

IIW Manufacturer Certification Scheme for the Management of Quality in Welding



Interpretation and Implementation of ISO 3834 Requirements



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IIW MCS

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Interpretation and Implementation of ISO 3834 requirements

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Foreword

IIW – IAB the International Authorisation Board of the International Institute of Welding established in 2000, has the purpose of offering internationally recognized qualifications and certification of personnel services and certification of Companies services in the field of welding and allied technologies.

Competence assurance in welding and related technologies contributes to public safety and the quality of life by ensuring that manufactured goods and welded constructions operate safely and reliably.

The International System for Education, Training, Qualification and Certification of Personnel (International System) was implemented by IIW-IAB in 2000 for welding personnel and has since then enlarged its scope to include also the certification of companies.

The International System is now used in more than 40 countries, and is continuing to grow rapidly worldwide.

The International Education, Training, Qualification and Certification System, managed by IIW-IAB, is an open system that ensures that any person or any Manufacturer, anywhere in the world, has unrestricted access to education, training, qualification and certification in welding and related technologies, in accordance with international standards, (e.g. ISO, etc).

The IIW IAB System is underpinned by a rigorous quality assurance regime which ensures the required standards are met uniformly throughout the world in an impartial and non-discriminatory way, complying with international trade legislation.

In order to comply with these requirements, the International System's operation is based on a network of Authorised Nominated Bodies (ANBs) and Authorised Nominated Bodies for Company Certification (ANBCCs), each specializing in a specific scope, and needing to comply with the IIW IAB quality assurance system.



Preface

“Special processes” in manufacture and maintenance are those processes for which the quality requirements of the product cannot be verified by final inspection and which require special competence, before and during operation, to assure the fulfilment of quality requirements.

With reference to the quality requirements of welded products, ISO 3834 “Quality Requirements for Welding” has been developed.

Based on the above, the International Institute of Welding (IIW), by virtue of its unique international expertise, has developed an integrated and specialised Certification Scheme to assure companies’ compliance with ISO 3834. This Scheme is referred to as the IIW Manufacturer Certification Scheme according to ISO 3834 (IIW MCS).

This document is based upon the Manufacturer Certification System developed by the European Federation for Welding, Joining and Cutting (EWF), through an Agreement between EWF and the International Institute of Welding (IIW), reached in 2006 at the Annual Meeting of the International Institute of Welding (IIW) in Quebec, Canada.

These rules have been developed following the principle of mutual recognition, which has been agreed between the International Institute of Welding and the European Federation for Welding, Joining and Cutting

Though the EWF Manufacturer Certification System is based on the Management of Quality, Environment and Health and Safety in Welding through:

- the EN ISO 3834 Certification Scheme;
- the Environment Certification Scheme;
- the Health & Safety Certification Scheme,

The scope of the Agreement between EWF and IIW only includes, for the time being, the management of quality in welding.

Advantages for the Manufacturers in getting a certification against the IIW MCS, can be summarised as follows:

- welded products are differently treated according to the specific needs of the welding manufacture process used;
- manufacturers can be guided to satisfy regional or international product standards’ requirements through implementation of the Scheme;
- the specific areas of competence (for personnel and companies) are explicitly encompassed and registered in the Schedule;
- manufacturers can get visibility through the Register (www.iiwelding.org) of Certified Companies.

It must be borne in mind that, although it has many advantages, certification is voluntary and does not, in itself, meet any statutory requirements.

In the field of quality management in manufacture and maintenance, the general trend is clearly moving towards a product/process approach. In order to help companies to satisfy specific requirements and regional or international product standards, consistently and with regard for the



type of product manufactured, IIW has developed specific supplementary guides for the processes/products considered (e.g. railway vehicle components, pressure vessels and construction products), taking into consideration the applicable standards and best practice manufacturing procedures, already shared by the main international manufacturers and customers.

Great care has been taken to detail the interpretation of ISO 3834 in terms of third party assessment, to specify and register properly trained assessors, and to devise an operational structure so that certification of companies will be consistent wherever the rules are applied.

The Scheme is based on the following set of four documents:

- IAB 337 “IIW Manufacturer Certification Scheme for the Management of Quality in Welding - Interpretation and Implementation of ISO 3834 requirements”
- IAB 338 “IIW Manufacturer Certification Scheme for the Management of Quality in Welding - Guidance for the implementation of ISO 3834 oriented to welded product Standards”
- IAB 339 “IIW Manufacturer Certification Scheme for the Management of Quality in Welding - Rules for ANBCC Operating the IIW Manufacturer Certification Scheme”
- IAB 340 “IIW Manufacturer Certification Scheme for the Management of Quality in Welding - ANBCC Assessment of Manufacturers of Welded Products Operating the IIW Manufacturer Certification Scheme”

The objective is that IIW certified companies will have demonstrated that they have achieved an identified, minimum level of capability over a specified scope of activity, irrespective of the country in which they had been certified.

The primary intention of IIW MCS certification is to ensure that manufacturers are competent and exercise adequate control of the special process of welding so that customers and others can have confidence that the welded products they produce will comply with the regulatory and/or contractual requirements as related to quality in welding.

In order to give evidence of such specific technical capabilities of manufacturers, the IIW Certificate indicates the scope of certification achieved together with the issue and expiry date of the Certificate itself. The company's data is supplemented with a Schedule, where technical information (reference standards, materials, welding processes, supplementary requirements, deviations, etc.) on the manufacture process adopted and the welded products manufactured are detailed, together with the name of the responsible welding co-ordinator.

These Rules establish the mechanism by which the guidelines for the IIW Manufacturer Certification Scheme according to ISO 3834 are implemented, such that the requirements are applied uniformly by all countries involved, and that the certificates granted are mutually recognised. This is done by appointing one organisation in each country to act in the name of IIW for a defined Scope of Operation, and these organisations are assessed and monitored for compliance with the Rules.

These organisations are known as the IIW Authorised Nominated Bodies for Company Certification (ANBCCs).



The criteria on which the IAB members will take the decision of appointing or not an ANBCC are defined in IAB-065 – Operational System and in OP-11 – ANB/ANBCC Requirements and Process for Initial Nomination (Part 1) and Extension of Scope (Part 2) (both documents latest revisions).

These Rules are prepared and updated by the IAB Group A and Group B and approved by the IAB Members Meeting.

These Rules only apply to IIW ANBCCs, that are authorised for the IIW Manufacturer certification scheme in accordance with ISO 3834.

These Rules shall be updated and reissued every three years and there is an obligation on all ANBCCs to implement the changes within one year of the date of issue.

Accreditation in accordance with the relevant ISO accreditation Standards is a basic requirement for the Certification Bodies. Though the accreditation, granted by a National Recognized Accreditation Body (Member of IAF and signatory of Multilateral Recognition Agreement MLA) is not specifically required for ANBCCs implementing the IIW MCS to ISO 3834, It is recognised that the EA-6/02 document (issued by the European co-operation for Accreditation) provides the basis for the harmonisation of the assessment of manufacturers of welded products by the accredited certification bodies and shall be adopted by all ANBCCs.

This Document describes the IIW Guidelines for a manufacturer of welded products willing to implement a manufacture process management scheme which ensures the quality of the welded product according to ISO 3834.



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DEFINITIONS AND ACRONYMS

For the scope of this document, the following definitions apply:

ANBCC:	Authorised Nominated Body for Company Certification.
ANBCC Authorisation:	The award of an IIW Certificate gained by the ANBCC following audit and authorisation by IIW, in accordance with the IIW requirements.
ANBCC Lead Assessor:	A qualified person appointed by the ANBCC to lead assessments in relation to an IIW Manufacturer Certification Scheme.
ANBCC Scheme Manager:	The person nominated by the ANBCC to administer the IIW Scheme certification activities.
Appeal:	A formal objection, by a person or organisation, to a decision made by the ANBCC or IAB such that the decision in question undergoes a formal review by the ANBCC or IAB respectively.
Complaint:	An expression of dissatisfaction, by a person or organisation, with some element of the ANBCC's or IAB's performance. If the complaint is in relation to a decision made by the ANBCC or IAB, it would normally be treated as an appeal, see below.
Council of the ANBCC	The body, which is legally responsible for ANBCC affairs. It could be the 'Board of Directors' or the 'General Assembly' of the organisation.
Decision making Personnel	Group or the individual that takes the final decision on granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification
EA	European Accreditation for Cooperation
IAB Lead Assessor:	A person elected by IAB Group B, who is responsible for leading an ANBCC assessors team.
IAF	International Accreditation Forum



IIW MCS:	IIW Manufacturer Certification Scheme According to ISO 3834.
IIW Requirements:	The conditions required by IIW to be an ANBCC.
IIW Rules:	The rules described in this document.
Manufacturer:	An organisation responsible for welding activities (e.g. welding, assembling of welded component without welding, erection on site by welding, maintenance, design of welded component, purchasing of welded product, etc) seeking certification in accordance with the IIW MCS.
Participating Assessment Body:	A Certification Body which has been qualified and approved by an ANBCC to conduct assessments on behalf of the ANBCC in relation to the IIW MCS.
Secretariat:	The secretariat of the International Authorisation Board.
Sub-contracting:	The delegation of activities to a body, over which the ANBCC does not have direct executive control.

For this document, the following references in their latest revisions are considered:

ISO/IEC 17021.	Conformity assessment - Requirements for bodies providing audit and certification of management Schemes.
ISO/IEC 17065	General requirements for Bodies operating product certification systems
EA 6/02	EA Guidelines on the Use of ISO/IEC 17065 and ISO/IEC 17021 for Certification to EN ISO 3834
IAB 337	IIW Manufacturer Certification Scheme for the Management of Quality in Welding - Interpretation and Implementation of ISO 3834 requirements
IAB 338	IIW Manufacturer Certification Scheme for the Management of Quality in Welding - Guidance for the implementation of ISO 3834 oriented to welded product Standards
IAB 340	IIW Manufacturer Certification Scheme for the Management of Quality in Welding - ANBCC Assessment of Manufacturers of Welded Products Operating the IIW Manufacturer Certification Scheme
OP-01	Operation Procedure System
OP-03	ANB/ANBCC Assessment, Surveillance, Reporting Procedure and Audit Feedback
OP-05	Annual Report of ANB and ANBCC activities
OP-07	Use of IIW certificate of authorisation
OP-11	ANB/ANBCC Requirements and Process for Initial Nomination and Extension of Scope
OP-12	Fees Calculation and Invoicing
OP-13	Confidentiality



1. General

The present document refers to the management of welding with regard to the quality requirements. The Manufacturer is fully responsible for his product conformity, therefore, an effective control of the whole manufacturing process must not be ignored, especially when welding, with its ancillary activities (e.g.: PWHT, NDT, etc), is involved. The control according to ISO 3834 over the whole manufacturing process is not only the correct way to discharge relevant responsibilities but also a useful tool to help manufacturers fulfil the welding contractual and regulatory requirements of the product without any waste or extra costs.

ISO 3834 consists of the following parts, under the general title “Quality requirements for fusion welding of metallic materials”:

- Part 1 Criteria for the selection of the appropriate level of quality requirements
- Part 2 Comprehensive quality requirements
- Part 3 Standard quality requirements
- Part 4 Elementary quality requirements
- Part 5 Documents with which it is necessary to conform to claim conformity to the quality requirements of ISO 3834-2, ISO 3834-3 or ISO 3834-4
- ISO/TR 3834-6 - Guidance on implementing ISO 3834

ISO 3834-1 provides a set of criteria that a manufacturer can use in defining which part of ISO 3834 (2, 3 or 4) should be applied. These are the following:

- The extent and significance of safety critical products.
- The complexity of manufacture.
- The range of products manufactured.
- The extent to which metallurgical problems may occur.
- The extent to which manufacturing imperfections (eg, misalignment, distortion or weld imperfections), affect product performance.

Product standards, regulatory requirements or contracts may specify particular quality levels of ISO 3834 to be applied. Where these are absent, the manufacturer shall select the standard part taking account of the criteria listed above. Further guidance is given in ISO TR 3834-6, clause 8.

As guidance the following criteria could be considered by the Manufacturer to select the appropriate ISO 3834 Part

ISO 3834-2

- Highly safety-critical; failure likely to result in loss of life, environment risk, etc.
- High level of manufacturing complexity; challenging materials, complex processes etc.
- Wide range of products manufactured involving a variety of different materials and/or processes
- Broad range of metallurgical problems, eg, toughness, corrosion, metallurgical imperfections, fatigue, etc
- High significance of manufacturing imperfections related to static/dynamic loading and product performance

**ISO 3834-3**

- Medium level of safety criticality; significant consequences of failure but not threatening loss of life.
- Medium level of manufacturing complexity
- Limited range of products manufactured
- Limited range of metallurgical problems
- Limited significance of manufacturing imperfections on product performance

ISO 3834-4

- Not safety-critical
- No manufacturing complexity; mature and routine processes.
- Simple products manufactured
- No or very limited metallurgical problems
- Manufacturing imperfections insignificant to product performance

In the IIW MCS, according to ISO 3834, the welded products are treated differently according to the specific needs of their manufacturing process (i.e. a bridge made with high strength C-Mn steel has requirements far different from those of a heat exchanger constructed with nickel alloy). Therefore, some specific Supplements, for the most important families of welded products (i.e., pressure equipment, steel structures, rail vehicles and components), have been published by IIW with the aim to guide the management of the specific manufacture process required. These can be found in Doc. IAB 338. This does not preclude the use of other internationally recognized Standards.

The specific manufacturing process orientation of ISO 3834, especially with regard to the operational aspects, does not require a Quality Manual. It also regards unwritten technical practices, when based on minimum specific technical competence, as having sometimes an equal value as documented procedures. If the Manufacturer does not have in place a quality management system, it should implement at least a documentation control system (see ISO TR 3834-6 clause 7.2).

In this regard, a great importance has been weighted on personnel competency, intended as a combination of knowledge and experience. Management systems cannot be successful in manufacturing or other industries without an appropriate specific technical competency. With respect to this Scheme, the Welding Coordinator has become the real “key” element around whom all the welding manufacturing process is performed. This is dealt with in ISO 14731 (referenced in ISO 3834-5)

ISO TR 3834-6 “Quality requirements for fusion welding of metallic materials – Part 6: Guidance on implementing ISO 3834” has also been prepared, so, for a proper implementation of ISO 3834, a Manufacturer should apply this reference document with the considerations reported in the following points.

2. IIW Guidance for ISO 3834-2

Any specific requirements of ISO 3834-2 can be fulfilled by using suitable reference standards (e.g. welder qualification shall be performed according to ISO 9606 series). Full conformity to ISO 3834



part 2 (as well as for part 3 and 4) may be achieved either by adopting the normative references given in ISO 3834-5 or by applying other standards that provide equivalent technical conditions. Moreover, what is referred to in ISO/TR 3834-6 clause 6 shall be applied. It is the responsibility of the Manufacturer to demonstrate the equivalence when ISO 3834-5 standards are replaced by alternatives and these are not a requirement of the product standard being used.

In the following paragraphs the ISO 3834-2 requirements worthy of additional guidance for their implementation, are considered (with the sequence as in ISO 3834-2).

2.1. *Review of requirements and technical review (Ref. ISO 3834-2 clause 5)*

Additional information

See ISO/TR 3834-6 clause 10.1

2.2. *Sub-contracting (Ref. ISO 3834-2 clause 6)*

Additional information

See ISO/TR 3834-6 clause 10.2

The Manufacturer shall keep evidence on sub-contractors' compliance with the relevant part (or just some specific items when full compliance is not necessary) of ISO 3834. Such documentation could be a list of sub-contractors with their capabilities, audit plan of sub-contractors, audit and inspection report carried out by the manufacturer itself or third party certificates of the sub-contractor.

2.3. *Welding personnel (Ref. ISO 3834-2 clause 7.3)*

Additional information

See ISO/TR 3834-6 clause 10.3

Welding coordination is one of the key concepts of ISO 3834. IIW also considers this as one of the most important items of the Certification Scheme, that is why manufacturers (as well as ANBCC's during third party assessment) must recognise only competent personnel as responsible welding coordinators taking into consideration ISO 14731.

One of the following additional criteria shall be considered for the evaluation of responsible welding coordination personnel:

- the certification according to IIW Personnel Certification Scheme (CIWE, CIWT, CIWS and CIWP) shall be considered adequate, provided the schedule of the personnel certificate and the level of knowledge are consistent with the type of products being manufactured by the manufacturer and the selected quality level per ISO 3834.
- the qualification according to IIW guidelines for welding coordination personnel (IWE, IWT, IWS and IWP) shall be considered adequate provided the holder has had appropriate experience and the level of knowledge consistent with the current production and the selected quality level per ISO 3834. The experience must be demonstrated by the holder of the qualification and assessed by the ANBCC.
- If no certification or qualification is available, adequate knowledge, experience and competence on welding technology, materials and their behaviour during welding,



design fundamentals of welded construction, as well as fabrication and inspection aspects (including standards knowledge) must be demonstrated, consistent with the current production and the selected quality level per ISO 3834. Knowledge and experience must be demonstrated by the personnel and assessed by the ANBCC

Due to the principle of mutual recognition between IIW and EWF whenever IIW qualification and/or certification of welding coordination personnel is mentioned, the correspondent EWF qualification and/or certification is considered equivalent.

The manufacturer shall define tasks and responsibilities of the welding coordination team, based on ISO 14731 “Welding coordination– Tasks and responsibilities”.

The role of the Responsible Welding Coordinator may be subcontracted but it remains the responsibility of the manufacturer to demonstrate full compliance with the requirements of ISO 14731.

2.4. *Inspection and testing personnel (Ref. ISO 3834-2 clause 8.1)*

Additional information

If a welding inspector is employed, he/she should be qualified in accordance with the IIW Guideline for Welding Inspection Personnel. Otherwise, the Manufacturer must be able to demonstrate that the inspector is competent to perform the assigned task.

In any case, an appropriate experience consistent with the current production must be demonstrated (e.g. by means of a national certification scheme).

2.5. *Welding and related activities (Ref. ISO 3834-2 clause 10)*

Additional information

See ISO/TR 3834-6 clause 9.1.4.2 and clause 10.5

2.6. *Inspection and testing (Ref. ISO 3834-2 clause 14)*

Additional information

Although ISO 3834 makes reference to “inspection” and “testing”, it does not specify criteria for organisations performing these activities. The results and tests carried out by the Manufacturer, or by subcontractors, shall anyway be based on an objective evidence to confirm satisfactory process controls and /or achievement of specification requirements.

2.7. *Calibration and validation of measuring, inspection and testing equipment (Ref. ISO 3834-2 clause 16)*

Additional information

See ISO/TR 3834-6 clause 10.7



As a general rule calibration and/or validation is required when the quality of the welded product is strongly influenced by an accurate and repeatable selection of parameters such as current, voltage, welding travel speed, preheating temperature, etc.

As a general rule calibration and/or validation is required for automatic welding equipment, temperature measurement devices, NDT equipment, etc.

2.8. *Identification and traceability (Ref. ISO 3834-2 clause 17)*

Additional information

When traceability of consumables is required, it may be assumed that it is not necessary to record the location of various batches of approved consumables within multi-run joints, provided such batches of consumables are accepted by review of supplier's documentation before use.

3. **IIW Guidance for ISO 3834-3**

Any specific requirements of ISO 3834-3 can be fulfilled by using suitable reference standards (e.g. welder qualification shall be performed according to ISO 9606 series). Full conformity to ISO 3834 part 3 (as well as for part 2 and 4) may be achieved either by adopting the normative references given in ISO 3834-5 or by applying other standards that provide equivalent technical conditions. Moreover, what is referred to in ISO/TR 3834-6 clause 6 shall be applied. It is the responsibility of the Manufacturer to demonstrate the equivalence when ISO 3834-5 standards are replaced by alternatives and these are not a requirement of the product standard being used.

Rev.2

In the following paragraphs, the ISO 3834-3 requirements worthy of additional guidance for their implementation are considered (with the sequence as in ISO 3834-3).

3.1. *Review of requirements and technical review (Ref. ISO 3834-3 clause 5)*

Additional information

See ISO/TR 3834-6 clause 10.1

3.2. *Sub-contracting (Ref. ISO 3834-3 clause 6)*

Additional information

See ISO/TR 3834-6 clause 10.2

The Manufacturer shall keep evidence on sub-contractors' compliance with the relevant part (or just some specific items when full compliance is not necessary) of ISO 3834. Such documentation could be a list of sub-contractors with their capabilities, audit plan of sub-contractors, audit and inspection report carried out by the manufacturer itself or third party certificates of the sub-contractor.

3.3. *Welding personnel (Ref. ISO 3834-3 clause 7.3)*

Additional information



See ISO/TR 3834-6 clause 10.3

Welding coordination is one of the key concepts of ISO 3834. IIW also considers this as one of the most important items of the Certification Scheme, that is why manufacturers (as well as ANBCC's during third party assessment) must recognise only competent personnel as responsible welding coordinators taking into consideration ISO 14731.

One of the following additional criteria shall be considered for the evaluation of responsible welding coordination personnel:

- the certification according to IIW Personnel Certification Scheme (CIWE, CIWT, CIWS and CIWP) shall be considered adequate, provided the schedule of the personnel certificate and the level of knowledge are consistent with the type of products being fabricated by the manufacturer and the selected quality level per ISO 3834.
- the qualification according to IIW guidelines for welding coordination personnel (IWE, IWT, IWS and IWP) shall be considered adequate provided the holder has had appropriate experience and level of knowledge consistent with the current production and the selected quality level per ISO 3834. The experience must be demonstrated by the holder of the qualification and assessed by the ANBCC.
- If no certification or qualification is available, adequate knowledge, experience and competence on welding technology, materials and their behaviour during welding, design fundamentals of welded construction, as well as fabrication and inspection aspects (including standards knowledge) must be demonstrated, consistent with the current production and the selected quality level per ISO 3834. Knowledge and experience must be demonstrated by the personnel and assessed by the ANBCC

Due to the principle of mutual recognition between IIW and EWF whenever IIW qualification and/or certification of welding coordination personnel is mentioned, the correspondent EWF qualification and/or certification is considered equivalent.

The manufacturer shall define tasks and responsibilities of the welding coordination team, based on ISO 14731 "Welding coordination– Tasks and responsibilities".

The role of the Responsible Welding Coordinator may be subcontracted but it remains the responsibility of the manufacturer to demonstrate full compliance with the requirements of ISO 14731.

3.4. *Inspection and testing personnel (Ref. ISO 3834-3 clause 8.1)*

Additional information

If a welding inspector is employed, he/she should be qualified in accordance with the IIW Guideline for Welding Inspection Personnel. Otherwise, the Manufacturer must be able to demonstrate that the inspector is competent to perform the assigned task.

In any case, an appropriate experience consistent with the current production must be demonstrated (e.g. by means of a national certification scheme).

3.5. *Welding and related activities (Ref. ISO 3834-3 clause 10)*

Additional information



See ISO/TR 3834-6 clause 9.1.4.2 and clause 10.5

3.6. *Inspection and testing (Ref. ISO 3834-3 clause 14)*

Additional information

Although ISO 3834 makes reference to “inspection” and “testing”, it does not specify criteria for organisations performing these activities. The results and tests carried out by the manufacturer, or by subcontractors, shall anyway be based on an objective evidence to confirm satisfactory process controls and /or achievement of specification requirements.

3.7. *Calibration and validation of measuring, inspection and testing equipment (Ref. ISO 3834-3 clause 16)*

Additional information if required

See ISO/TR 3834-6 clause 10.7

As a general rule calibration and/or validation is required when the quality of the welded product is strongly influenced by an accurate and repeatable selection of parameters such as current, voltage, welding travel speed, preheating temperature, etc.

As a general rule, calibration and/or validation is required for automatic welding equipment, temperature measurement devices, NDT equipment, etc.

3.8. *Identification and traceability (Ref. ISO 3834-3 clause 17)*

Additional information

When traceability of consumables is required, it may be assumed that it is not necessary to record the location of various batches of approved consumables within multi-run joints, provided such batches of consumables are accepted by review of supplier's documentation before use.

4. **IIW Guidance for ISO 3834-4**

Any specific requirements of ISO 3834-4 can be fulfilled by using suitable reference standards (e.g. welder qualification shall be performed according to ISO 9606 series). Full conformity to ISO 3834 part 4 (as well as for part 2 and 3) may be achieved either by adopting the normative references given in ISO 3834-5 or by applying other standards that provide equivalent technical conditions. Moreover, what is referred to in ISO/TR 3834-6 clause 6 shall be applied. It is the responsibility of the Manufacturer to demonstrate the equivalence when ISO 3834-5 standards are replaced by alternatives and these are not a requirement of the product standard being used.

In the following paragraphs, the ISO 3834-4 requirements worthy of additional guidance for their implementation are considered (with the sequence as in ISO 3834-4).

4.1. *Review of requirements and technical review (Ref. ISO 3834-4 clause 5)*

Additional information



See ISO/TR 3834-6 clause 10.1

4.2. *Sub-contracting (Ref. ISO 3834-4 clause 6)*

Additional information

See ISO/TR 3834-6 clause 10.2

The Manufacturer shall keep evidence on sub-contractors' compliance with the relevant part (or just some specific items when full compliance is not necessary) of ISO 3834. Such documentation could be a list of sub-contractors with their capabilities, audit plan of sub-contractors, audit and inspection report carried out by the manufacturer itself or third party certificates of the sub-contractor.

4.3. *Inspection and testing (Ref. ISO 3834-4 clause 12)*

Additional information

Although ISO 3834 makes reference to “inspection” and “testing”, it does not specify criteria for organisations performing these activities. The results and tests carried out by the manufacturer, or by subcontractors, shall anyway be based on an objective evidence to confirm satisfactory process controls and /or achievement of specification requirements.