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Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation

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Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation

1. PREAMBLE

- 1.1 This document forms part of the conditions of laboratory accreditation under the ISTA Laboratory Accreditation Standard.
- 1.2 Laboratory accreditation can either be voluntarily terminated or suspended by the laboratory or suspended or withdrawn by ISTA for specified reasons. Withdrawal normally follows a suspension.
- 1.3 Termination, suspension or withdrawal of accreditation may be applied to all or only one or more specific test methods or species included in the laboratory's scope of accreditation. Due to the requirements of the ISTA Rules, termination, suspension or withdrawal of accreditation for a test will automatically include a termination, suspension or withdrawal of accreditation for all test methods which require the use of that test. In such cases the Secretariat will notify the laboratory as to which other tests are involved.
- 1.4 Any recommendation for suspension of, withdrawal from or reinstatement of accreditation must be formally agreed upon by the ISTA Executive Committee.

2. RELATED DOCUMENTS

- 2.1 ISTA Laboratory Accreditation Standard
- 2.2 PT-G-01-The ISTA Proficiency Test Programme
- 2.3 Acc-D-03-Appeals and Complaints Procedure
- 2.4 Acc-D-02-Use of ISTA Logo Policy

3. TERMINATION

3.1 *Definition*

Termination of accreditation means that a laboratory is no longer accredited after voluntary termination or because the accreditation period has ended without an application for re-accreditation.

3.2 *Voluntary termination*

An accredited laboratory may voluntarily terminate its accreditation for all or for parts of its scope of accreditation, at any time within the period of validity of the Certificate of Accreditation, by giving written notice to the ISTA Accreditation Department. A voluntary termination will invalidate the Certificate of Accreditation. A partial termination will lead to the issuance of a new Certificate of Accreditation for that part of the scope of accreditation which was not terminated, with an unchanged period of validity.

Voluntary termination will be referred to in the list of accredited laboratories by the words "voluntary termination".

4. SUSPENSION

4.1 *Definition*

Suspension of accreditation means a temporary ban for a defined period of time preventing the laboratory from making use of the entire or parts of the ISTA Accreditation. This means that the laboratory loses the privileges of the entire or parts of the ISTA Accreditation.

A laboratory may lose the privileges of parts of the ISTA Accreditation if the suspension was due to proficiency test performances below the minimum standard (BMP) but not for all of the accredited tests of the laboratory (see 4.4). In this case the laboratory must not issue ISTA Certificates for the corresponding test; this also includes associated tests. Suspension of this part will

- result in a change of the Scope of Accreditation, removing the tests for which the laboratory did not show its competency. Tests associated with the deleted ones will also be deleted.

A laboratory may lose the privileges of the entire ISTA Accreditation. In this case it may not identify itself as an ISTA accredited laboratory in letters and reports and the laboratory cannot issue ISTA International Seed Analysis Certificates. Suspension of accreditation will

- not relieve the accredited laboratory of its obligations towards ISTA incurred during the accreditation period (e.g. paying fees, informing about changes in the laboratory that affect accreditation).
- be referred to in the list of accredited laboratories by the words "temporarily suspended".
- not affect the period of validity of the Certificate of Accreditation.

The aim of the suspension is to allow the laboratory to act in order to avoid the withdrawal of accreditation.

4.2 *Voluntary suspension*

The laboratory may request suspension as a voluntary step when exceptional circumstances temporarily prevent the laboratory from complying with the accreditation criteria, but where a future return to normal circumstances can be expected. The period of suspension must be defined by the laboratory when the request is made. As a rule, the maximum period of suspension in such a case should not exceed 6 months. It is up to the laboratory whether or not it takes part in the proficiency test programme during the voluntary suspension.

4.3 *Suspension due to unpaid fees*

If the annual membership fee has not been paid by the end of the calendar year, the laboratory's accreditation will be suspended for 3 months at maximum.

If the annual accreditation fee has not been paid by the end of the calendar year, the same procedure will be followed as in the case of the unpaid membership fee, but only the accreditation will be suspended and not the membership.

In the event of delayed payment for the audit visit, ongoing accreditation procedures will be halted. At the end of the deadline of the second reminder, which shall not exceed the period of three months after an on-site assessment took place, accreditation will be suspended.

4.4 *Suspension due to proficiency test performance below minimum standard*

The laboratory's accreditation will be suspended for either of the following:

- The cumulative proficiency test performance is below the minimum performance standard as defined in 'The Proficiency Test Programme';
- It is obvious that the cumulative proficiency test performance will result in an overall below minimum performance standard and the laboratory has not provided evidence of appropriate corrective actions taken;
- The laboratory fails to participate in two of the last six mandatory test rounds of the Proficiency Test Programme (late return of results is considered as a failure to participate).

4.5 *Suspension due to non-conformity with the ISTA Laboratory Accreditation Standard*

If during a re-accreditation a laboratory does not comply with the terms of accreditation, the laboratory will be so notified in writing. If immediate suspension of the laboratory is warranted as a result of observations during a re-accreditation audit, the laboratory will be advised during the exit briefing that the audit team will recommend immediate suspension of the laboratory.

Appropriate corrective actions are required to be completed by a deadline agreed upon with the auditors. If an accredited laboratory has not completed and reported the required corrective actions by that deadline, the audit team will recommend suspension of the laboratory's accreditation. The Executive Committee will consider the recommendation and decide whether to support or not support the recommendation for suspension. In justifiable cases, and after consultation with the lead auditor, a second deadline may be granted upon request, which may not exceed a period of 3 months after the first deadline.

If, after a second deadline, non-conformities are not considered to have been appropriately addressed, the audit team will recommend suspension of the laboratory's accreditation. The Executive Committee will consider the recommendation and decide whether to support the recommendation for suspension or not.

If the laboratory does not comply with the accreditation requirements within the suspension period, the audit team will issue a recommendation not to grant (re-) accreditation. The Executive Committee will then decide as to whether to support or not support this audit team recommendation.

4.6 *Suspension due to changes in the laboratory*

If within 90 days of any significant changes in the laboratory's ownership, management, equipment, key personnel or physical location, the laboratory cannot demonstrate that the changes have had no influence on the technical competence or that the changes have been considered adequately in the laboratory's quality manual and daily work, the accreditation of the laboratory will be suspended.

4.7 *Suspension due to misuse of the ISTA logo*

The accreditation will be suspended immediately, if there is evidence that the laboratory has misused the ISTA logo. Depending upon the severity of the misuse, the laboratory might have its accreditation withdrawn immediately (see 5.4).

4.8 *Notification about suspension*

As soon as the Executive Committee has suspended accreditation for one of the reasons listed under 4.3 to 4.7, the laboratory will be notified. This notification will include the scope of suspension, the date of the beginning and end of the suspension period, the measures to be taken for re-instating of the accreditation, as well as the conditions under which the suspension will lead to a withdrawal of accreditation.

4.9 *Period of suspension*

The period of suspension is dependent upon the reasons for suspension and the time required for taking the measures necessary for re-instating accreditation. The usual period of suspension is 3 months, but in special cases (as e.g. in case of unsatisfactory proficiency test performance) the period may be longer. The Executive Committee shall decide on any extension of the period of suspension.

4.10 *Appeal against the suspension*

The laboratory has the right to appeal against the suspension within a 30 day period after notification. The 'Appeals and Complaint Procedure' applies accordingly.

4.11 *Re-instating of accreditation*

Voluntary suspension of accreditation according to 4.2 will be cancelled by re-instating accreditation upon the decision of the Executive Committee within the period as defined by the laboratory under the condition that the laboratory states the reasons why accreditation can be re-instated. No audit or other check is required for re-instating accreditation after a voluntary suspension.

A suspension of accreditation and membership due to unpaid fees according to 4.3 can be cancelled by paying the fees owed within the suspension period. No audit or other check is required for re-instating accreditation after suspension due to unpaid fees.

A suspension of accreditation due to a cumulative below minimum performance in the proficiency test programme according to 4.4 can be cancelled by the completion of as many test rounds as required to obtain again an overall rating that is at least a "C". The period of suspension may be reduced if corrective actions that ensure prevention of recurrence are taken and evidence thereof is presented. Effectiveness of measures taken may be evaluated on the basis of the following:

- Desktop review of corrective action and associated documents
- Organisation of a mini-PT round
- Additional on-site audit

Any of these measures or a combination thereof may be applied, depending on the individual situation.

Accreditation of a laboratory that has provided sufficient evidence of corrective action may be reinstated under the following conditions:

- The rating for rounds following the reinstatement must be a "C" or better.
- Effectiveness of corrective action must be corroborated by subsequent test rounds. Until a new overall rating based on six test rounds is available, the average performance since reinstatement of accreditation must be equivalent to a "C" rating or better.

A suspension due to failure to participate in two of the past six test rounds can be cancelled by the completion of a minimum of two test rounds with an A, B, or C rating and by the provision of records of corrective action which provides confidence that such an incident will not reoccur.

Suspension due to persistent non-conformities according to 4.5 can be terminated after rectifying the non-conformities within the suspension period and by satisfying the auditors that the corrective actions made are appropriate. If necessary, the audit team might conclude that an on-site assessment is necessary to verify if the laboratory has addressed the non-conformities appropriately and complies with the accreditation requirements.

Suspension due to significant changes in the laboratory's ownership, management, equipment or key personnel according to 4.6 can be terminated by satisfying the auditors that the changes have had no adverse effect on the technical competence and are adequately considered in the laboratory's quality manual and daily work. An on-site audit by an audit team of two auditors or a technical auditor may be necessary based on the outcome of the evaluation of submitted documents.

The laboratory must bear the costs of an additional on-site assessment. Fees are to be determined in advance.

5. WITHDRAWAL

5.1 Definition

Withdrawal of accreditation means that the entire or parts of the accreditation of the laboratory ends before the end of the accreditation period as stated in the Certificate of Accreditation or following a re-accreditation assessment that does not result in continued accreditation.

Withdrawal of the entire accreditation implies:

- the return of the Certificate of Accreditation,
- the return of any unused ISTA International Seed Analysis Certificates,
- the removal from the list of accredited laboratories.

The laboratory will be notified about the withdrawal of the accreditation in writing.

Withdrawal of parts of the accreditation implies:

- the Scope of Accreditation remains changed as it will exclude the tests for which the laboratory was not able to demonstrate competency as well as any associated tests

5.2 Withdrawal due to unprofessional practice

The accreditation will be withdrawn immediately, if there is evidence that the laboratory has wilfully taken actions which question the credibility of the results produced by the laboratory. Examples of such unprofessional practice are the falsification of results or data or the wilful destruction of evidence, samples or records that would demonstrate incompetence in the testing of a particular sample or group of samples.

5.3 Withdrawal due to expiration of the suspension period

For laboratories that lost the privileges of the entire ISTA Accreditation: If the laboratory did not take appropriate measures to re-instate the accreditation during the suspension period, the accreditation will be withdrawn at the end of the suspension period.

For laboratories that lost the privileges of parts of the ISTA Accreditation: If the laboratory did not take appropriate measures to re-instate the accreditation during the suspension period, the Scope of accreditation will remain with deletion of the tests for which the laboratory performed below minimum standard. Tests associated with those that have been deleted may also not be performed if they rely on results from deleted tests.

5.4 Withdrawal due to misuse of the ISTA logo

The accreditation will be withdrawn immediately, if there is evidence that the laboratory has misused the ISTA logo in any way

5.5 Appeal against the withdrawal of accreditation

The laboratory has the right to appeal against withdrawal of accreditation within a 30 days period after notification. The 'Appeals and Complaint Procedure' applies accordingly.

5.6 Publication of withdrawal of accreditation

All instances of withdrawal of accreditation will be publicised by ISTA. Notices will be placed in Seed Testing International and ISTA online.

6. RE-APPLICATION

6.1 The withdrawal of accreditation will not preclude a laboratory from re-applying for accreditation at a future date. Such application will be evaluated under the same requirements and procedures applicable to every other applicant laboratory. The laboratory will have no privileges from the withdrawn accreditation when applying for a new accreditation.

ANNEXE TO PROCEDURES FOR TERMINATION, SUSPENSION AND WITHDRAWAL OF ISTA ACCREDITATION

