



**Procedure for the approval of manufacturers of Non-Automatic Weighing Instruments to EC-declaration of type conformity (guarantee of production quality) relating to directive 90/384/EEC Annex II, section2**

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## 1. PURPOSE, VALIDITY AND REVISION OF THIS DOCUMENT

### 1.1 Purpose

The purpose of the present document is to describe the procedure of **DS Certificering A/S (DSC)** in connection with the approval of manufacturers of NAWI to EC-declaration of type conformity.

### 1.2 Scope

The procedure encompasses the approval of manufacturers in conformity with:

- Council Directive 90/384/ECC

### 1.3 Validity

The document applies to the approval of manufacturers of NAWI and describes the compulsory stages of the process as well as the optional stages, which are offered as a service.

The document is to be regarded as part of the contractual basis between **the company** and **DSC**.

**DSC** and **the company** are under an obligation to observe the present procedure.

### 1.4 Revision

**DSC** will revise the document in the event of material changes, for instance, to accreditation factors, international standards, national or international agreements, or whenever **DSC** deems it necessary.

The revised document is to all approved manufacturers and to other customers and interested parties.

In case of changes to the requirement model and thus the approval procedure the **company** is under an obligation to comply with the changed requirements of the procedure within a fixed time limit.

## 2. APPROVAL

### 2.1 Requirement model

The requirement model consists of the Council Director mentioned in section 1.2.

### 2.2 The company

As a system basis, the company shall establish a quality management system to ensure that activities are in conformity with:

- Council Directive 90/384/ECC, Annex II, section 2
- Own requirements.
- Requirements, if any, from other relevant interested parties (e.g. sectors, customers).

To obtain the approval the company must ensure that it's documented quality management system conforms to the requirement model;

- has been fully implemented;
- has been tailored to conditions of the company and are suitable and effective.

In addition, the actual activities must conform to the quality management system described.

The company undertakes to perform at least one management review of the quality management system before the approval audit is initiated.

## 2.3 DSC

DSC' approval activities are carried out in accordance with the present procedure and in conformity with the publication "Rules for the services provided by DS Approval".

## 3. DEFINITIONS

Applied concepts relating to quality management systems are in conformity with the wording of the **Quality management system** standards mentioned in section 1.2.

Reference is further made to section 8, "**Vocabulary**".

## 4. APPROVAL PROCEDURE

Approval comprises the following compulsory elements:

- Approval agreement with DS.
- Pre-evaluation of system documentation.
- Preliminary examination.
- Approval audit.
- Internal DS verification/Issue of declaration.
- Surveillance audit.

During the approval process **DS** may use one or several external specialist(s), if **DS** does not have internal staff with the requisite sector competency at its disposal.

The names of external specialists will be presented in writing to **the company**. **The company** is entitled to demand a person replaced if there are weighty arguments for this, such as competitive considerations.

Before the approval agreement is drawn up an information meeting may be held on the company's premises. Moreover, an offer may be prepared at **the company's** request for the desired approval service.

### 4.1 Approval agreement

A **company** deciding to apply for approval must fill in an "Agreement form" and send it to **DS**.

Before the agreement is confirmed to **the company**, **DS** reviews the contract to ensure that the necessary capability is available in order for it to perform the approval in a professionally correct manner.

In connection with reviewing the contract and confirming the agreement, **DS** will make the reservation that further activities in **the company** may be uncovered during the pre-evaluation (see section 4.2 below)

In its written confirmation of the agreement **DS** states the name of the person responsible for the case and explains the further process, including the company's possibilities of self-evaluation in accordance with a questionnaire which DS encloses with the agreement (a check list containing the requirements of the directive, translated into questions).

### 4.2 Pre-evaluation

Enclosed with the confirmation of the agreement **the company** will receive a questionnaire for self-evaluation for compliance with the chosen requirement model.

Self-evaluation is often appropriate as it gives **the company** the possibility of ensuring that relevant

system requirements have been incorporated into the quality management system described.

As an alternative to self-evaluation, **the company** may choose to fill in a cross-reference table linking the selected system standard and **the company's** system documentation.

The documentation which **the company** must send to **DSC** shall comprise  
a list of relevant regulatory requirements, stating the commitment of the authority (approval, supervision, etc.);  
a quality handbook with pertinent procedures.

The assessment of the system documentation received is carried out for the purpose of evaluating whether it meets the requirements of the chosen requirements and whether **the company's** system documentation is sufficient with regard to the quality objectives stated and the quality policy established.

**DSC** may require clarifying details from **the company**.

The assessment of the system documentation may take place on **the company's** premises or by reviewing the documentation on **DSC's** premises. **DSC** will to the widest extent possible consider **the company's** wishes in this respect.

The pre-evaluation is documented in a report which is given or sent to the company.

#### **4.3 Preliminary examination/clarifying meeting**

The preliminary examination is carried out on the company's premises according to agreement.

The examination includes a visit to all key functions (departments) of **the company** which are planned for inclusion in the approval audit. The purpose of the preliminary examination is, among other things, to provide an overview of:

- the scope of the approval, the size and structure of the company, including an unambiguous definition of the requested scope of the approval;
- which activities are performed where;
- manufacturing methods, processes, equipment and other conditions of importance to the appraisal of **the company's** quality management system and the planning of the approval audit;
- preliminary evaluation of the scope of the documentation relating to the quality management system;
- the need for specialist assistance during the approval audit;

When **the company** has received the report from the pre-evaluation there may be a need for clarification of comments.

It may be agreed with **the company** to clarify such matters at a clarifying meeting, which may be held in connection with the preliminary examination, for the purpose of

Ensuring **the company** the best possible conditions for preparing for the approval audit;

Clarifying the issues brought up in the report;

**The company** and **DS** reaching agreement on the necessary remedial/corrective actions and the timetable for their implementation.

All matters brought up in connection with the pre-evaluation must be solved before the approval audit to ensure that changes, if any, can be implemented before the approval audit.

*Note: **DSC** reserves the right, also at a later stage, such as during the approval audit, to point out areas of the documentation, the list of relevant regulatory statutory requirements, or quality objectives set, which are considered not to meet the requirements of the chosen system standard.*

#### **4.4 Approval audit**

In preparation for the approval audit, **DSC** submits a draft audit programme to **the company**

containing a timetable for the performance of the approval audit.

The audit programme specifies the lead auditor and auditors appointed by DS and whether specialists are required for the audit.

**The company's** acceptance of the audit programme, external auditors, if any, and the external specialists are given in writing to **DSC**.

The approval audit is performed by an audit team composed to take into account the specific technical area to be audited.

The audit is performed in accordance with the audit programme agreed upon, divided into:

- Preliminary meeting.
- Approval audit.
- Final meeting.

#### 4.5 Preliminary meeting

**The company** is typically represented at the preliminary meeting by:

- The managing director (management) and the heads of sections.
- The contact to DS (often the quality manager).
- Other employees, as requested by the company.

**DSC** is represented by the audit team.

The purpose of the meeting is

- to introduce the audit team to **the company's** representatives and to ensure agreement on the approval audit procedure;
- to establish a formal communication channel between the management and the audit team, including the appointment of "guides";
- to clarify, and reach agreement on, the issues relating to the approval audit, or to answer questions about specific issues, including issues relating to the practical performance of the audit.

#### 4.6 Performance of the approval audit

At the approval audit the company's quality management system is assessed as a whole by **DS's** audit team. The audit is performed as an extensive spot check procedure to ascertain whether the quality management system described by **the company**

- has been fully implemented, and
- has been tailored to **the company's** conditions and applied processes and is effective, and whether
- actual activities are in conformity with the requirements in the described quality management system and other documented relevant requirements.

To ensure a sufficiently extensive approval audit, the auditors will use

- **the company's** documented quality management system;
- the pre-evaluation report;
- a check list (the same as that used for self-evaluation, containing the requirements of the quality management system standard translated into questions);

- any relevant regulatory requirements will be included in the audit.

During the audit the appointed guides from **the company** will accompany the auditors and assist in establishing the necessary contact and sign any non-conformities found, which are to be documented in a non-conformity report.

The audit team will meet at appropriate intervals to verify non-conformities found and agree on any required adjustment of the activities to the audit programme.

Daily summing-up meetings are held with **the company's** contact and the responsible managers in order to:

- evaluate the progress in relation to the audit programme and agree upon changes, if necessary;
- present any non-conformities found;
- solve any problems suddenly arisen.

If it turns out at an early stage of the approval audit that the quality management system in several respects deviates from the requirement model so that the lead auditor is unable to recommend the granting of an approval, or if specific problems have been encountered, it is the duty of the lead auditor to inform **the company's** management accordingly so that unnecessary costs are avoided.

In such cases, the company and DSC can agree in:

- to continue the audit as agreed to get an overall impression of all non-conformities of the quality management system;
- to discontinue the audit until the non-conformities found have been remedied;
- to continue the audit as an audit of limited scope.

#### 4.7 Final meeting

A final meeting is to be held as soon as the planned audit activities have been completed.

**The company** may be represented by those attending the preliminary meeting as well as any members of staff who have been involved in the work of the audit team.

At the meeting the lead auditor will summarize the observations of the audit team and make a statement on the recommendation made to the **DSC** verifier about the granting of an approval to **the company**.

If the granting of an approval is recommended, the company is informed of the guidelines which apply to the verification of the requirement model, performance and result of the audit.

The guidelines outlined below apply to the recommendation for the granting of an approval:

- Where no non-conformities (see vocabulary, section 8) are ascertained, the lead auditor may immediately recommend that an approval be granted. The recommendation must appear from the audit report.
- Where one or more non-conformities are found, the lead auditor cannot recommend that an approval can be granted until remedial/corrective action has been implemented and affirmatively verified by **DSC**. This conclusion shall appear from the audit report.

The company representative will go through and sign non-conformity reports, if any. Time limits for presenting proposals for remedial/corrective actions are to be agreed upon. The audit report may refer to non-conformity reports, if any.

Queries from **the company** are answered by the audit team.

The time for carrying out a post-audit or the time for the first surveillance audit to be performed must be appearing from the report. The audit report as well as any non-conformity reports is submitted to **the company**.

If, during the approval audit, one or more non-conformity reports are issued, **the company** must in these reports state the reason for the non-conformity brought up and present a proposal for remedial/corrective action, and subsequently send this to **DSC** within the agreed time period. **DSC** will notify the company of acceptance of the reports or submit a reasoned rejection within an agreed time of receipt (usually two weeks).

Implementation of remedial/corrective action must be verified by **DSC** within the agreed time period. Depending on the type of remedial/corrective action, the verification may in a few cases be implemented solely on the basis of the documentation received. In other cases it may be necessary to verify the implementation and the effectiveness of remedial/corrective actions on the premises of the company by means of a post-audit.

A post-audit is carried out to verify that remedial/corrective actions have been implemented in practice and function effectively. A post-audit is to be carried out with a positive result not later than six months after an approval audit. Otherwise a new approval audit will be required.

In a post-audit report **DSC** must inform **the company** of recommendations made by the audit team as regards **the company's** possibilities of being granted an approval.

Moreover, **DSC** must also state in the same post-audit report those cases of non-conformity with the requirements which still exist and which require further remedial/corrective action.

The post-audit is not concluded until all remedial/corrective actions have been made and their implementation has been verified and approved by **DSC**, so that the audit team is able to recommend to the **DSC** verifier that an approval be issued to **the company**.

Where **the company** fails to meet the requirements after the second post-audit or after a period of six months following the approval audit, a new approval audit will be required.

#### **4.8 Internal verification at DSC/Issue of approval**

The DSC verifier will approve the recommendation on the basis of a review of the case documentation. This is to ensure that the audit has been performed in accordance with the specified requirement model and the procedures of the system approval department's quality manual and supplementary accreditation conditions, if any.

As the basis for assessing the conformity with the requirement model, the complete set of documentation from the implementation of all audit activities is used, including the audit report and the recommendation by the audit team for issuing an approval. The approval is issued by a **DSC** managing director.

The approval must contain the following information:

- Name of the company.
- Address(es) of all locations covered by the approval.
- The activity areas covered by the approval.
- The relevant requirements to which the approval must demonstrate conformity.
- The processes and/or services covered by the approval.
- Date of issue and date of validity.
- Accreditation logo(s) (if relevant).

The approval can be issued in Danish, English, French and German, the Danish or English version being the legally valid version. **The company** may obtain the approval in other languages upon request and according to agreement.

**The company** is registered as an approval company and added to the DSC list on [www.dscert.dk](http://www.dscert.dk).

#### 4.9 Surveillance audit

##### *Method*

The method consists in surveillance audits being carried out at intervals not exceeding 12 months.

The surveillance audit is performed in such a way that all clauses of the requirements will be audited every time, but **DS** is entitled at its own discretion and without prior notice to perform supplementary surveillance audits, as **the company** should at any time be able to demonstrate compliance with the requirements of the standard.

Any complaints from a third party regarding non-conformities in the quality management system may give rise to a supplementary audit being carried out.

**The company** is under an obligation to record all complaints lodged by interested parties. Complaints and misuse of the approval and/or approval logo will be audited at least once a year.

If major non-conformities (see vocabulary, section 8) are ascertained during a surveillance audit, non-conformity reports are drawn up. Where the audit demonstrates minor non-conformities (see vocabulary, section 8) these are to be documented in the audit report, stating a time limit for the remedying of the non-conformities.

At the termination of a surveillance audit, **DSC** shall give **the company** an oral statement of the result and within no more than two weeks, the result of the surveillance audit is to be documented in writing in an audit report.

The report must also notify **the company** of any elements which fail to comply with the requirements and which require corrective action to be taken.

## 5. SPECIAL ACTIVITIES

The activities described above are the compulsory activities which **DSC** must perform as a minimum.

Some companies may for various reasons require other services, such as

- information material about the approval of quality management systems;
- information meetings about **DSC** and **DSC's** method for carrying out approval systems;
- participation by **DSC** in seminars etc. where information on the approval scheme mentioned in section 1.2 is given;
- an additional information day attended by a larger or different group of **company** employees than was the case on the first information day;
- the performance of a preliminary audit (carried out some time before the approval audit) with the purpose of reducing, by small spot checks, the number of non-conformities at the approval audit;
- an extra surveillance audit where **the company** finds that there is a need for a surveillance audit in addition to the periodic surveillance audits;
- the performance of an audit according to quality management standards other than the quality management standards mentioned in section 1.2.

Special activities are usually subject to a fee payable in accordance with the current rates, as specified

in the publication "Rates and fees for approval services". A quotation is given upon request.

## 6. APPROVAL

The DSC approval demonstrates to the public and other companies that **the company** has established, operates and maintains a quality management system which conforms to the requirements of the chosen EC Directive as well as other specified supplementary requirements, if any.

### 6.1 Scope of approval

Consequently, the approval is limited to cover:

- activities performed at the address(es) given within the field of operation of **the company**; other areas, addresses, processes, activities and/or services not mentioned are not encompassed by the approval.

**The company** may request **DSC** to change the scope of approval, e.g. to another system standard or other processes, activities and/or services and and/or addresses. **DSC** will then decide whether renewed or supplementary approval is required.

### 6.2 Validity

Issued approvals are valid, provided that it is regularly verified by means of surveillance audits that **the company's** quality management system continues to satisfy the conditions for approval.

If the conditions for obtaining approval have not been fulfilled, the case will be dealt with in accordance with "DSC's "Rules for the services provided by DSC Approval", section 7."

### 6.3 Use of the approval

The holder of a **DSC**-approval is allowed to use it for business purposes, e.g. by enclosing a copy of it in offers, order confirmations or confirmations to authorities, and for advertising.

Validity of the approval may be claimed only in relation to the address (part(s) of **the company**) specifically stated on the approval and only for the processes, activities and/or services covered by the approval.

Approved companies will receive information about changes to the present procedure in the form of new revisions. Unless information is given to the contrary, **the company** will always be given a period of at least six months to adapt to the new or amended requirements in the procedure.

### 6.4 Publication

All issues of, and changes to approvals will be published by **DSC** on [www.dscert.dk](http://www.dscert.dk).

## 7. MAINTENANCE OF THE QUALITY MANAGEMENT SYSTEM

**The company** has an obligation to maintain its quality management system and is allowed to introduce changes to it without notifying **DSC**, provided that the modifications do not influence conformity with the requirement model stated on the approval or in the scope of the approval.

**The company** has an obligation to inform **DSC** immediately of changes to the conditions of the approval which may result in **the company** not fulfilling the requirement model specified in the approval or its scope, including:

- Change of corporate form and ownership structure.
- Replacement of key persons from the point of view of quality management.

- Changes to the organisational structure.
- Suspension of payments.
- Transfer of the approved product area to another company.
- Change of the approval process areas and/or service areas.

Any change of the quality management system, which may result in failure to conform to the chosen requirement standard for approval, must be presented to **DSC** for comments before implementation.

**The company** must accept the decision of **DSC** as to whether or not the planned and notified changes require a new audit or further investigation.

**DSC** may request the company to forward the controlled copy of the system documentation, e.g. prior to surveillance audits.

## 8. VOCABULARY

This vocabulary contains terms whose definitions cannot be found in the **Council Directive** mentioned in section 1.2. The terms are listed alphabetically.

### **Auditor:**

A person authorised by **DSC** to perform an audit. A lead auditor is an auditor authorised by **DSC** to be in charge of the approval audit and to be responsible for its performance. Auditors may be **DSC** employees or may work for **DSC** as external auditors under **DSC**' management and responsibility.

### **Approval audit:**

Comprises an audit of the quality management system carried out on the premises of **the company** by **DSC**' audit team. The audit comprises an evaluation of the compliance of the quality management system with the provisions of the relevant standard and other relevant requirements and, through spot checks of all elements of the described quality management system, an appraisal of the extent to which the system has been implemented, its adjustment to the conditions of **the company** and the conformity of activities carried out with the described quality management system.

### **Clarifying meeting:**

A meeting arranged to be held on the premises of **the company** with the purpose of discussing the contents and the consequences of the pre-evaluation report and planning the approval audit.

### **DSC verifier:**

A member of the permanent staff of **DSC** who has been authorised to sign approvals.

### **Information meeting:**

A meeting to be held on the premises of **the company** attended by **DSC**, is usually held before the company makes a final decision to apply for **DSC** approval.

### **Non-conformity:**

A major non-conformity exists when:

- a relevant provision of the standard in question is not documented (described) or is not observed;
- a requirement described in the quality management system is not fulfilled in practice;
- a situation which, on the basis of objective evidence, raises doubt as to the quality of the service supplied by **the company**;
- a number of minor discrepancies do not constitute any significant non-conformity when occurring as single events; however, when occurring in greater numbers, they are an indication of systematic defects which may affect the operation and effectiveness of the system.

An minor non-conformity exists when:

- a fault or deficiency is not considered to be a major non-conformity, but is significant enough for it to result in demands being made on the company for it to be remedied.

The granting of an approval cannot be recommended until all non-conformities have been remedied.

**Post-audit:**

An audit performed by DSC. Its purpose is to ensure that any agreed remedial/corrective action to be taken after the approval audit has been successfully implemented so that the approval can be issued.

**Pre-audit:**

Comprises pre-evaluation and preliminary examination, see the relevant definitions.

**Pre-evaluation:**

Assessment of the company's documented quality management system prior to the approval audit.

**Preliminary examination:**

Visit to the company's premises for the purpose of planning the audit.

**Specialist:**

A person who has a profound knowledge of the technical aspects of the provision or use of a particular process, product or service or the applicable regulatory requirements, and who is therefore a member of the audit team and available with any required expertise. Generally, the specialist does not have the competence of an auditor.

**Surveillance audit:**

An audit carried out once a year by **DSC** in order to verify that the requirement model for approval is continuously observed and that the quality management system has not been subject to any changes or omissions which may influence the conditions for maintaining the approval.

**System documentation:**

The company's documented quality management system, viz. the documents, procedures and instructions, etc. describing the implementation of quality management in the company.

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