree a plan for any additional visit activities.

Such visits may be carried out as separate visits or may be combined with a scheduled (Surveillance or Certificate Renewal) visit.

Irish Engineering Services Certification Services will issue an amended certificate(s), using the same expiry date as on the current certificate.

Expanding the Scope of Certification

In the case of a request for expanding the scope of Certification of the Applicant, a formal request shall be made by the Applicant using the relevant part of the Application form which is available from Irish Engineering Services.

Sampling

It is important to remember that even though a problem may not have been identified in an area of activity, it does not necessarily mean that there are no problems. As assessment work is based on sampling techniques, statistically there is always a possibility that issues will not be identified during an assessment. You should always remember this when you audit your own management system.

Confidentiality
We will not pass on any of the information we gather about your organisation (including the contents of reports) to any other person or organisation without your permission (except as required by the accreditation body).

Suspension and withdrawal of approval

Introduction
This document outlines the process and implications when there is a failure to maintain your management system, or when you request your approval to be suspended or withdrawn. The Irish Engineering Services Certification Services Agreement and associated schedules define the conditions for maintaining your management system approval. Failure to meet these conditions may result in suspension and / or withdrawal of your certificate of approval and termination of the Irish Engineering Services Certification Services Agreement.

Suspension of approval
Suspension of your approval may be:

- at your request
- due to a failure to maintain your approved management system, or
- due to Irish Engineering Services Certification Services being denied the opportunity to verify the continued implementation and conformity of the approved management system.

Implications of suspension
When your approval is suspended you:

- may no longer claim to be approved by Irish Engineering Services Certification Services
- may no longer accept orders in which your approval is a condition of contract
- may no longer promote your Irish Engineering Services Certification Services approval
- must notify any customer with whom you have contracts for which approval is a contractual requirement, that your approval has been suspended.

Failure to maintain your approved Management System
If we raise a mandatory nonconformity at a routine surveillance or certificate renewal visit, you will be required to implement all corrective actions necessary to bring your system back into conformity with the assessment standard to maintain your approval.

Our assessor will discuss, and agree with you, arrangements and timescales for us to verify the corrective action that you have taken. The method of follow up and timescales will depend on the nature and severity of the nonconformity.

In most cases, we will verify your corrective action by conducting a special surveillance visit within three months of the Major nonconformity being raised. In some circumstances, it may be appropriate for the assessor to conduct a review of your corrective action remotely without needing to visit your premises. In extreme circumstances, such as the unlikely event that your entire management system has broken down (as evidenced by the raising of multiple Major nonconformities), Irish Engineering Services Certification Services may elect to suspend your approval with immediate effect.

If the special surveillance visit (or other review) confirms that effective corrective action has been taken so that the Major nonconformity can be downgraded or closed, Irish Engineering Services Certification Services will confirm this to you in writing and your approval will be resumed in line with the existing surveillance programme.

If the special surveillance visit finds that you have failed to take the corrective action required, you will be advised that your approval has been suspended.

Requests to suspend approval
If at any time you require your approval to be suspended, you must submit your request to Irish Engineering Services Certification Services in writing giving reasons for the request. If, after review and authorisation by Irish Engineering Services Certification Services, your request for suspension is granted, suspension will remain in force until you request your approval to be reinstated and Irish Engineering Services Certification Services have conducted a satisfactory special surveillance visit, or until the expiry of your certificate - when approval automatically ceases.

Failure to agree to a scheduled visit
If we have been unable to agree to a scheduled visit taking place within a reasonable timescale such that Irish Engineering Services Certification Services has been denied the opportunity to verify the continued implementation and conformity of your approved management system, your approval will be suspended.

Special circumstances
If you are unable to demonstrate continuing implementation of your approved management system due to unusual circumstances (for example, a temporary lack of business) a decision may be made to temporarily suspend your approval.

Notification of suspension
In all cases, we will notify you in writing that your approval has been suspended. This notification will include:

- the timescale by which you must respond. (Note: for cases of failure to maintain the approved management system, you will be required to respond within 14 days of the date of notification)
- where appropriate, the duration of the suspension period. (Note: suspension normally remains in force until the satisfactory completion of a special surveillance visit, or the certificate expiry date)
- the implications of suspension.

Response to suspension
If your approval has been suspended because of your failure to maintain the approved management system, there are three possible responses you may make:

- you may claim to have taken appropriate corrective action and request us to verify its effectiveness and then reinstate your approval (for example, a second special surveillance visit)
- if you do not agree with Irish Engineering Services Certification Services' justification for suspending your approval, you may invoke the Irish Engineering Services Certification Services appeals procedure, or
- you may decide to make no response or take no further action. If so, Irish Engineering Services Certification Services will initiate the withdrawal of approval process. If a second special surveillance visit is requested, this will only be undertaken if the timescale for the visit is acceptable to Irish Engineering Services Certification Services (that is, normally within one month of the first special surveillance visit).

Withdrawal of approval Request to terminate approval
You may request your approval contract to be terminated and approval to be withdrawn at any time in line with the 'Termination' terms defined by your Irish Engineering Services Certification Services Agreement.

Termination by Irish Engineering Services Certification Services

Irish Engineering Services Certification Services will terminate your contract and withdraw your certificate of approval if any of the following circumstances occur:

- if you fail to respond to a suspension letter resulting from a failure to maintain your approved management system
- if you decide to opt for withdrawal of approval as an alternative to implementing corrective action
- if we find corrective action not to be acceptable after a second special surveillance visit, or
- other reasons (for example, financial).

Notification of withdrawal

In all cases you will be notified in writing by Irish Engineering Services Certification Services that your approval has been (or will be) withdrawn, stating the date from which the withdrawal is (or becomes) effective. You will be required to:

- destroy all copies of relevant Irish Engineering Services Certification Services certificates of approval
- make no further claims to be approved by Irish Engineering Services Certification Services withdraw from circulation any documents bearing the Irish Engineering Services Certification Services logo
- review current tenders and contracts to find out if your approval is a condition of contract and to notify any customers imposing such requirements that your approval has been withdrawn. We will notify the withdrawal of your approval to any interested parties by whatever means is considered by Irish Engineering Services Certification Services to be most effective. This will normally include notification to any approved company directory that was notified of your original approval

Refusal of Certification

If for any reason Certification is refused, this shall be explained in full and in writing to the Applicant outlining the specific reasons for refusal of Certification. The Applicant retains the right to address the corrective actions required to remove the decision of for refusal. However Irish Engineering Services shall always have the final decision on whether Certification can be granted.

Restoring Certification

If certification is withdrawn or lapses into expiry, you can reapply for Certification in full. Irish Engineering Services shall maintain the final decision and overall responsibility on the decision to restore Certification to the Applicant.

Product Certification Process

Standards and Specifications

Once the design parameters have been specified, it shall be verified that the risk categorization is correct in accordance with the relevant Regulation.

The applicable technical standards and specifications (Designated or Harmonised) are identified at an early stage in the process and their relevance to the end use is checked where possible. The validity of the standard is also reviewed in relation to existing knowledge about regulations / Directive governing the acceptable standards in use, for example the validity of non-European standards . The current issue or revision is also ascertained and justification obtained if this is not the current issue. Where the standard or regulation / Directive contains more than one module or option, the identity and relevance of the selection is confirmed. Current versions of documentation are made available by access to relevant web sites and also by subscription to approved supplier services which are identified through the external links provided on the BMS Home Page.

Resource

The Scheme Leader, or Technical Consultancy Pricing Team selects personnel for the job in dialogue with the technical discipline manager and based on the authorisations of the relevant staff. Selection is on the basis of technical background, knowledge of the specification and experience of the product or its application.

Consideration is given to any potential conflicts of interest for example if the person involved has been employed with the manufacturer or a major competitor in connection with this type of application within say the past 2 years. In this event, an alternative person is found or the matter is cleared with the client before proceeding.

The availability of application, design, safety, quality plan(s) and product data are important considerations and free access is required to current sources of the data. A decision is taken about whether to validate the selection of computer programs for design checking and use the same program as in the original work or to take an alternative approach for checking.

The existence of type approvals for the class of item is established, together with certification and/or any report of verification and validation which was carried out in connection with the approval or separately. This data is used in the checking process.

Design

Having established the design parameters in terms of standards and their validity, the design appraisal process involves reviewing data including General Arrangements and detailed drawings, checking assumptions and calculations, then concluding whether the design meets the specified parameters. Generic requirements such as Health & Safety are also included in the appraisal process, insofar as the intended use or local legislation are known.

If critical areas are identified on the original work, design checks are particularly rigorous in these areas. Irish Engineering Certification Services also checks that acceptance criteria are clear on the design data for manufacture and test stages.

The process by its nature cannot check interfaces, but checks are made on the availability of input and output data and any numeric values or assumptions arising from the design of the item.

If there are supplementary justifications and/or restrictions relating to manufacture or use, they are examined from the point of view of consistency with the design, but the process is unlikely to identify omissions.

Before issuing a report or certificate stating the acceptability of the design or otherwise, a check is made on the approval status of the design documentation supplied and the cross referencing of versions of calculations and supporting work to the current status of the design. In the event of doubt about this, an index of the documents involved is included in the report or annexed to the certificate.

Check Calculations

Check calculations are recorded and retained as quality records in the contract file. They shall indicate the drawing / design and revision to which they refer.

Independent checks of calculations are included in the Peer Review.

For hand calculations, or those using internally-developed calculation software (such as Microsoft Excel or Mathcad), the output shall include

- the origin of the calculation formula (Standard (or other reference), revision and page / paragraph)
- the input data
- the formula
- the output data
- the acceptability (i.e. pass / fail with any justification necessary)

In cases where this is not possible (such as finite element analysis, pipework flexibility, etc.), controlled software shall be used in accordance with procedure.

The printed output shall contain

- the origin of the calculation formula (Standard, revision and paragraph or other reference)
- the input data
- the output data

the acceptability (i.e. pass / fail with any justification necessary).

Product Manufacture and Testing

Inspection Schedules are available for the Engineer Surveyor on the BMS. These indicate the minimum inspection involved.

The process begins by checking the availability of an approved design with associated documentation and if a prototype product has been tested satisfactorily. In the event that this is the first off or only item, close attention is given to the Quality Plan(s) and the control points stated on it. If there is no quality plan, inspection or sampling plan, Irish Engineering Certification Services may specify minimum requirements consistent with the relevant technical specifications.

If the product is made under a recognised quality system (e.g. accredited registration to ISO 9001), this is noted together with verifying the relevance of the certificate to the current work. Examples of this include checking that the certificate is current, applicable to the address, class of product or service and suitable for the activity.

If (special) processes such as joining and NDT are subject to approval, checks are made to confirm that they are in order and have been applied to the job in question.

If part of the work or testing is sub-contracted, Irish Engineering Certification Services checks the qualification of the subcontractor and any controls on the work to confirm adequacy or to complement potential weaknesses. Sources of raw materials and bought-in sub-assemblies or components are noted.

The relationship of final test results to validate the design is also considered, particularly if data is fed back to the design function for approval. Any reservations arising from this are noted.

Where a final report is considered necessary, the status of the documentation used and any reservations are recorded.

Current versions of external documentation which may be required during this activity are made available by access to relevant web sites and also by subscription to approved supplier services which are identified through the external links provided on the BMS Home Page.

Irish Engineering Certification services reserve the right to carry out unannounced visits on the manufacturer and their premises, to monitor the manufacture of equipment at any time.

Sampling and Surveillance

Unless covered by correspondence at intervals between visits, surveillance provides an opportunity for the manufacturer to inform Irish Engineering Certification Services about intended changes to the quality system, specification, design or manufacturing route that could affect the conformity of the product. The effects of the proposed changes are assessed appropriately and if necessary, holds placed on the release of certified products until revised approval is given to the manufacturer.

Where there are on-going manufacturing and supply activities, surveillance comprises both the ongoing implementation of any related quality system (e.g. ISO 9001) and the test regimes associated with the product.

Manufacturers operating a formal quality system are expected to carry out sufficient random product and/or process testing and trend analysis of the results. Irish Engineering Certification Services reviews these in surveillance.

All measuring , testing and indicating devices used in the manufacturing process are calibrated in accordance with BS EN ISO 10012, manufacturers recommendations, or contractual requirements.

The standard and frequency of calibration shall reflect the significance of the measurements to the quality of the finished item.

Normally, Irish Engineering Certification Services will survey the results of manufacturer's testing in relation to declared quality plans. However, Irish Engineering Certification Services may request separate sampling, for example by nominating a particular specimen and following that specimen to completion of testing, or by selecting an example from stock or the field and obtaining corroboration by testing or re-testing some or all of the attributes.

If Irish Engineering Certification Services has contracted to arrange regular or statistically significant testing, the results will be regarded as part of the surveillance process.

The appropriate use of marks (e.g. logos, CE marking) is checked during surveillance. Refer to 02-140-P030.

Reporting of Field Examination

The Inspection Schedule shall be returned when all inspection stages have been signed off.

Inspection Report

An Inspection Report that details ALL of the activity required by the Inspection Schedule can be produced on RDC as an alternative to the Inspection Schedule.

Where the inspection report is required (such as for Module A2) an SS3B report or equivalent shall be issued (on RDC ; or otherwise using the suitable BMS form) which includes all the results of examinations and the determination of conformity made from these results as well as all the information needed to understand them.

At the discretion of the Engineer Surveyor, or where required by the client a report can be issued on a visit by visit basis, or where significant activity, or information is required to be conveyed to the client, or Consultancy Engineer.

All Inspection Reports, Inspection Schedules and Release Notes (where required), should be submitted to the RDC reporting system, or to the controlling Consultancy Engineer within 5 working days of the final activity.

Release Note (Where Required)
If requested by the client, the release note shall be generated by the Consultancy Engineer or the Engineer Surveyor from the contract control database and issued when the ES is satisfied that the item is acceptable for release from the manufacturer's works.

The 'RELEASE NOTE STATUS' shall be defined as one of the following:

CONDITIONAL, generally granted when delivery is required urgently, although manufacture or documentation are incomplete. Written approval of the client MUST be obtained before issuing this type of release note.

INTERIM, used for release of part of an order, or of a subcontracted item to the main contractor.

FINAL, when all parts of the manufacturing order are fully completed, documentation is complete, and all non-acceptance notes have been closed out.

Immediately on completion, copies of the release note shall be issued to the fabricator (a responsible official) and either faxed or emailed to the client (a responsible official), and Head Office as directed by the contract specification.

Concessions
The contract specification may also require deviations to be dealt with formally by means of a written concession. This shall be raised by the manufacturer, together with the proposed repair / rectification procedure, for formal approval by the client followed by the Consulting Engineer (the ES shall not approve these procedures).

The ES shall ensure that the repair / rectification procedure is complied with, and that the documents relating to it are retained in the data dossier.

Non-Conformance Reports (NCRs) shall be issued immediately by the ES in respect of inspections when there is:

- Conflict with the manufacturer's inspection department
- Deviation from an approved drawing, or specification
- Deviation from specified requirements necessitating Consultancy Engineer or client approval/assessment
- Multiple repeat inspections due to required repair or rework.

- A technical problem which will significantly affect the production programme or the clients requirements / expectations.

NCRs are not expected for first time referral of materials / units and where prompt rectification can be undertaken in accordance with the specification.

Where a non-conformance requires a separate repair procedure the ES shall satisfy himself that it complies with all code and contractual requirements. The ES shall contact the Consultancy Engineer in case of any doubt.

Copies of the NCR shall be issued immediately to the fabricator (a responsible official) and Emailed to

- The client (a responsible official)
- Head Office – Consultancy Engineer as directed by the contract specification.

Certification ISO 17065

The Certification process follows a 3 stage approach and shall be documented.

Outsourcing is not undertaken.

Stage 1 – Evaluation

The Authorised Engineer assigned to the contract shall:

- Ensure all necessary information and documentation is available.
- Ensure that if any non-conformities have been raised as part of the Certification process, these have been addressed and closed out accordingly.
- Ensure that all steps in sections have been completed and are ready for Review as required
- Ensure that all steps outlined in the procedures have been completed and are ready for Review as required

The results of the evaluation process shall be documented. Only if the Evaluation has been completed satisfactorily, shall the form be submitted for Review to a separate Authorised Engineer not involved in the Evaluation process.

Stage 2 - Review

A Consultancy Engineer, (not involved in the Evaluation process), shall undertake a Review of all the information and results related to the Evaluation process. Following successful Review, a recommendation for Certification shall be made and documented.

Authorised Engineers undertaking the Review shall be Authorised by the Technical Manager (Pressure) or Scheme Leader using the CN40 Global Skills Matrix and the appropriate competency checklist.

Stage 3 – Certification Decision

A Consultancy Engineer (that may have undertaken and documented the Review but not involved in the Evaluation process) shall then make the Certification decision based on the Evaluation and Review. The Certification Decision shall be documented on the appropriate form.

The final certificate relates clearly to the model, design, drawing or part number uniquely, with supporting packages of the other documentation that relate to the version of the product that was subject to scrutiny.

Certificates are drafted referring to the reports raised by the Engineer Surveyor, Consultancy Engineer, auditor and/or technical experts, as required.