

NATL INST. OF STAND & TECH



A11106 891881

NIST
PUBLICATIONS

REFERENCE

NISTIR 6440
2004 ED

NVCASE Program Handbook

Procedures for Obtaining NIST Recognition as an Accreditor

Jogindar S. Dhillon
David F. Alderman

NIST

National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

OC
100
.U56
#6440
2004

NISTIR 6440
2004 ED

NVCASE Program Handbook

Procedures for Obtaining NIST Recognition as an Accreditor

Jogindar S. Dhillon
David F. Alderman
*Standards Services Division
Technology Services
National Institute of Standards and Technology
Gaithersburg, MD 20899-2150*

December 2004



U.S. Department of Commerce
Carlos M. Gutierrez, Secretary

Technology Administration
Michelle O'Neill, Acting Under Secretary for Technology

National Institute of Standards and Technology
Hratch G. Sewerjian, Acting Director

Table of Contents

1.0	INTRODUCTION	1
1.1	Definitions.....	1
1.1.1	Authorized Representative.....	1
1.1.2	Evaluation	2
1.1.3	Assessment/Audit	2
1.1.4	Witness Audit	2
2.0	REQUESTING EVALUATION	2
2.1	Who May Apply.....	2
2.2	Application Package	2
2.3	NIST Acknowledgment	3
3.0	FEES	3
3.1	Application Fee.....	3
3.2	Re-assessment Period and Fee	3
3.3	Additional Costs	3
3.4	Refund Policy.....	3
3.5	Payment of Fees.....	4
4.0	NVCASE EVALUATION PROCESS	4
4.1	Assessment Team.....	4
4.2	Ethics - Confidentiality	4
4.3	Quality System Review and Evaluation.....	5
4.4	On-site Assessment.....	5
4.4.1	Entrance Meeting	5
4.4.2	Walk Through and Staff Introductions	6
4.4.3	Assessment.....	6
4.4.4	Development of Draft Assessment Report.....	6
4.4.5	Exit Meeting.....	6
4.5	Witness Audits/Assessments	6
4.6	Final Report	7
4.7	Applicant Response to Assessment Report/Deficiency Notification.....	7
4.8	Recognition Decision.....	7
4.9	Surveillance.....	8
5.0	PROGRAM ACTIONS	8
5.1	Granting Recognition.....	8
5.2	Denial.....	9
5.3	Suspension	9
5.4	Termination.....	9
5.4.1	Voluntary Termination.....	9

5.4.2	Involuntary Termination	9
5.4.3	Involuntary Termination Procedures.....	10
5.5	Options in Response to an Adverse Action	10
5.6	Appeal.....	11
5.7	Scope Amendment (Extension or Reduction)	11
5.7.1	Scope Extension	11
5.7.2	Procedures for Scope Extension	12
5.7.3	Recognition Decision	12
5.7.4	Procedures for Scope Reduction	12
5.7.5	Involuntary Scope Reduction	12
6.0	OBLIGATIONS OF A RECOGNIZED ACCREDITOR	13
6.1	Continuous Conformance	13
6.2	Proper Use of Accredited Status and Claims.....	13
6.3	Keeping NVCASE Informed	14
6.3.1	Organizational Changes	14
6.3.2	Accredited Body Status.....	14
6.3.3	Recognized Accreditors List.....	14
7.0	ACCREDITOR REQUIREMENTS	14
ANNEX A -	Requirements for accreditors of testing laboratories.....	16
ANNEX B-	Requirements for accreditors of certification bodies	18
ANNEX C -	Requirements for accreditors of management system registrars.....	20

1.0 INTRODUCTION

This handbook provides guidance to bodies desiring to obtain recognition as an Accreditation Body (accreditor) under the National Voluntary Conformity Assessment Systems Evaluation Program (NVCASE). It explains the generic procedures, conditions, and requirements for NIST recognition. NIST established NVCASE in 1994. Its operating rules are found at 15 CFR Part 286. This 2004 edition supersedes the 2002 edition.

The NVCASE program supports NIST obligations as a Designating Authority for Conformity Assessment Bodies (CABs) as specified in inter-governmental Mutual Recognition Agreements/Arrangements (MRAs) with other nations (e.g., the U.S./European Union (EU) MRA, the Asia Pacific Economic Cooperation (APEC) MRA, Inter-American Telecommunications Commission (CITEL) MRA). It also supports requests from other Government regulatory agencies when CAB evaluation is required, (e.g., the Federal Communications Commission (FCC) Telecommunications Certification Body (TCB) Program, FCC Docket 98-68. In addition, industry can request to set up a program in order to fulfill a need in the market place facilitating trade.

A CAB that has been accredited by a NIST-recognized accreditor through the NVCASE evaluation process can request CAB designation under one of the MRAs that have been implemented between the United States and foreign governments. Under the domestic program, NIST recommends a conformity assessment body, which has been accredited by a NIST-recognized accreditor, to an appropriate Regulatory Agency. Qualified CABs may then test and/or certify products either to satisfy mandatory foreign requirements or to support domestic or international regulatory programs.

Prior to September 2004, the requirements described in this handbook were based upon ISO/IEC documents Guides 58 and 61. Since publication of ISO/IEC 17011 standard, this Handbook has been revised to conform to the requirements of the new standard. Annexes A, B, and C provide criteria for the type of accreditation offered by an applicant, namely laboratory accreditation, certification body accreditation, and management system registrar accreditation, respectively. Technical requirements for the scope of accreditation under a particular MRA agreement or regulatory program are contained under "Specific Requirements" in the annexes.

NIST invites readers/users to offer comments, suggestions for clarification or improvement, or other constructive feedback regarding the NVCASE program or this document.

1.1 Definitions

For purposes of this handbook the following definitions are used.

1.1.1 Authorized Representative: An employee of an accreditor with the authority to make binding commitments on behalf of the organization. The authorized representative is the person who is responsible for all communications with NVCASE and who ensures that the accreditor complies with all NVCASE program requirements.

1.1.2 Evaluation: The overall process of NVCASE review and appraisal of an accreditor, to determine if an entity (an accreditor, a laboratory, a certifier, or a registrar) satisfies all applicable requirements (e.g., quality system review, results of on-site assessment, witness audits, applicant proposals to correct non-conformities, etc.)

1.1.3 Assessment/Audit: The NVCASE on-site review of an accreditor, or the on-site review of a client of an accreditor (i.e., laboratory, certifier, or registrar) by the accreditor. (The term “assessment” is normally used in conjunction with review of laboratories and product certifiers; “audit” is normally used in conjunction with review of quality systems.)

1.1.4 Witness Audit: The observation by NVCASE staff and/or its designated technical experts/assessors of an applicant accreditor's assessor(s)/auditor(s) performing an assessment/audit of a client's facilities.

2.0 REQUESTING EVALUATION

2.1 Who May Apply

Any domestic accreditor, government or private, that wishes to be recognized may submit an application for evaluation to NVCASE. The application must be completed and signed by the Authorized Representative of the accreditor.

2.2 Application Package

An application package may be requested from the NVCASE Program Manager, NIST, 100 Bureau Drive, Stop 2150 Gaithersburg, Maryland, 20899-2150. The package may include the General Application, the Program Handbook, and other pertinent information needed for understanding of the program and requirements. Requests may be made by mail, or by fax to: (301) 975-5414.

All application forms must be completed in English with sufficient information and detail to fully describe the accreditation organization. The applicant may submit any applicable enclosures or attachments appropriate to describe capabilities or resources.

An application may be amended at any time prior to a final decision. However, depending upon the nature of changes, the applicant may incur delay and additional cost in order for NVCASE to evaluate such changes. An application may be withdrawn at any time prior to a final decision. If an application is withdrawn, the entity may later reapply. (See section 3.4 for NVCASE's refund policy).

2.3 NIST Acknowledgment

NVCASE will acknowledge receipt of each application, confirm payment of the application fee, and specify to the applicant the next step(s) in the evaluation process. If necessary, further information may be requested. If an applicant is deemed to be ineligible, all submitted information and fees will be returned with an explanation of the ineligibility.

3.0 FEES

NVCASE Program operates on a cost-reimbursable basis; fees are charged to users for services rendered.

3.1 Application Fee

The application fee is based on the scope and type of evaluation. Upon request, NVCASE will provide an estimation of the fees that will be charged to process a specific application. The fees may include consultant cost, travel costs, contract administration, and any other incidental expenses in the course of evaluation. Evaluation will begin upon the submission of the application and the estimated fee. Once the evaluation has been completed, the applicant will either be billed for, or refunded, the difference between the amount submitted and the actual costs incurred by NVCASE.

3.2 Re-assessment Period and Fee

Each recognized accreditor will undergo a re-assessment visit every two years. The re-assessment fees are based on the scope and type of evaluation. Upon request, NVCASE will provide an estimation of the fees that will be charged to conduct the re-assessment. Re-assessment begins upon submission of the application form and the fees.

3.3 Additional Costs

From time to time, additional NVCASE evaluation activities may be necessary. Since these activities are not predictable (e.g., special assessments resulting from citation of major deficiencies, investigation of complaints received, changes in management or location of a participant, etc.), attendant costs will be billed to participants as appropriate. The costs incurred for on-going surveillance activities must be paid in advance by the recognized accreditor.

3.4 Refund Policy

If an applicant is deemed to be ineligible or withdraws the application prior to any action by NVCASE described in section 4, the application fees will be fully refundable. Once NVCASE has begun an evaluation and has incurred costs, it will refund the application fees

minus these incurred costs. Refunds must be requested from the NVCASE Program Manager.

3.5 Payment of Fees

All fees must be paid before recognition can be granted. An applicant must also pay all fees for costs incurred in processing the application or in conducting the reassessment even if recognition is not granted.

4.0 NVCASE EVALUATION PROCESS

The process of evaluating an applicant consists of a number of activities that must take place prior to and after granting recognition. The process begins with an initial review of the application followed by review of the applicant's quality system (document review), on-site assessment/reassessment of the premises, witness audits of assessments performed by the applicant's assessors, writing an assessment report, review of applicant response to the assessment report, and final evaluation and decision. Re-assessments of recognized accreditors are conducted every two years as specified in Section 3.2. Surveillance activities are conducted as specified in Section 4.9.

4.1 Assessment Team

An assessment team consisting of one or more NVCASE staff members and one or more appropriate technical experts conducts the assessment. In some instances selected observers may also be involved, such as representatives of cognizant regulatory agencies, special technical consultants, persons participating in cooperative assessments, NIST staff for training.

4.2 Ethics - Confidentiality

All persons involved in the evaluation process, including NVCASE staff, the assessment team, review panel, observers, etc., will maintain the confidentiality of all information and conversations pertaining to the evaluation. Such information will be disclosed only as required by law. All persons involved in the evaluation process are required to sign an ethics statement. The ethics statement contains provisions that address confidentiality of assessment information, freedom from conflict-of-interest, impartiality, and other requirements needed to ensure the integrity of the assessment process. All persons participating in the evaluation process will also be required to adhere to a strict code of conduct.

All persons participating with the evaluation process who review information considered proprietary shall take all reasonable measures necessary to maintain the confidentiality of that information. Refusal by an applicant to provide access to all materials needed for the conduct of the assessment may result in denial of recognition.

4.3 Quality System Review and Evaluation

Each applicant must submit copies of its quality documentation for review and evaluation. The applicant will complete a checklist, based on ISO/IEC 17011, providing cross-reference to each clause where compliance can be validated in the applicant's documents. The applicant shall provide all supporting documents. The documentation must show that the quality system is capable of ensuring an adequate level of performance and quality.

Before visiting the applicant's facilities for on-site assessment, NVCASE staff in coordination with a technical expert/assessor, will review applicant's documents for completeness. NVCASE may request that the applicant provide clarification of items contained in the documentation or may request additional information.

4.4 On-site Assessment

An on-site assessment of an applicant's facilities is conducted prior to initial recognition and every second year thereafter unless the recognition is terminated. The assessment includes an on-site review of selected procedures and operations for all sites involved in accreditation activities covered by the recognition.

NVCASE will contact the applicant to arrange a mutually convenient date for the visit, and to develop an agenda, and will inform the applicant of the identity of the assessment team. The applicant may appeal the inclusion of any member of the team. Such appeals must be received in writing at least 20 working days prior to the scheduled date of the visit and must include the reason why the team member is unacceptable.

If the applicant's accreditation personnel normally speak a language other than English (or any documentation needing review is not available in English), either NVCASE or the applicant may arrange for an independent interpreter to accompany the assessment team. Any cost incurred by NVCASE for interpretation services will be charged to the applicant.

The normal sequence of a NVCASE on-site assessment is:

4.4.1 Entrance Meeting: Upon arrival at the applicant's premises, the assessment team meets with management to discuss the scope and content of the assessment and to agree on a plan of action. The meeting allows all parties to become acquainted and gives the assessment team the opportunity to understand the applicant's organizational structure. It is recommended that a staff member be designated as the liaison between the applicant and the assessment team.

4.4.2 Walk Through and Staff Introductions: The assessment team briefly tours the premises to familiarize themselves with its layout and to become acquainted with staff

members who are responsible for areas of interest.

4.4.3 Assessment: The assessment focuses on ascertaining if the accreditor's actual operation is the same as that described in the accreditor's quality documentation. All procedures involved in the accreditation process are reviewed. All phases of the operation that are relevant to the scope of the request for recognition are subject to review. The criteria contained in Section 7 of this Handbook are used to guide the review and to ensure uniformity of assessment from one applicant to another.

The assessors review relevant documents and files, observe specific operations, and interview staff members on such topics as: information and reporting systems; database systems; files, records, documents relating to accreditation procedures, policies, and activities; assessment reports of selected clients; final evaluation reports on which accreditation was based; appeals and complaints regarding the accreditor; and auditor qualification, training, and competency records.

All staff involved in the functions of accreditation must be available for interview. The auditors/assessors, and persons (accreditation committee) who make accreditation decisions, need not be on-site but must be able to be contacted for interview.

4.4.4 Development of Draft Assessment Report: The assessment team develops a draft report that includes a comprehensive review of its findings. The report will include assessment results from both the on-site visit of the applicant and any witness audits. Any deficiencies requiring resolution are clearly identified in the report. [Note: The terms "findings" and "non-compliances" are used interchangeably.]

4.4.5 Exit Meeting: Once the assessment team is satisfied that the on-site assessment is complete and the team has developed a draft report, the team holds a meeting with the applicant's management representatives to discuss the findings in the draft report. At the conclusion of this meeting, the Authorized Representative of the Accreditor must sign the draft report, acknowledging the discussion of the findings and the applicant's responsibility to respond to all identified deficiencies within a specified time.

4.5 Witness Audits/Assessments

As part of the evaluation process, an applicant must allow NVCASE assessment team members to witness the applicant's auditors/assessors performing an assessment/audit of a client's facilities. NVCASE staff will discuss with the applicant the number and identity of the witness audits to be performed. The applicant must pay all applicable costs incurred by NVCASE in conducting witness audits.

4.6 Final Report

After the assessment, the NVCASE staff prepares a final report and forwards it to the

applicant. The final report will be essentially the same as the draft report unless additional information relevant to the assessment has been uncovered after the completion of the on-site assessment, or other issues have arisen that require clarification.

The final report normally includes all definitive findings of the assessment. However, if additional information surfaces that is significant and relevant to the assessment after the issuance of the final report, a supplementary report may be necessary. Any supplementary report that requires action will be promptly forwarded to the applicant.

4.7 Applicant Response to Assessment Report/Deficiency Notification

The applicant must provide a written response to NVCASE on all identified deficiencies. The written response must include detailed information on all completed corrective actions and any proposed plans to be taken to resolve cited deficiencies. Plans must include detailed information on the specific actions to be taken and the time frames or dates when the actions are to be conducted and/or completed. In some cases, an additional on-site visit may be necessary to observe stated resolutions of deficiencies. Costs associated with the conduct of such additional audits will be billed to the applicant.

New applicants are generally expected to resolve deficiencies within 90 days. NVCASE must be informed if additional time is required. If deficiencies are not corrected within 90 days, or within a mutually agreed upon time period, NIST may terminate further evaluation and refund any unused funds. The applicant may reapply after paying necessary fees. If the applicant's actions cause the evaluation process to take longer than one year, additional administrative costs may be incurred.

Accreditors holding a current NIST recognition must resolve all deficiencies cited within 30 days of the receipt of a deficiency notification. If any cited deficiencies are not resolved within 30 days of the receipt of the notification, recognition may be suspended until full conformance is demonstrated.

4.8 Recognition Decision

Upon completion of all evaluation activities, NVCASE will convene an evaluation panel to review all information collected regarding an applicant and make a final decision on the appropriate recognition action. (See 5.0 Program Actions)

The decision is based on the review and evaluation of all materials submitted by the applicant, reports covering the quality system review, on-site assessment(s) report, witness audit reports, and deficiency resolution information.

The panel consists of NIST staff, selected technical experts, and representatives of cognizant regulatory agencies and representatives of joint evaluation bodies, as appropriate. Observers from NIST staff who are not the voting members of the panel may also be invited.

The panel will consist of a minimum of three voting members, including at least one technical person, preferably from a federal or state government regulatory agency. The NVCASE assessor will present the results of the on-site evaluation, witness audit(s) reports, deficiency reports and their resolutions by the candidate accreditor, and will make a recommendation for a decision. The presentation will be followed by a question/answer and discussion session. At the end of the discussion period, the NVCASE assessor will ask for a vote on his/her recommendation. Consensus is always the desired goal. However, one-hundred percent agreement may not always be possible. If a formal vote is necessary, a minimum of two-thirds favorable vote by the voting panel members is required for recognition of the candidate accreditation body. In addition, at least one technical panel member's vote must be favorable.

4.9 Surveillance

NVCASE may, at its discretion, whether or not for cause, conduct a full or partial on-site visit or other forms of surveillance of a recognized accreditor or any accredited body to observe or verify conformance with program requirements. Any deficiencies noted as a result of surveillance must be responded to in accordance with Para. 4.7.

On-going surveillance may be conducted as agreed upon with the recognized accreditor which may include periodic meetings or teleconferences with accreditor's staff to review on-going activities. These activities may include changes in: personnel, contact information, changes in policies and procedures, internal audits, management reviews, complaints and appeals logs, updates on accredited bodies, etc.

5.0 PROGRAM ACTIONS

NVCASE may grant, deny, suspend, or terminate recognition of an accreditor.

5.1 Granting Recognition

An applicant who demonstrates conformance with all Program requirements will be granted recognition as having demonstrated the ability to evaluate and accredit bodies and to publicly attest to such bodies' conformance with NVCASE requirements. The applicant is provided with documentation stating the terms and conditions of the recognition and the specific Scope of Activities for which recognition is granted.

5.2 Denial

Recognition will be denied if an applicant fails to demonstrate conformance with the NVCASE Program requirements. NVCASE will notify the applicant in writing of its intention to deny recognition and the reason(s) for denial. An applicant is given 90 days to resolve all deficiencies that form the basis of the proposed denial. Unless resolution is

achieved in that time, the applicant will be denied recognition.

An applicant may appeal a denial by submitting a statement of reasons why recognition should not be denied to the NIST Director (See 5.6 Appeal.)

5.3 Suspension

If it is determined that a recognized accreditor temporarily cannot demonstrate conformance (e.g., a serious deficiency is uncovered during surveillance, or the accreditor has changed ownership or location, or other substantive reason emerges), NIST may suspend recognition until full conformance has again been demonstrated.

If recognition is suspended by NIST, the accreditor may neither grant any additional accreditations, nor conduct any other evaluation activities covered by the recognition after the date of the suspension. Within five days of receipt of notification of suspension, the accreditor must provide written notification to all bodies that it has accredited under the terms of the NIST recognition that the accreditor's NIST recognition has been suspended.

The accreditor's written notice shall state the effective date of its suspension and shall also inform the accredited bodies that their current status with NIST will not change unless the bodies contributed to the conditions which led to the accreditor's suspension or if, in NIST's judgment, a change is otherwise justified.

5.4 Termination

Termination of participation in the NVCASE Program of a recognized accreditor may be voluntary or involuntary.

5.4.1 Voluntary Termination: A recognized accreditor may at any time voluntarily terminate its participation in the Program by giving written notice to NVCASE and to all bodies it has accredited.

5.4.2 Involuntary Termination: NIST may terminate, fully or partially, the recognition of an accreditor whenever it deems such action to be in the public interest. Such an action may result if the recognized accreditor engages in fraud or other illegal activity, is unable to meet NVCASE requirements, or exhibits other factors detrimental to producing an acceptable accreditation program.

5.4.3 Involuntary Termination Procedures: NIST will notify the recognized accreditor in writing of the intent to terminate the recognition and the reason(s) therefore. The notice will state, as a minimum, that recognition is suspended as of the date of the notice, and that the accreditor may not grant any additional accreditations or conduct any evaluation activities covered by the recognition.

The recognized accreditor is given the opportunity to respond to or rebut stated reasons for termination or to correct any deficiencies which formed the basis of the proposed termination. If the basis for the termination is not reconciled within 30 days, or such longer time as NIST may allow, the termination becomes effective.

The recognized accreditor may appeal to the NIST Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, delay implementing the termination action pending a final decision by the Director. If recognition is terminated, the accreditor may neither state nor imply that it has NIST recognition, nor may it grant any accreditation covered by the terminated recognition.

NVCASE may send a written notice to all bodies accredited by the terminated accreditor informing them of the termination and the effective date. The notice shall inform all affected bodies that their accredited status will not change unless they contributed to the conditions which led to the suspension of the accreditor. They will be advised that, if they want to continue their accredited status, they should expeditiously seek accreditation from another NIST-recognized accreditor.

An accreditor whose recognition has been terminated may submit a request for re-evaluation when it believes that it can again demonstrate conformance with the NVCASE requirements.

5.5 Options in Response to an Adverse Action

If NVCASE proposes to deny, suspend, or terminate recognition, and the applicant or recognized accreditor has been so notified in writing, citing the specific reasons or elements of nonconformance with the requirements, the accreditor may choose to:

- a) Appeal the decision and request that recognition be granted or continued by providing appropriate justification.
- b) Submit additional information for further evaluation. If additional on-site visits, etc., are required, additional costs may be incurred by the accreditor.
- c) Accept the decision.

5.6 Appeal

An applicant or a recognized accreditor under the Program may appeal to the Director of NIST for any action taken against it. All appeals must be in writing and must include complete documentation setting forth the appellant's position. The appeal of an action must be filed with NIST within 30 days of that action.

Appeals should be addressed to: The Director, National Institute of Standards and

Technology, Stop 1000, Gaithersburg, Maryland 20899-1000. The applicant or recognized accreditor will be informed of the Director's decision within 60 days following receipt of an appeal.

5.7 Scope Amendment (Extension or Reduction)

A NIST-recognized accreditor under the NVCASE program may apply for scope amendment (extension or reduction). The types of scope extension/reduction available may relate to any of the following:

- (a) The requirements of a product certification program administered by a Federal agency (e.g., FCC's Telecommunication Certification Bodies Program)
- (b) Government-administered product certification requirements of an individual country signatory to a Mutual Recognition Agreement/Arrangement (MRA) that the United States Government has negotiated with that government (e.g., Industry Canada's product certification requirements under the Asia Pacific Economic Cooperation MRA for Telecommunications Equipment)
- (c) Product certification requirements of an industrial sector
- (d) Product categories (e.g., telecommunications equipment that includes fixed terminal equipment, radio, and transmitter equipment)

5.7.1 Scope Extension: A NIST-recognized accreditor may request an extension of its current scope of recognition by providing the following documentation to NVCASE:

- (i) A cover letter requesting the type(s) of scope extension
- (ii) Copies of any additional documents or documents that have been revised as a result of scope extension. These documents may include the revised Policy/Quality Manual, Procedures, and Forms etc. Provide a list of revised sections in these documents. There is no need to submit documents that have not changed and were included in the prior assessment.
- (iii) The name(s) and qualifications of the assessor(s)/technical expert(s) who have the capability to assess the expanded scope.

NVCASE will provide an estimate for the scope extension fee in conformance with Section 3.0 of this Handbook. The accreditor must pay the estimated fees to NVCASE before the request for scope extension can be acted upon.

5.7.2 Procedures for Scope Extension

- (i) Upon receipt of a request for scope extension, NVCASE will review the request and the documentation.

- (ii) If an on-site visit is necessary, NVCASE will inform the accreditor and schedule an on-site evaluation for scope extension at a mutually agreeable date. The on-site evaluation may be combined with a regularly scheduled audit.
- (iii) NVCASE will participate in at least one witness audit conducted by the accreditor's assessors that involves an assessment to the expanded scope being sought by the accreditor.

5.7.3 Recognition Decision: Upon successful completion of evaluation activities, NVCASE will obtain a panel decision in accordance with Section 4.8 of this Handbook. This decision will be communicated to the accreditor. If the scope extension is denied, the accreditor may appeal in accordance with Section 5.6 of this Handbook.

5.7.4 Procedures for Scope Reduction: A NIST-recognized accreditor may in writing voluntarily reduce its currently recognized scope.

- (i) The accreditor shall inform NVCASE for a voluntary scope reduction in a letter listing all the current scopes, specifying the scope that is to be reduced.
- (ii) The accreditor shall inform in writing all the Certification Bodies that are affected by its scope reduction.

5.7.5 Involuntary Scope Reduction: NVCASE may involuntarily reduce the scope of an accreditor if NVCASE determines that the accreditor is unable to comply with the requirements of a particular type of scope.

- (i) The matter will be discussed with the accreditor before taking this action.
- (ii) If the accreditor is not agreeable to reduce the scope as discussed by NVCASE then a surveillance visit will be required. NVCASE shall conduct the surveillance in accordance with Section 4.9 of this Handbook. The accreditor must pay the fees for the surveillance visit as assessed by NVCASE.
- (iii) The procedures for an accreditor's appeal of an adverse action shall be in accordance with Section 5.6 of this Handbook.
- (i) Upon a reduction in scope by NVCASE, the accreditor shall inform in writing all the Certification Bodies that are affected by its scope reduction.

6.0 OBLIGATIONS OF A RECOGNIZED ACCREDITOR

6.1 Continuous Conformance

It shall be incumbent upon a recognized accreditor to conform to all requirements throughout

the period of participation. Failure to maintain conformance is cause for suspension/termination of recognition.

Upon request, a recognized accreditor shall make available to NVCASE any document, information, or material related to the recognized accreditation activities.

6.2 Proper Use of Accredited Status and Claims

A recognized accreditor shall not make any claim which:

- a) constitutes or implies certification, approval, or endorsement by NIST or any other agency of the U.S. government of any product manufactured or entered into commerce in the United States based on its recognition by NIST.
- b) constitutes or implies that the accreditor, or an accredited body is recognized by NIST or NVCASE for any activities other than those specifically stated in the NIST recognition documents.

A recognized accreditor must follow NVCASE guidance when advertising its accredited status on letterheads, brochures, reports, or in professional, technical, trade, or other publications.

- a) Certified products must not be stamped with the acronym "NVCASE" signifying that the product is endorsed or approved by NIST.
- b) A NIST-recognized accreditor may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the accreditor except to state that they have been recognized by NIST to offer accreditation for a specific scope of recognition.
- c) An accredited body may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the body except to state that they have been accredited by a NIST-recognized accreditor and that accreditor is specifically named in the statement.

6.3 Keeping NVCASE Informed

6.3.1 Organizational Changes: A recognized accreditor must inform NVCASE within 10 days of any major change in any factors which might affect its ability to operate, such as replacement of personnel (e.g., the Executive, key supervisors, and accreditation decision makers); any major change in procedure, policy making or direction; or change in location, ownership, or business affiliations. Failure to provide timely and accurate information may result in suspension or termination of recognition.

6.3.2 Accredited Body Status: NVCASE will maintain a list of all bodies that have

been accredited by all accreditors recognized by NIST. The list will be made available through various media including the Internet. Alternatively, NVCASE may provide a link to the recognized accreditor's web page that lists accredited bodies.

Each recognized accreditor must keep NVCASE informed of all accreditation actions under the NIST recognition. This information is vital for maintaining up-to-date lists. All applicable new accreditations, renewals, terminations, revocations, suspensions, changes in scope (additions or deletions) must be reported to NVCASE within a reasonable time but not to exceed 90 days, in English, by the recognized accreditor. This information could be provided during periodic on-going surveillance meetings and/or teleconferences.

6.3.3 Recognized Accreditors List: NVCASE will maintain a list of the names and pertinent information for all recognized accreditors. A recognized accreditor must remain in conformance with all NVCASE conditions and requirements to retain its listing. The list will be made available through various media including the Internet.

7.0 ACCREDITOR REQUIREMENTS

Accreditors must comply with the appropriate generic standard (e.g., ISO/IEC 17011 Standard) and specific requirements. The annexes noted below contain the requirements for each specific type of accreditation body. Each annex has specific requirements with additional criteria for the specific sector, MRA or regulatory program.

Annex A - Requirements for accreditors of testing laboratories

Annex B - Requirements for accreditors of certification bodies

Annex C - Requirements for accreditors of management system registrars

ANNEX A - Requirements for accreditors of testing laboratories

1.0 INTRODUCTION

This annex sets out generic organizational, operational and other requirements that must be met in order for an accreditor of testing laboratories to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a testing laboratory desiring accreditation.

2.0 ACCREDITOR REQUIREMENTS

2.1 General

The basic generic criteria that an accreditor must satisfy are contained in ISO/IEC 17011:2004 - *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies (or its replacement)*.

2.2 Specific NIST requirements

- a) **The Senior Executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.
- b) **The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical area(s) that it will perform accreditation under the NIST recognition.
- c) **The Technical Experts/Assessors** of the accreditor must be knowledgeable about the technical requirements specified in paragraph 3.2 of this annex for the specific MRA/Sector/Economy/Program for which a conformity assessment body is being evaluated.

3.0 ACCREDITATION CRITERIA FOR LABORATORIES

3.1 General Requirements

An accreditor shall accredit applicant laboratories against ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories (or its replacement)*.

3.2 Specific Requirements

- a) US-EU MRA: Follow links to specific Sectoral Annex technical requirements for which

NIST is accepting CAB designations at <http://ts.nist.gov/mra>. NIST has implemented following Sectoral Annexes in the Operational Phase of this MRA:

- i) Electromagnetic Compatibility (EMC)
- ii) Telecommunications

b) APEC MRA Phase-I: Follow links to specific economy's technical requirements for which NIST is accepting CAB designations at <http://ts.nist.gov/mra>. NIST has implemented phase-I of this MRA with the following economies:

- i) Australia
- ii) Canada
- iii) Chinese-Taipei
- iv) Hong Kong
- v) Korea
- vi) Singapore
- vii) In future, APEC MRA will be implemented with additional economies. For up-to-date information regarding implementation of this MRA with additional economies, refer to the above web site.

c) CITEL MRA Phase-I: Follow links to specific country's technical requirements for which NIST is accepting CAB designations at <http://ts.nist.gov/mra>. As of December 2004, NIST is in process of implementing this MRA with CITEL countries. For up-to-date information, refer to the above web site.

ANNEX B- Requirements for accreditors of certification bodies

1.0 INTRODUCTION

This annex sets out generic organizational, operational and other requirements that must be met in order for an accreditor of certification bodies to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a certification body desiring accreditation.

2.0 ACCREDITOR OF CERTIFICATION BODIES REQUIREMENTS

2.1 General

The basic general criteria that an accreditor must satisfy are contained in ISO/IEC 17011:2004 - *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies (or its replacement)*.

2.2 Specific NIST requirements

- a) **The Senior Executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.
- b) **The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical areas that it will perform accreditation under the NIST recognition.
- c) **The Technical Experts/Assessors** of the accreditor must be knowledgeable about the technical requirements specified in paragraph 3.2 of this annex for the specific MRA/Sector/Economy/Program for which a conformity assessment body is being evaluated.

3.0 ACCREDITATION CRITERIA FOR CERTIFICATION BODIES

3.1 General Requirements

An accreditor shall accredit applicant certification bodies to ISO/IEC Guide 65 - *General Requirements for Bodies Operating Product Certification Systems (or its replacement)*.

3.2 Specific Requirements

- a) Telecommunications Certification Bodies under the Federal Communication

Commission (FCC): Visit the NIST web site at <http://ts.nist.gov/tcb>.

i) Commission's Report and Order (R&O) in GEN Docket 98-68 (FCC 98-338).

Follow link to

http://www.fcc.gov/Bureaus/Engineering_Technology/Orders/1998/fcc98338.txt

ii) FCC's Public Notice DA 99 1640.

Follow link to

http://www.fcc.gov/Bureaus/Engineering_Technology/Public_Notices/1999/da991640.txt

b) US-EU MRA: Follow links to specific Sectoral Annex's technical requirements for which NIST is accepting CAB designations at <http://ts.nist.gov/mra>. NIST has implemented following Sectoral Annexes in the Operational Phase of this MRA:

i) Electromagnetic Compatibility (EMC)

ii) Telecommunications

c) APEC MRA Phase-II: Follow links to specific economy's technical requirements for which NIST is accepting CAB designations at <http://ts.nist.gov/mra>. NIST has implemented phase-II of this MRA with the following economies:

i) Canada

ii) Hong Kong

iii) Singapore

iv) In the future, APEC MRA for Phase-II will be implemented with additional economies. For up-to-date information regarding implementation of this MRA with additional economies, refer to the above web site.

d) CITELE MRA Phase-II: Follow links to specific country's technical requirements for which NIST is accepting CAB designations at <http://ts.nist.gov/mra>. NIST is in the process of implementing this MRA with CITELE countries. For up-to-date information, refer to the above web site.

e) International Federation of Organic Agriculture Movements (IFOAM) norms: The information about IFOAM requirements can be obtained at www.ifoam.org which contains:

i) IFOAM Basic Standards

ii) IFOAM Accreditation Criteria which is based on ISO/IEC Guide 65 plus some additional requirements

ANNEX C - Requirements for accreditors of management system registrars

1.0 INTRODUCTION

This annex sets out generic organizational, operational and other requirements that must be met in order for an Accreditor of Quality System Registrars to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a quality system registrar desiring accreditation and the requirements for a registrar to register an organization as satisfying specified quality system requirements.

2.0 ACCREDITOR REQUIREMENTS

2.1 General

The basic generic criteria that an accreditor must satisfy are contained in ISO/IEC 17011:2004 - *Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies (or its replacement)*.

2.2 Specific NIST requirements

- a) **The Senior Executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.
- b) **The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical area that it will perform accreditation under the NIST recognition.
- c) **The Technical Experts/Assessors** of the accreditor must be knowledgeable about the technical requirements specified in paragraph 3.2 for the specific MRA/Sector/Economy/Program for which a conformity assessment body is being evaluated.

3.0 ACCREDITATION CRITERIA FOR REGISTRARS

3.1 General Requirements

An accreditor shall accredit applicant registrars against ISO/IEC Guide 62 - *General Requirements for Bodies operating assessment and certification/Registration of Quality Systems (or its replacement)*.

3.2 Specific Requirements

The specific requirements will be posted as NVCASE sub-programs develop under this section.

4.0 REQUIREMENTS FOR REGISTERED ORGANIZATIONS

A registrar shall audit organizations desiring registration against the appropriate quality standard(s) required by the particular MRA partner, regulatory requirement or other document specified in the applicable supplement to this annex.

