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STANDARDS
MALAYSIA

**DEPARTMENT OF STANDARDS MALAYSIA
SCHEME FOR THE ACCREDITATION OF CERTIFICATION BODIES
(The ACB Scheme)**

**ACB 7
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THE CONDUCT OF ACCREDITATION ASSESSMENTS

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**Director General
Department of Standards Malaysia**

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1. INTRODUCTION

- 1.1 This document prescribes general guidance and procedures for the conduct of accreditation assessment of certification bodies (CBs) under the STANDARDS MALAYSIA accreditation system.
- 1.2 The main function of STANDARDS MALAYSIA as a national accreditation body is to accredit, following successful assessment, those certification bodies found to be competent and impartial to manage a certification system appropriate to its scope, type and volume of its accreditation activities.

The main function of assessment is to determine whether or not the CB complies with the general criteria and requirements published by STANDARDS MALAYSIA.

- 1.3 STANDARDS MALAYSIA assessors should be aware that the problems encountered in actual assessment will be many and varied, and the procedures provided in this document only cover general issues. It will always remain the duty of the individual assessor to weigh all the evidence available before a judgment is made on a particular situation in a certification body.
- 1.4 Accreditation assessments should be conducted with objectivity, courtesy and tact but with sufficiently firmness to ensure that the assessor obtains access to all information necessary to form a balanced judgment of the certification body with STANDARDS MALAYSIA accreditation criteria and requirements.
- 1.5 Assessors are hereby reminded that information that they acquired during assessment visits is confidential to the certification body and STANDARDS MALAYSIA, and must not under any circumstances be divulged to any other party. Assessors should have signed letters of undertaking of confidentiality and STANDARDS MALAYSIA assessor` Code of Ethics before embarking on an assessment.
- 1.6 This document should be read in conjunction with the relevant published criteria, policies and procedures governing the ACB scheme.

2. ACCREDITATION REQUIREMENTS

- 2.1 Accreditation requirements are set out in STANDARDS MALAYSIA criteria document MS ISO/IEC Guide 62, IAF GD 2, MS ISO/IEC Guide 66 IAF GD 6, MS ISO/IEC Guide 65, IAF Guidance 65, ACB-HALAL PRODUCT, ACB-OSH, ACB-ISMS and ACB-HACCP. Assessors are therefore reminded that the certification body is to be assessed against the STANDARDS MALAYSIA published criteria and requirements and not to the requirements of other management standards which they may have become familiar with. Assessors are required to familiar themselves fully with the provisions of STANDARDS MALAYSIA published requirements and policies before embarking upon an assessment. STANDARDS MALAYSIA Secretariat representative who may be accompanying the assessment team may be consulted in the event of any clarification on STANDARDS MALAYSIA policies and procedures are required.

3. DEFINITIONS

3.1 For the purpose of this document, definitions in the relevant ISO standards and the relevant ISO/IEC Guides shall apply. The following definitions and abbreviations shall also apply.

Accreditation: Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accredited Certification Body: A body that has been accredited by STANDARDS MALAYSIA in accordance with specific criteria, procedures and requirements to operate, on a continuing basis, as a certification body.

Accreditation Criteria: Includes the appropriate accreditation standard, and all STANDARDS MALAYSIA approved policies and procedures at the time of application, and those approved from time to time subsequent to accreditation, that are applicable to the accreditation program under which accreditation is sought..

Accreditation Review Panel (ARP): A Panel established by the Director General of STANDARDS MALAYSIA with appropriate members drawn from a pool of experienced individuals in the relevant accreditation scheme to perform an impartial and independent evaluation or review of assessment / reassessment reports and make appropriate recommendations to the Director General on the acceptability of certification bodies for accreditation.

Accreditation system: A system that has its own rules of procedure and management for the conduct of assessment and for granting of accreditation.

Assessment: Process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and / or other normative documents and for a defined scope of accreditation-

Assessor: An authorised agent of STANDARDS MALAYSIA who is qualified and competent to carry out some or all functions of assessment under all accreditation schemes administered by STANDARDS MALAYSIA.

Conformity Assessment Body (hereinafter referred to as CAB): Body that performs conformity assessment services and that can be the object of accreditation

Certification system: A system having its own rules of procedure and management for carrying out conformity certification.

Director General: The Chief Executive Officer of the Department of Standards Malaysia appointed in accordance with Section 9 of the Standards of Malaysia Act 1996 and for the purpose of carrying out the duties and functions detailed in Subsection 10 of the same Act.

STANDARDS MALAYSIA Secretariat (hereinafter referred to as Secretariat): Staff employed by STANDARDS MALAYSIA with delegated powers and authority to implement the policies and procedures of STANDARDS MALAYSIA and manage accreditation activities.

Nonconformity: The absence of, or the failure to implement and maintain, one or more requirements of the STANDARDS MALAYSIA Accreditation Criteria, or a situation which would, on the basis of available objective evidence raise significant doubt as to the credibility of the certificates issued by the applicant body.

- a) **Major nonconformity** - may be an individual nonconformity or a number of minor but related nonconformities, which when considered in total are judged to contribute to an overall system failure.
- b) **Minor nonconformity** - a single failure to comply with STANDARDS MALAYSIA Accreditation Criteria, or with the certification body's own documented quality system, or if a series of minor but related discrepancies are observed, which together are judged to be a quality risk, without constituting an overall system failure in the area concerned.

Malaysian Standards and Accreditation Council, MSAC (hereinafter referred to as the Council): An Advisory Council established under Section 13 of the Standards of Malaysia Act 1996 with delegated functions under the said Act in advising the Minister on policies, criteria and procedures for the administration of a national accreditation system.

Malaysian National Accreditation Committee (MyNAC): A Committee of the Council established by MSAC under Section 14 of the Standards of Malaysia Act 1996 and act on behalf of the Council for discharging the duties and functions of the Council in connection with accreditation matters.

Observation: An assessment finding that does not warrant a nonconformity but is identified by the assessment team as an opportunity for improvement. The CB is strongly recommended to take corrective / preventive actions to indicate commitment to continual improvement.

Reassessment: A periodic accreditation assessment activity designed to re-evaluate conformity of products, services or systems with criteria specified by STANDARDS MALAYSIA.

Surveillance: Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity-

Verification assessment: A partial assessment where only part of the quality system of a certification body is covered under the assessment programme.

4. ADMINISTRATIVE PROCEDURES FOR ASSESSMENT

- 4.1 **Application for accreditation:** A CAB desiring to be accredited by STANDARDS MALAYSIA must submit a prescribed application form, duly signed by its authorised representative and providing details of its name, addresses, legal structure, and accompany with the following:
 - (a) a clearly defined scope of accreditation sought;
 - (b) its published rules or terms and conditions governing the certification scheme operated by the CB;

- (c) information that provides a description of the certification services it undertakes, and a list of standards, methods or procedures for which it seeks accreditation including limits of capability where applicable;
- (d) general information concerning its relationship in a larger corporate entity, if any, and addresses of all its physical location(s) to be covered by the scope of accreditation;
- (e) its Quality Manual and relevant associated documents and records;
- (f) information on the size or volume of its current activities, and its current human and technical resources;
- (g) an agreement to fulfil the requirements for accreditation and the other obligation of the CAB

4.2 Basic Requirements

STANDARDS MALAYSIA Secretariat shall check that all the basic requirements have to be complied with. The officer shall:

- (a) provide further information on STANDARDS MALAYSIA requirements if necessary. However, this activity is normally carried out when the full information pack is given to potential applicants
- (b) request further information from the CB in support of the application, where necessary
- (c) advise the CB of acceptance of application
- (d) provide reasons if the application is rejected

4.3 Acceptance of Application

The following are basic requirements for acceptance of application:

- (i) applicant is from a formally constituted body, legally identifiable
- (ii) applicant has provided all information required by STANDARDS MALAYSIA for processing application
- (iii) declaration of undertakings duly signed by authorised representative of CB
- (iv) written confirmation from CB on the following:
 - CB must be operational, rather than a proposed system;
 - CB must have a minimum level of operational experience and has granted a reasonable number of certifications;
 - CB must have a full-time secretariat;
 - head of CB or the senior support staff should have sufficient experience in the development or operation of a CB;

- information on its regional / branch offices, if any; and
- information on existing Mutual Recognition Arrangements or existing relationship with similar bodies

The letter of acceptance will then be sent together with the invoice for the application fees. The accreditation process will not commence further until payment is received.

4.4 Composition of Assessment Team

Following acceptance of a certification body's application, the Secretariat shall, as far as is practical, advise the CB of the composition of the assessment team selected for the accreditation process. The compliance assessment of the accreditation process will not proceed until the CB is in a position that will enable STANDARDS MALAYSIA assessors to evaluate the management of all the certification system components and the conduct of CB's auditors undertaking certification audits. Therefore, important preparatory works by the STANDARDS MALAYSIA Secretariat for the conduct of assessment shall also commence concurrently.

5. PREPARATION FOR ASSESSMENT

5.1 General

Under the STANDARDS MALAYSIA system, accreditation assessment shall consist of three (3) stages which come under the responsibilities of a STANDARDS MALAYSIA assessment team. These are:

Stage 1: This is known as **Documentation Review** stage which involves carrying out an "adequacy audit" to review the CB's documentation and its compliance with STANDARDS MALAYSIA accreditation criteria. Depending on a particular circumstance, STANDARDS MALAYSIA Secretariat staff may also assist in this system assessment exercise.

As mentioned earlier, Stage 1 Documentation Review is to ensure that the CB is in a position that will enable STANDARDS MALAYSIA assessors to evaluate the management of all certification system components including that component on the witnessing of CB's auditors in action.

Stage 2: A **Preliminary Assessment** of the CB's management system and its general competence may be carried on request of the CB or as recommended by the Lead Assessor based on results of the documentation review carried out in Stage 1.

Stage 3: This is a **Compliance Assessment** which involves the assessment of both the CB's headquarters and regional offices, where applicable. An important component of this compliance assessment involves the witnessing of CB's auditors carrying out audits on their clients. (See **ANNEX 1**).

The process in Stage 3 constitutes a complete "Compliance Assessment" is to ensure that the documented procedures are implemented and adhered to.

5.2 Administrative support by Accreditation Secretariat

The following preparatory steps, properly executed by the STANDARDS MALAYSIA Secretariat is to ensure that accreditation assessment and subsequent decision on accreditation will be carried out professionally and with full integrity:

- The need for exchange of formal letters agreeing to pursue accreditation assessment;
- Advise the CB on the membership of assessment team and team leader;
- Obtain formal agreement on the acceptability of assessment team including agreement of expected cost of assessment to be borne by the CB;
- Obtain agreement on assessment dates and duration;
- Confirmation of criteria which will be used in the assessment process such as MS ISO/IEC Guide 62, IAF GD 2, MS ISO/IEC Guide 66, IAF GD 6, MS ISO/IEC Guide 65, IAF Guidance 65, and any other additional criteria and requirements which will be made known to all parties and agreed to by the CB.
- Agreement on the scope of accreditation sought and a current list of CB's auditors and their competence in accordance to NACE code or other SIC codes;
- Obtain information such as subcontracting arrangements, a list of current MOUs or MRAs the CB has with other similar bodies;
- Assessment team be provided with up-to-date assessment documents, procedures and instructions and forms, scope of accreditation sought;
- Obtain written confirmation or obtain additional information from the CB on 4.3 (iv) above;

5.3 Scope of accreditation sought

5.3.1 The scope of a CB shall be unambiguously defined, according to the function performed and the fields concerned by the operation of these functions. This ensures that clients are provided with an accurate and unambiguous description of the areas of capability within which the certification body is accredited.

5.3.2 For an extension of scope, accredited CB shall formally apply to the Secretariat using the official application form. Each request for an extension of scope will be individually reviewed and a decision on whether or not the extension of scope requires additional assessment will be determined by the Secretariat.

5.3.3 The precise details of the accredited scope will be identified on a schedule accompanying STANDARDS MALAYSIA Certificate of Accreditation.

Note: See Section 6.3.2 in the event that assessors' findings require scope to be redefined or reduced.

- 5.3.4 Full agreement should be reached between STANDARDS MALAYSIA and the certification body on the scope before assessment takes place. This is important in order to help the assessment team to:
- focus their attention on those areas of activity appropriate to its application
 - operate effectively
 - avoid possible misunderstandings
 - facilitate the preparation of assessment report
 - basis for the preparation of certificate of accreditation and its accompanying schedule or scope

6 THE CONDUCT OF ASSESSMENT

6.1 The assessment procedure

Stage 1 System assessment is normally a function of STANDARDS MALAYSIA Secretariat or STANDARDS MALAYSIA appointed lead assessor. A written report on documentation review will be provided to the applicant CB who will then make the necessary adjustments, if any, required by STANDARDS MALAYSIA Secretariat or STANDARDS MALAYSIA lead assessor assigned to perform the task.

Normally progression from Stage 1 to Stages 2 and 3 can only be done when such adjustments, including corrective actions, if any, have been carried out.

Aside from Stage 1 system assessment, the next important phase of the assessment is the compliance assessment (Stage 3) where STANDARDS MALAYSIA assessors observe the CB putting the procedures into practice:

- (a) in their own administrative areas
- (b) in the conduct of certification audits, and
- (c) in the ongoing surveillance of certified organisations.

6.2 Opening meeting

6.2.1 The on-site assessment of CB shall commence with an opening meeting involving the senior management of the CB. Its purpose is to:

- (a) confirm the objectives of the assessment and the scope of activities to be covered;
- (b) confirm the audit programme including on-site witnessing of CB auditors in action
- (c) make arrangement for reporting the outcome of the assessment in the form of the final report

The opening meeting is held on arrival and immediately before the assessment commences. It is intended to enable the team and the CB's representatives to become acquainted, and to clear up any difficulties or confusion about the purpose of the assessment and what is expected of the CB during the visit. It is chaired by the Lead Assessor.;

6.3 Progress of Assessment

- 6.3.1 The next stage of the evaluation after the opening meeting will involve detailed evaluation of the administration of the CB's scheme. This involves a process of discussions and interviews with the full-time secretariat of the scheme, and examination of the scheme's implementation of its documented policies and procedures to determine compliance with STANDARDS MALAYSIA relevant Accreditation Criteria.
- 6.3.2 During the course of the assessment, if it has become apparent that the CB is not really in a position to achieve accreditation in certain areas within the originally conceived scope, the Lead Assessor shall bring this matter up at the final closing meeting with the CB's senior management to suggest a suitably reduced, or redefined scope, within which the CB has satisfactory resource competence or coverage.
- 6.3.3 The assessment team shall go about its assessment by following the assessment programme or the agreed and readjusted programme.
- 6.3.4 The object of assessment is to establish by observation whether the work of the CB is being carried out in accordance with the Accreditation Criteria. Any such observations must be fair and must also be seen to be fair. They must therefore be based on objective evidence of deficiencies in operating procedures, evidence which can be logged and verified. To secure the greatest possible agreement on the facts, and to avoid subsequent dispute, assessors are provided with Nonconformity Report Forms for making an agreed record of any occurrence or observation which may indicate a failure to comply with the accreditation criteria and requirements.

7. RECORDING OBSERVATIONS/NON-CONFORMITIES

- 7.1 Nonconformity report (NCR) forms shall be used by STANDARDS MALAYSIA assessors to record instances where the CB's arrangements do not comply with the accreditation criteria or the CB's documented quality system. These will form part of the evidence on which the Lead Assessor's proposals to STANDARDS MALAYSIA will be based.
- 7.2 The categorisation of nonconformity is done by the lead assessor as a separate exercise, aided by advice from the assessment team, before formal presentation to the CB's management. The assessors will need access to a separate room for this exercise, so that the observations and their categorisation may be discussed away from the CB staff.

8. WITNESSING OF CB'S AUDITORS CONDUCTING AUDITS

- 8.1 Arrangement for witnessing CB's auditors in action should be planned ahead by the STANDARDS MALAYSIA Secretariat, the CB and the Lead assessor during the drawing up of assessment programme. Whatever the case, the following administrative arrangements are necessary:
- (i) The CB to seek prior agreement of any client concerned and shall explain the reason for the presence of the STANDARDS MALAYSIA assessors, and assure that the team's presence will have no bearing on the outcome of the CB's own audit.

- (ii) Once consent is given, the CB shall communicate to the CB's client together with a list of essential information required by the STANDARDS MALAYSIA assessment team and such information shall be given to the Lead Assessor well in advance of each visit.
- 8.2** STANDARDS MALAYSIA requires applicant and accredited certification bodies to have an enforceable arrangements with organizations holding STANDARDS MALAYSIA accredited certificate that commit the holder of the accredited certificate to provide, on request, access to STANDARDS MALAYSIA assessment teams to witness the certification body's audit team performing an audit at the organisation's site.
- 8.3** Certification Bodies and certified organisation should be aware, that failure to witness an audit or an auditor in a particular scope sector may ultimately lead to STANDARDS MALAYSIA removing that scope sector from the accreditation scope.
- 8.4** The assessment team shall assess the CB's auditors for the following:
 - (i) compliance with CB's procedures;
 - (ii) whether CB's audit team membership complies with CB's and STANDARDS MALAYSIA procedures; and
 - (iii) auditor personal attributes
- 8.5** The STANDARDS MALAYSIA assessor(s) will follow the CB's auditor(s) during the whole of the audit, he will take notes, examine documents or other items, but will ask no questions and make no comment until after the closing meeting between the CB's auditors and the client.
- 8.6** The total number of witness audits for the CB concerned shall be completed before the expiry date of accreditation. Should the CB be unable to do so, STANDARDS MALAYSIA reserves the right to initiate suspension.

9. WRITING OF SUMMARY REPORT

- 9.1** After the assessment team has completed the compliance assessment, the results will be combined with those of the system assessment, allowing an overall impression to be gained of the CB's competency over the scope of accreditation sought.- At this stage, the Lead Assessor can complete the Summary Report Form taking into account his own findings and those of any other assessors involved.
- 9.2** The Summary Report Form should record the assessors' findings, any matters needing corrective action and the Lead Assessor's proposal for accreditation. Proposals may be for unconditional acceptance, for acceptance to be deferred until the nonconformities have been remedied, or for rejection. The Summary Report should make it clear which of these proposals is being made.
- 9.3** The summary report prepared and signed by STANDARDS MALAYSIA lead assessor shall be handed over to the CB's representative on the last day of the assessment visit. This should contain the main conclusions and any agreed corrective actions needed to recommend award of accreditation.

- 9.4 A summary report at the end of a surveillance assessment may not include a discussion on witnessed audits carried out. The witnessed audit may be reported separately.
- 9.5 If, in the opinion of the assessor with specialised experience, there is any reason to doubt the CB's competence against the scope of accreditation sought, for example, through lack of experienced staff, this should be noted in the Summary Report with a recommendation for remedial action.

10. CLOSING MEETING WITH CB'S SENIOR MANAGEMENT

- 10.1** The purpose of the final meeting is to enable the Lead Assessor to present the CB with a brief summary of the results of the assessment, to inform the CB of his proposal for accreditation and to point out any corrective action that may be called for a condition of accreditation. No matters should be included in the formal presentations that do not appear in the Summary Report.
- 10.2** The Lead Assessor will liaise with the STANDARDS MALAYSIA representative and the CB to convene a closing meeting, during which he will present to CB's management a brief summary of the results of the combined system and compliance assessments, inform the CB of his proposal for accreditation and point out any corrective action that may be called for as a condition of accreditation. A representative of the STANDARDS MALAYSIA Secretariat will normally be present at this meeting, to answer any points of a policy nature.
- 10.3** During this closing meeting, the Lead Assessor shall:
- (a) thank the CB for their assistance and cooperation and refer to individuals as appropriate
 - (b) emphasise that because the assessment did not cover every aspect of the CB's activities or is done on sampling basis, it does not follow that no nonconformity exist in areas where none have been reported;
 - (c) explain the significance of categories of nonconformities;
 - (d) present all the nonconformity report forms, if any, that have been raised and ensure that they are fully understood by the management teams;
 - (e) answer any questions raised on points of clarification
 - (f) secure any corrective action that the certification body intends to carry out, and the agreed time scale for its completion. If for some reasons, agreed corrective actions could not be secured or the CB concerned is yet in a position to propose the appropriate corrective actions, the CB is given 10 working days to response to STANDARDS MALAYSIA on the corrective actions on nonconformities raised;
 - (g) obtain the signature of the CB or management representative on the summary report form;

- (h) advise the CB the acceptability of transmittal to STANDARDS MALAYSIA of the necessary documented evidence that the corrective action on nonconformities raised;
- (i) advise the CB and then the Secretariat whether a full re-audit , an partial audit or verification audit is required before accreditation is granted or defer verification until the first surveillance audit;
- (j) leave original copies of the individual NCR form and the summary report with the management;
- (k) close the meeting.

11. ASSESSMENT SUMMARY REPORT

- 11.1** A summary report on the outcome of the assessment will be prepared by the team leader and promptly brought to the attention of the CB.
- 11.2** The assessment report contains comments on competence and conformity, and identifies non-conformities, if any, to be resolved in order to conform with all STANDARDS MALAYSIA Accreditation Criteria.
- 11.3** The CB is invited to respond to the assessment report and to describe the specific actions taken or planned to be taken, within a defined time, to resolve any identified non-conformities.

12. FINAL ASSESSMENT REPORT

- 12.1** A comprehensive report, including the assessment team's overall conclusions and proposal for accreditation shall be prepared by the team leader, and submitted to the STANDARDS MALAYSIA Secretariat.
- 12.2** If the final report differs from the summary report referred to in Section 9 above, an explanation of any differences from the previous report shall be highlighted by the Lead Assessor to the STANDARDS MALAYSIA Secretariat.
- 12.3** A copy of the report shall be forwarded by the Secretariat to the Accreditation Review Panel for their deliberation and final recommendation for accreditation to the Director General.

13 FACTORS AFFECTING RECOMMENDATION FOR ACCREDITATION

- 13.1** In deciding on his proposal for accreditation, the Lead Assessor will take into account of the following:
 - (a) the number and seriousness of the individual nonconformities found during the assessment.
 - (b) the adequacy of control of the certification body's management to operate its certification / registration system and reach proper conclusion as to awarding certificate.

- (c) the range of knowledge and experience of the assessed certification body relevant to the scope of accreditation sought
- 13.2 Where competence is established and no nonconformities are found or where they are few and have been closed out before the closing meeting, the Lead Assessor will normally proposed that accreditation be awarded.
- 13.3 Where competence is established and some minor nonconformities are found and are still outstanding at the closing meeting, the Lead Assessor will normally proposed accreditation conditional upon the satisfactory completion of the agreed corrective action at an agreed period and the CB provides STANDARDS MALAYSIA with evidence that the nonconformities have been corrected.
- 13.4 The period allowed for correcting nonconformities should be specified. The period allowed for sending the evidence of the corrective action for minor nonconformity should not, except in very unusual circumstances, be more than 3 months; and sending the evidence of corrective action for major nonconformity should not be more than 1 month.
- 13.5 Depending upon the nature of the nonconformities, evidence that the corrective action has been taken may be provided by submitting the necessary documents to STANDARDS MALAYSIA. The Lead Assessor shall then assess the proposed corrective action following advice from the CB but no later than the agreed period. The Lead Assessor shall advise the CB whether verification visit is required before accreditation is granted or defer verification until the first surveillance audit.
- 13.6 When the CB could not perform the necessary corrective actions and has not submitted the evidence to STANDARDS MALAYSIA within the agreed time frame, where necessary, a verification visit may be made (e.g to verify the satisfactory implementation of the corrective action). Should the CB be unable to close out the nonconformity(ies) within 3 months, STANDARDS MALAYSIA reserves the right to initiate suspension pending appropriate corrective action. In order for STANDARDS MALAYSIA to maintain its credibility and to fulfill IAF MLA requirements, STANDARDS MALAYSIA also reserves the absolute right to terminate the application as unsuccessful.
- 13.7** Where,
- (a) competence is not established,
- (b) one or more major nonconformities is found,
- (d) the number and seriousness of the nonconformities found are such that the whole of the CB's quality system and organisation is demonstrably inadequate,
- the Lead Assessor's proposal will be that accreditation is refused.
- 13.8** With regard to the above, the Lead Assessor in his assessment report shall indicate to the Accreditation Review Panel what action is required on the part of the CB, and what verification is required before STANDARDS MALAYSIA could reconsider the application for accreditation.

14. DECISION ON ACCREDITATION

- 14.1 The decision on whether or not to grant accreditation shall remain with the Department of Standards Malaysia and such authority cannot be delegated. The decision on accreditation shall be based on the assessment findings and the recommendation of the Accreditation Review Panel.

15 SURVEILLANCE AND REASSESSMENT

- 15.1 The purpose of periodic surveillance and reassessment is to determine whether a CB is continuing to comply with the accreditation criteria. The general approach described in the previous paragraphs should be followed for the conduct of surveillance or reassessment. Any failure on the part of the accredited body to do so, may result in a reduction of scope, suspension or withdrawal of its Certificate of Accreditation.
- 15.2 Except for the larger CBs, as a general guide, surveillance visits will usually be undertaken by one or two assessors. Normally assessors will not be expected to check the whole of the CB activities for which a CB is accredited, during a single visit. .
- 15.3 Surveillance on site assessment will be planned taking into account other surveillance activities such as;
- a) enquiries from STANDARDS MALAYSIA to the CB on aspects concerning the accreditation
 - b) reviewing the declarations of the CB with respect to what is covered by the accreditation
 - c) requests to the CB to provide documents and records (e.g. audit reports, results of internal quality control for verifying the validity of the CB services, complaints records, management review records)
- 15.4 The surveillance should take into account the internal audit programme and the reliability that can be attributed to it.
- 15.5 Surveillance visits will generally be arranged at the frequency of six-month intervals. However, after the first cycle of 3 years, the frequency of surveillance will be reduced as follows:
- i) Surveillance I : 11 months after the renewal of its Certificate of Accreditation
 - ii) Surveillance II : 11 months from Surveillance I
 - iii) Re-assessment : 10 months from Surveillance II
- 15.6 However, the frequency of visits will vary according to circumstances and visits at shorter intervals than usual may be required in certain cases such as recommendation of the Lead Assessor in his recommendation report or by the ARP, or visits without prior warning, for example, if there is reason to believe that standards may have deteriorated.
- 15.7 The surveillance program shall include witnessing of audits carried out by CB's auditors as determined by Annex 1.

- 15.8 A reassessment visit will provide the opportunity for a more comprehensive examination of a CB's performance. The procedure for reassessment shall be that for initial assessment and be conducted in accordance with this document.
- 15.9 The Lead Assessor at the conclusion of a surveillance or reassessment visit, as with an initial assessment, will be required to make a proposal on the continuing accreditation of the CB. Depending on the number and seriousness of any nonconformities found the Lead Assessor will propose whether accreditation should be:
- (a) maintained unconditionally (this recommendation will only be made when no nonconformities have been found);
 - (b) maintained on the understanding that any non-compliances found are corrected within a specified period (usually not more than 4 weeks);
 - (c) suspended until the CB has corrected the nonconformities found within a specified time period (a recommendation that the accreditation of a CB is suspended will almost certainly require a further visit to confirm that the nonconformities have been corrected);
 - (d) withdrawn (a recommendation that accreditation be withdrawn will involve the CB in having to make a new application and undergoing a further full assessment if it wishes to regain its accreditation).

16 POST ASSESSMENT

- 16.1 Accreditation shall not be granted or maintained until all nonconformities have been corrected and the correction verified.

ANNEX 1

GUIDELINES FOR THE SELECTION OF WITNESSING OF AUDITS

1. INTRODUCTION

1.1 The objective of the witness is to:

- (i) Assess an audit team to determine whether or not the team:
- applies the procedures and instructions of the certification body;
 - members exhibit the characteristics of an auditor as detailed in ISO 19011
 - has the required expertise of the sector in which the audit is being undertaken;
 - applies appropriate expertise in the correct sense;
 - undertakes the audit effectively, and
- (ii) Test the effectiveness of the applicant/accredited body internal monitoring of auditor competence.

2. GUIDANCE

2.1 Witnessing associated with new applicants shall include an initial/reassessment per programme. Where this policy may cause unnecessary delays to the accreditation of the applicant, two surveillance audits may be witnessed as an alternative.

2.2 Table 1 details the witnessing that will be undertaken as part of the maintenance activity associated with each accredited programme.

Table 1

WITNESS AUDITS					
Certificates Issued per program	1 - 100	101 - 500	501- 1000	1001- 2000	2001+
Annual number of witnessed audits per program, minimum	2	3	4	5	6

2.3 The above requirements may be increased on a case-by-case basis by the Accreditation Review Panel following review of information provided by the audit team and the Secretariat to support the variation. One of the primary considerations for either an increase or decrease in the number of witnessed audits is the confidence that can be established in the auditor monitoring system.

2.4 STANDARDS MALAYSIA assessment teams shall witness the complete audit associated with an initial application. The duration of witnessing associated with

maintenance and scope extension shall be left up to the discretion of the Lead assessor. The Lead assessor shall ensure that the coverage is sufficient to ensure that the witnessing team is able to establish confidence in the certification body's procedures to satisfy the applicable requirements of the Accreditation Criteria.

3. IMPLEMENTATION

3.1 The Secretariat shall liaise with new applicants to establish availability of audits that may be witnessed. The applicants shall submit list of organisations available for on-site witnessing of performance of certification auditors at organisations' premises. The list shall include dates of audits, names of auditors and NACE code of organizations. The Secretariat shall select the number of audits that should be witnessed by reference to paragraph 2.1. The actual audits to be witnessed shall be determined, from those that are available, by using Para 3.3 as a guide.

3.2 For accredited bodies, Secretariat staff shall check STANDARDS MALAYSIA records on the date of granting accreditation for each accreditation programme to establish the total number of certificates that have been issued per accredited programme, annually. The number of witnessed audits for the next twelve-month period shall then be determined by reference to Table 1. In determining the organisation to be witnessed, Secretariat staff shall use Para 3.3 as a guide.

Example: A certification body has been accredited for both their QMS and EMS programmes on 28 October 2006 and has issued between 101-500 certificates for each programme, then the number of witness audits to be conducted from 28 October 2006 to 28 October 2007 will be six audits (three for each programme).

3.3 The following list shall be used as a guide to the selection of witnessed audits:

- risk to the public, environment, occupational health and safety
- technical risk of sector
- number of auditors
- coverage of auditing staff over their assessed scope of competence
- performance of auditors already witnessed
- adequacy of auditor training and selection procedures as found by the audit
- concentration of certificates
- availability of audits
- geographical coverage
- availability of STANDARDS MALAYSIA staff and experts
- certification standard e.g ISO 9001, ISO 14001
- confidence in applicant/accredited body's auditor monitoring system.