THE ARSO CERTIFICATION SYSTEM (ARSO-CERT)

Guide on the Procedure for Assessment of a Factory for the Award of the ARSO Mark

THE ARSO CERTIFICATION SYSTEM (ARSO-CERT)

Guide on the Procedure for Assessment of a Factory for the Award of the ARSO Mark

P.O. Box 57363 Nairobi, Kenya
Telephone: 224561/330882/330895
Telex: 22097 ARSO
Telefax: +2542218792
ISBN 9966-832-31-9

Contents

PREFACE

This document describes the steps to be taken, and the considerations to be given, when a factory is assessed by a National Standards Body (NSB), as a preliminary to the granting of approval to use the National Mark of Conformity in combination with the ARSO Mark.

It traces the steps from the time that an application is made to the National Standards Body for a license, through the process of assessment, reporting, and follow-up actions.

This document will therefore, serve as a guide to the NSB Assessors and producers seeking the certification of their products.

This document should be read in conjunction' with the Guide on the National Certification System of National Members of ARSO-CERT issued by ARSO in November 1990 to which reference is herein made.

1. TYPE OF CERTIFICATION SYSTEM

The type of certification system operated under the framework of ARSO-CERT consists of:

(i) Assessment of the factory quality system based on the relevant quality system standard e.g. ARS 9002 (ISO 9(02);

(ii) Initial product testing carried out in accordance with applicable standards and specific rules of the scheme. .

Following the acceptance of these two elements; Surveillance of the factory is carried out by:

(i) Auditing the factory quality system;
(ii) Testing of samples from the factory; and
(iii) Testing of samples from the open market.

There are General Rules issued by the National Standards Body, which cover the principles of operation, the configuration of the National Mark of Conformity, the responsibilities of the licensee, the right of appeal and other general matters.

There are also **Specific Rules** established by the National Standards Body for each certification
scheme applicable to a product or group of products, and these spell out the requirements in greater detail.

2. APPLICATION FOR A LICENCE

The application shall be made on a special form which may be obtained on application to the NSB (a National Member of ARSO-CERT). This is a formal document, which identifies the applicant, and specifies a particular product, or group of related products. The application shall cover products from one factory only.

A questionnaire shall be completed by the applicant, and returned with the Application Form. This provides preliminary information on the producer and his capability to control the quality and continuing conformance of his products to the requirements of the relevant standards It requests information concerning factory organization. It asks for specific details of the procedures/documentation that is used to control the quality system. It requires the applicant to define his QC staff organization, and seeks information regarding their training, reporting and general responsibilities.

The questionnaire also covers such subjects as:

(i) purchase specifications/materials QA;
(ii) manufacturing system;
(iii) maintenance system, for plant and equipment;
(iv) quality control system;
(v) test equipment/instruments, gauges and tools;

(vi) records and documents relating to compliance with the specification;
(vii) method of application of the National Mark of Conformity.

An example of a proposed questionnaire given in Annex C of the **Guide on the National Certification System of National Members of ARSO-CERT** is reproduced here as Annex A.

Most of the required information should be contained in the factory's Quality Manual, but the completed questionnaire will be used as a check-list by the National Standards Body's assessors during any preliminary visit to the factory, or during the course of the initial assessment.

On receipt of the completed Questionnaire, Application Form, Quality Manual and appropriate fee, the National Standards Body will confirm this to the applicant and provide further information on the processing of the application.

3. ASSESSMENT OF THE APPLICANT

3.1 Quality system assessment

3.1.1 Initiating the Assessment

As a basis for planning the assessment the assessor should review for adequacy the applicant's recorded description of the methods for meeting the quality system requirements (such as the Quality Manual or equivalent).

If this review reveals that the system described by the applicant is not adequate to meet the requirements, further resources should not be expended on the assessment until such concerns are resolved to the satisfaction of the NSB, the assessor and, where applicable, the applicant.

3.1.2 Preparing the Assessment

3.1.2.1 *Assessment plan*

The assessment plan should be approved by the NSB and communicated to the assessors and applicant. The assessment plan should be designed to be flexible in order to permit changes in emphasis based on information gathered during the assessment and to permit effective use of resources. The plan should include:

- the assessment objectives and scope;
- identification of the individuals having significant direct responsibilities regarding the objectives and scope;

- identification of reference documents (such as the applicable quality system standard
- and the applicants Quality Manual);
- identification of assessment team members;
- the language of the assessment;
- the date and place where the assessment is to be conducted;
- identification of the organizational units to be assessed;
- the expected time and duration for each major assessment activity;
- the schedule of meetings, to be held with applicant management confidentiality requirements;
- assessment report distribution and the expected date of issue.

If the applicant objects to any provisions in the plan, such objections should immediately be made known to the Lead Assessor. They should be resolved between the Lead Assessor and the applicant, before starting the assessment.

3.12.2 ***Assessment team assignments***

Each assessor should be assigned specific quality system elements or functional departments to assess. Such assignments should be made by the Lead Assessor in consultation with the assessors concerned.

3.12.3 *Working documents*

The documents required to facilitate the assessor's investigations, and to document and report results, may include:

(i) check-list used for evaluating quality system elements (normally prepared by the assessor assigned to assess that specific element); see 3.1.3.2;
(ii) forms for reporting assessment observations;

(iii) forms for documenting supporting evidence for conclusions reached by the assessors.

Working documents should be designed so that they do not restrict additional assessment activities or investigations which may become necessary as a result of information gathered during the assessment. Working documents involving confidential or proprietary information shall be suitably safeguarded by the National Standards Body.

3.1.3 Executing the Assessment

3.13:1 Opening meeting

The purpose of an opening meeting is to:

- introduce the members of the assessment team to the applicant's senior management;
- review the scope and the objectives of the assessment;
- provide a short summary of the methods and procedures to be used to conduct the assessment;
- establish the official communication links between the assessment team and the applicant;
- confirm that the resources and facilities needed by the assessment team are available;
- confirm the time and date for the closing meeting and any interim meetings of the assessment team and the applicant's senior management;
- Clarify any unclear details of the assessment plan.

3.1.3.2 Examination

The check lists referred to in 3.1.2.3 should be compiled to cover all the relevant quality system elements of the appropriate part of ARS 9000, as they affect the Specific Rules for the Certification Scheme.

In most cases they will assess the applicant's

a) Published Quality Policy (4.1.1)*;
b) Organization of its quality resources, including the delegation of responsibility and authority, to control the quality system, and the appointment of management representative as a focal point to liaise with the National Standards Body (4.1.2);
c) Arrangements to carry out Management Reviews to ensure the continuing effectiveness of the quality system (4.1.3); d) Contract review procedure, to resolve any problems before production commences (4.3);
e) Document control system (4.4);
f) Purchasing procedures, with its control of sub-contractors (including test laboratories), completeness of purchasing data (4.5);
g) Control of product identification and traceability (4.7);
h) Process control (4.8);
i) Inspection and testing procedures, including receipt and final inspection (4.9);
j) Inspection, measuring and test equipment -calibration (4.10);

k) Inspection and test status (4.11);
l) Control of non-conforming products (4.12);
m) Corrective action procedures, including the recording and actioning of customer complaints (4.13);
n) Control of handling, storage, packaging and delivery of the products (4.14); 0) Retention and preservation of quality records (4.15);
p) Internal quality audits -a continuing self-examination of the quality system (4.16);
q) Training of all employees associated with the quality system (4.17);
r) Statistical control system, if applicable (4.18).

Where design of the product is a responsibility of the applicant, the design controls will be checked by the National Standards Body .

3.13.2.1 Collective evidence

Evidence should be collected through interviews, examination of documents, and observation of activities and conditions in the areas of concern. Clues suggesting non conformities should be noted if they seem significant, even though not covered by Check Lists, and should be investigated. Information gathered through interviews should be tested by acquiring the same information from other independent sources, such as physical observation, measurements and records.

During the assessment the Lead Assessor may make changes to the assessor's work assignments, and to the assessment plan with the applicant's agreement, if this is necessary to ensure the optimal achievement of the assessment objectives.

If the assessment objectives appear to become unattainable, the Lead Assessor should report the reasons to the applicant.

3.1.3.2.2 Assessment observations

All assessment observations should be documented. After all activities have been assessed, the assessment team should review all of their observations to determine which are to be reported as nonconformities. The assessment team should then ensure that these are documented in a clear, concise manner and are supported by evidence. Nonconformities should be identified in terms of the specific requirements of the standard or other related documents against which the assessment has been conducted. Observations should be reviewed by the Lead Assessor with the responsible applicant's manager. All observations of nonconformities should be acknowledged by the applicant's management.

3.1.3.3 Closing meeting with applicant

At the end of the assessment, prior to preparing the assessment report, the assessment team should hold a meeting with the applicant's senior management and those responsible for the functions concerned. The main purpose of this meeting is to present assessment observations to the senior management in such a manner so as to ensure that they clearly understand the results of the assessment.

The Lead Assessor should present observations, taking into account their perceived significance. The Lead Assessor should present the assessment team's conclusions regarding the quality system's effectiveness in ensuring that quality objectives will be met. Records of the closing meeting should be kept.

3.1.4 Assessment report

3.1.4.1 The assessment report is prepared under the direction of the Lead Assessor, who is responsible for its accuracy and completeness. The assessment report should faithfully reflect both the tone and content of the assessment. It should be dated and signed by the Lead Assessor. It should contain the following items, as applicable:

- the scope and objectives of the assessment;
- details of the assessment plan, the identification of assessment team members and applicant's representative, assessment dates, and identification of the specific organization assessed;
- identification of the reference documents against which the assessment was conducted (quality system standard, applicant's quality manual, etc);
- observations of nonconformities;
- assessment team's judgment of the extent of the applicant's compliance with the applicable quality system standard and related documentation;
- the system's ability to achieve defined quality objectives;
- the assessment report distribution list.
- Any communication made between the time of the closing meeting arid the issue of the report should be by the Lead Assessor

3.1.4.2 Report distribution

The assessment report should be sent to the applicant by the NSB. Any additional distribution should be determined in consultation with the applicant. Assessment reports containing confidential or proprietary information shall be suitably safeguarded by the National Standards Body.

The assessment report should be issued as soon as possible. If it cannot be issued within an agreed time period, the reasons for the delay should be given to the applicant and a revised issue date established.

3.1.5 Corrective action follow-up

The applicant is responsible for determining and initiating corrective action needed to correct a nonconformity or to correct the cause of a non-conformity. The assessor is only responsible for identifying the nonconformity.

Corrective action and subsequent follow-up assessments should be completed within a time period agreed to by the applicant in consultation with the National Standards Body.

3.2 Initial Product Testing

3.2.1 Sampling

The sampling of items for initial testing should be defined in the Specific Rules for the scheme that is being assessed. These Rules should specify the precise selection method of taking samples for inspection and test, in a formalized sampling procedure. The sampling should be 'carried out by an inspector, or an authorized representative of the National Standards Body. The samples should be representative of the entire line or group of production to be certified, and be made from production tools and assembled using methods established for the production run.

A sample report should be prepared, which indicates the following information:

a) Name and address of the National Standards Body;

b) Date of sampling;

c) Description of samples;

d) Drawn/purchased/submitted by (how was the sample obtained);

e) Place of sampling: Factory -pre final inspection or post final inspection; or

Open market -stockist or retail;

f) Address where samples were aken;

g) Condition of batch/production lot;

h) Size of batch/production lot;

i) Number of samples drawn;

j) Sampling procedure;

k) Condition of sample(s);

1) Identification marks on samples (batch No. etc.);

m) Signature of sampler;

n)' Signature of supplier (where applicable);

o) Remarks.

3.2.2 Conduct of initial testing

The samples selected for testing, as defined in 3.2.1 should be tested in accordance with the ,applicable standards and the Specific Rules of the scheme.

They should be tested in a laboratory which has been accredited in accordance with the Rules of ARSO-CERT. This requirement applies, whether or not the laboratory is owned or contracted to by the National Standards Body.

3.2.2.1 The Work carried out by the Testing Laboratory should be covered by a comprehensive Test Report which accurately, clearly, unambiguously and objectively presents the test results and all relevant information.

3.2.2.2 A Test Report shall include the following information:

'a) Name and address of Testing Laboratory;

b) A unique serial number of the Test Report;

c) On each page, a page number, the total number of pages in the Test Report and the serial number of the Test Report;

d) Name of client (who submitted the sample?);

e) Description and identification of the sample, and date of receipt;

f) An appropriate title for the Test;

g) Identification of the test specification, method and procedure;

h) Any deviations, additions to or exclusions from the test specification;

i) Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

j) A statement of measurement uncertainty (where relevant);

k) A statement as to whether or not the samples comply with any requirements against which they were assessed;

1) Signature of officer accepting technical responsibility for the Test Report and date of issue.

3.2.2.3 Particular care and attention should be paid to the, arrangement of the Test Report, especially with regard to presentation of the test data and ease of assimilation by the reader. The format should be carefully and specifically designed for each type of test carried out, but the headings should be standardized as far as possible throughout the Testing Laboratory.

3.2.2.4 Corrections or additions to a Test Report after issue shall be made only by a further ' document marked "Supplement to Test Report, Serial Number" and shall meet the relevant requirements of the preceding paragraphs.

3.2.2.5 The Test Report should be submitted to the applicant, and he should be informed if all the requirements of licensing, with respect to testing, are not being met. He should be notified of those tests in which his application has failed.

3.2.2.6 If the applicant can show objective evidence that remedial action has been taken by him to meet all the requirements within a specified period of time, only the appropriate parts of the initial testing need be repeated.

4 APPROVAL AND LICENSING

4.1 The National Standards Body shall, on the basis of the initial assessment of the applicant's Quality System (3.1) and the results of the initial product testing (3.2) assess whether the applicant's quality system and products meet the requirements of the Standards and Specific Rules.

4.2 If the overall assessment of the applicant indicates that he conforms to the requirements of ARSO-CERT, and the product(s) have been certificated under the national certification system for not less than 12 months, the NSB shall then proceed to apply to ARSO for the use of the ARSO Mark in combination with the national mark of conformity by the producer.

4.3 The following documents concerning the particular scheme shall be made available to the Secretary-General of ARSO by the NSB:

(i) Product standards that form the basis for the certification;
(ii) Specific rules for the certification scheme;
(iii) Assessment, sampling and test report.

4.4 The above document shall be evaluated by ARSO for conformance to the provisions of ARSO-CERT. If satisfactory. an approval for the use of the ARSO Mark by the producer shall be given.

4.5 In some cases, further information might be required by ARSO from the NSB before approval could be given. If however, some critical conditions have not been met, the application will be rejected and the reason communicated to the national member.

5. SURVEILLANCE

5.1 To ensure that a licensee's quality system and products continue to meet the requirements of the relevant standard and the Specific Rules, surveillances are carried out by the National Standards Body.

5.2 The surveillance may be carried out by the National Standards Body, or it may appoint an agent to act on its behalf. In such cases the agent shall have the facilities and qualified staff necessary to effectively administer the Rules of ARSO-CERT.

5.3 The Surveillance shall, as a minimum requirement, consist of:

a) Examination of the licensee's quality records;

b) Ensuring that the required sampling and testing of the product has been carried out at the specified frequency;

c) Determining that appropriate corrective action has been taken in the event of any failure occurring;