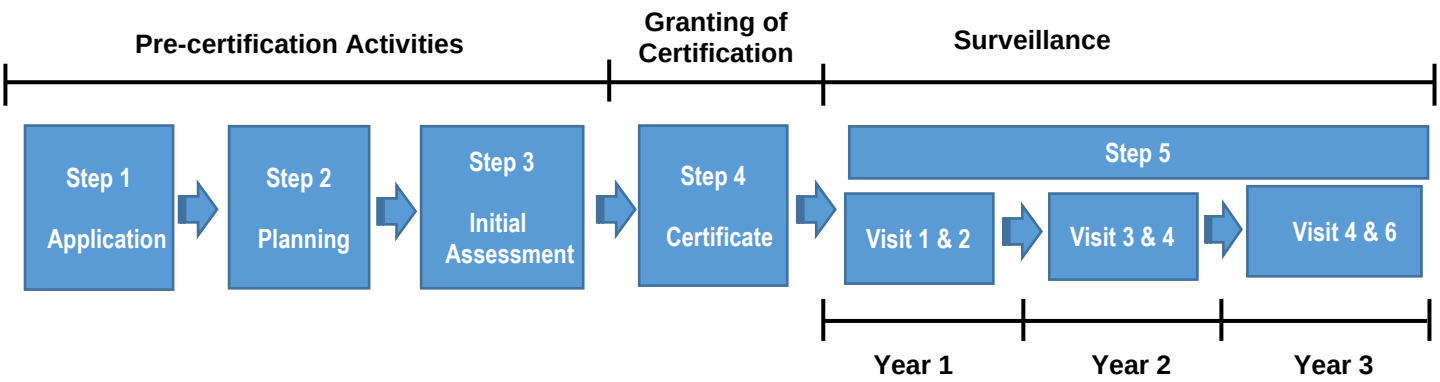
General Description of the Process for Certification of Products

Certification of a product based on the national standard or other technical specification means that an organization has been assessed and has met the requirements of the relevant standard. This guidance document explains the key stages of the Zambia Bureau of Standards (ZABS) process for assessment and certification of a product.



STEP 1 APPLICATION AND AGREEING THE CONTRACT

Preliminary Enquiry. When an enquiry is received from a prospective client, our sales staff provides an outline of certification process and discusses your certification requirements. We are happy to arrange a visit discuss your requirements. The client is provided with a Request for Quotation (RFQ) form and a Pre-Licence Factory Assessment Questionnaire.

Request for Quotation. The RFQ form is designed to obtain complete information on the client's certification requirements, and is the basis for the certification proposal. The RFQ should be submitted to the relevant certification office.

Pre-Licence Factory Assessment Questionnaire. This form is designed to evaluate the client's eligibility and readiness for product certification by evaluating the client's factory production control system as well as to prepare a detailed initial assessment plan. This questionnaire must be submitted together with the RFQ form. Significant issues arising out of review of the questionnaire may have to be addressed before a certification proposal is made to the client.

Certification Proposal. Upon receipt of the RFQ and the Pre-Licence Factory Assessment Questionnaire, we prepare a no obligation detailed quotation or certification proposal covering the client's requirements.

Application. The client makes an 'Application' by signing the quotation/proposal returning it to the relevant ZABS certification office.

Contract. Once the client's signed certification quotation/proposal is also signed by a ZABS representative, this constitutes the entire 'contract' for certification services. The contract must be signed before any work can commence. The proposal is valid for 90 days. Once the 90 days end, we will review the contract again and issue a new proposal if necessary.

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STEP 2 PLANNING THE ASSESSMENT

Agreeing the Assessment Dates. Following the signing of the contract and payment of the initial assessment fees, the ZABS and the client mutually agree the assessment dates. The initial assessment consists of the factory audit and product evaluation. The factory audit date is set and arrangement for product evaluation or testing made

Assessment Team Selection. The assessment team is selected taking into account the nature of the client's business. The roles of the assessment personnel involved is as follows:

The Team Leader is responsible for the whole assessment process and the production of the assessment plan. They are responsible for managing the members of the team, including allocating activities to the team members to ensure that the assessment plan can be completed, the compilation of the assessment report and assessment findings and making the recommendations in relation to your certification. The Team Leader will ask that you appoint personnel from your organization who will act as guides for the assessment team during each of the visits and who will assist the assessment team.

The Team Members undertake the assessment process under the direction of the Team Leader. They undertake the detailed assessment work in accordance with the assessment plan, producing a report of the work they have undertaken, including any findings, for inclusion within the overall assessment report.

A Technical Expert will be used on an assessment where specialist knowledge is required to supplement that of the assessment team. Whilst they will act as advisors to the assessment team they will not undertake any assessment work.

An Assessor in Training may be included within the assessment team, and performs the duties of either a team member or team leader under the direction of an experienced assessor.

An Observer may, from time to time, accompany the assessment Team. An observer is not a part of the assessment team and will not influence or interfere with the conduct of the assessment. An observer can be from ZABS, an accreditation body or regulator, or from another interested party who wishes to witness the assessment.

Our planning office will inform you of the makeup of any assessment team in advance of the visit, including where applicable any technical experts, and if the team will be accompanied by any observers.

Assessment Plan. Prior to the initial assessment, a detailed assessment plan will be prepared and provided to the client at least two weeks in advance of the assessment.

The Team Leader prepares for the assessment plan based on the information provided by the client in the Pre-Licence Assessment stage, and discusses and agrees the further procedures, such as logistics, safety requirements, test arrangements etc., with the organization to be assessed.

The assessment plan will at least include or refer to the following:

- the assessment objectives;
- the assessment criteria;
- the assessment scope, including identification of the organizational and functional units or processes to be assessed;
- Product testing or other product evaluation activities.
- the dates and sites where the on-site assessment activities will be conducted, including visits to temporary sites and remote assessment activities, where appropriate;
- the expected duration of on-site assessment activities;
- the roles and responsibilities of the assessment team members and accompanying persons, such as observers or interpreters.

STEP 3 INITIAL ASSESSMENT

Factory Audit

A factory visit is conducted and consists of an assessment of the implementation of the management system to confirm conformity with certification requirements such as the factory production control system and certification scope

The factory audit assessment determines conformity to your documented system and the requirements of the assessment standard(s). In order to fully assessment the agreed scope it is necessary that the products included within the certification scope are in manufacture/process at the time of the assessment. Should any product not be available for review during the assessment, then these items will not be included in the scope of the certificate.

All assessment conclusions are based on sampling of assessment evidence to demonstrate effective implementation regarding requirements of the standard(s) and factory production control requirements

On conclusion of the assessment the assessor will make a recommendation dependent on findings. This recommendation will reflect the level of findings identified during the assessment.

Product Evaluation

ZABS Certification accepts the following sources of test results:

a) Test results from an accredited or recognised laboratory prior to the application < 3 months old for food
b) Test results for factory audit samples tested using ZABS own Test facilities
c) Test results from the manufacturer's test facilities (after assessment of the test facilities)
d) Test results from outsourced accredited or recognised test facilities.

Reporting

The Team Leader will issue an assessment report to the client within 14 days from the last day of the certification assessment. If test results for product certification are not yet available, this will be a preliminary report based on the factory audit only.

The report is sufficiently detailed to clearly show the level of conformity of your factory production control system with the scheme criteria. The report will contain a record of assessment findings, progress against the assessment plan, positive comments, and points of clarification or interpretation. We record non-conformities in a Nonconformity Report (NCR) form, and identify them as major nonconformity or minor nonconformity. These nonconformities are defined below.

Follow-up and Close Out of NCs

Major non-conformity is identified and is caused through a significant breakdown of system control, the certification decision will be deferred until corrective action has been taken. Major NC is also a circumstance in which direct impact on the product without appropriate action by the organization is observed during the assessment or when legality and/ or certification integrity is at stake.

A major nonconformity negatively affects the capability of the factory production control system to achieve product conformity. In other words, the absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve:

- the factory production control requirements
- compliance with the applicable regulatory requirements
- Conformity to the product standard or specification.

A major nonconformity can also be raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan of a minor nonconformity at the next scheduled on-site assessment.

When a major nonconformity is issued during an assessment, the organization must provide ZABS with objective evidence of an investigation into causative factors, and the proposed corrective action plan (CAP). This shall be provided within 14 days after the assessment. The corrective action shall be implemented by the organization within 60 days after the assessment and evidence of this implementation shall be send to the assessor (team leader).

Our assessor will plan a follow-up assessment within 60 days after the assessment, to review the corrective action and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve and corrective action (CA).

The objective of the follow up assessment is to review the effectiveness of the correction and corrective action taken after the raising of a Major Nonconformity.

This follow-up includes the review of the documented root cause analysis by the company, actions taken and documented evaluation by the company for the effective close out of the non-conformity.

In cases where documentary evidence is sufficient to close out the major nonconformity, the assessor may decide to perform a desk review.

The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

In such cases, the major nonconformity can be downgraded by the assessor to a minor nonconformity.

A follow-up assessment shall be conducted to verify the permanent corrective action and to close the nonconformity.

Downgrading of a major nonconformity is not possible if the major is defined based on the event of non-completion of the approved action plan of a minor nonconformity.

Recommendation for certification is not possible when major nonconformities are not closed or downgraded to minors.

Minor Nonconformity: nonconformity that does not affect the capability of the factory production control system to achieve the product conformity. In other words: a finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the factory production control system or put at risk the product, but needs to be addressed to assure the future capability of the system.

Minor non-conformity will not prevent recommendation for certification but may delay it, as planned action must be submitted to and reviewed by ZABS prior to the certification decision taking place. Follow up of minor non-conformities is usually by means of evaluation of documented evidence. Verification and closure of minor non-conformity will take place at the next routine surveillance visit.

STEP 4 GRANTING OF CERTIFICATION

Certificates are awarded to the client when all assessment activities have been satisfactorily completed, the assessment Team Leader has recommended that certification is granted, any non-conformities raised during certification assessment are cleared and ZABS Certification has formally reviewed the assessment report and reached a certification decision in accordance with its procedures.

Certificates are maintained and held in force subject to satisfactory completion of the requirements for maintenance of certification (see Step 5 Surveillance) but remain the property of ZABS. Normally the certificates are valid for 3 years

Details of certified clients are listed on the website at: www.zabs.org.zm

STEP 5 SURVEILLANCE

Once issued certificates are only valid subject to satisfactory maintenance of your system and product conformity. Ongoing assessments (surveillance visits) are conducted either six-monthly or annually to verify continued implementation of your factory production control system in accordance with “planned arrangements” and the requirements within the scheme criteria. The first surveillance must be conducted within 6 months of the end of the initial factory audit . The choice of surveillance period will be agreed at the proposal stage and will depend on the scale, nature of your operations and scope of certification. Regardless the surveillance interval, certain mandatory elements will be reviewed at every visit together with other pre-selected processes. We will work with you to identify areas that are not conforming to support opportunities for improvement. An assessment plan will be forwarded in advance of the agreed assessment date.

STEP 6 RECERTIFICATION

ZABS operates a system of continuous certification. As part of this programme, it is not necessary to conduct a complete assessment. Rather, we conduct a recertification visit which is more in-depth than surveillance visits but will ensure that we review all aspects of your system. The recertification assessment must be carried out and the /major non-conformities closed prior to the expiry of your current certificate. The recertification assessment is the first visit of your new certification cycle.