



Standard Operation Procedure

Method validation

-process administration-

Note: Any electronic or hard copies of this document are not subject to change service

Created: 14.02.2008	Checked: 20.08.2008	Approved: 20.08.2008	Version 1.0
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Scope

Process description and activities within the ISTA Secretariat related to Method Validation from submission of the draft study report until filing of the final Validation Report

ABBREVIATIONS

TCOM – Technical Committee

TCord - TCOM Coordinator

RELATED DOCUMENTS

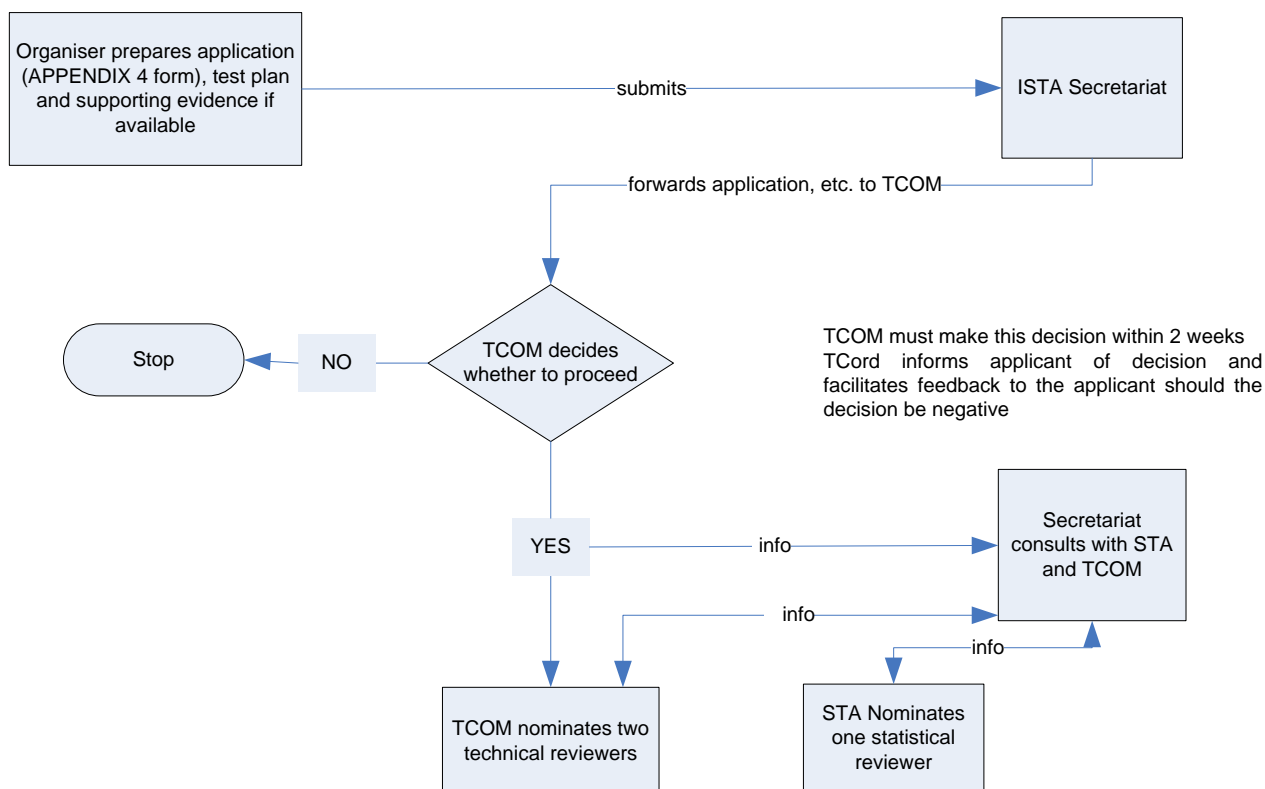
ISTA Method Validation for Seed Testing

TCM-F-2-ISTA Validation -review process checklist

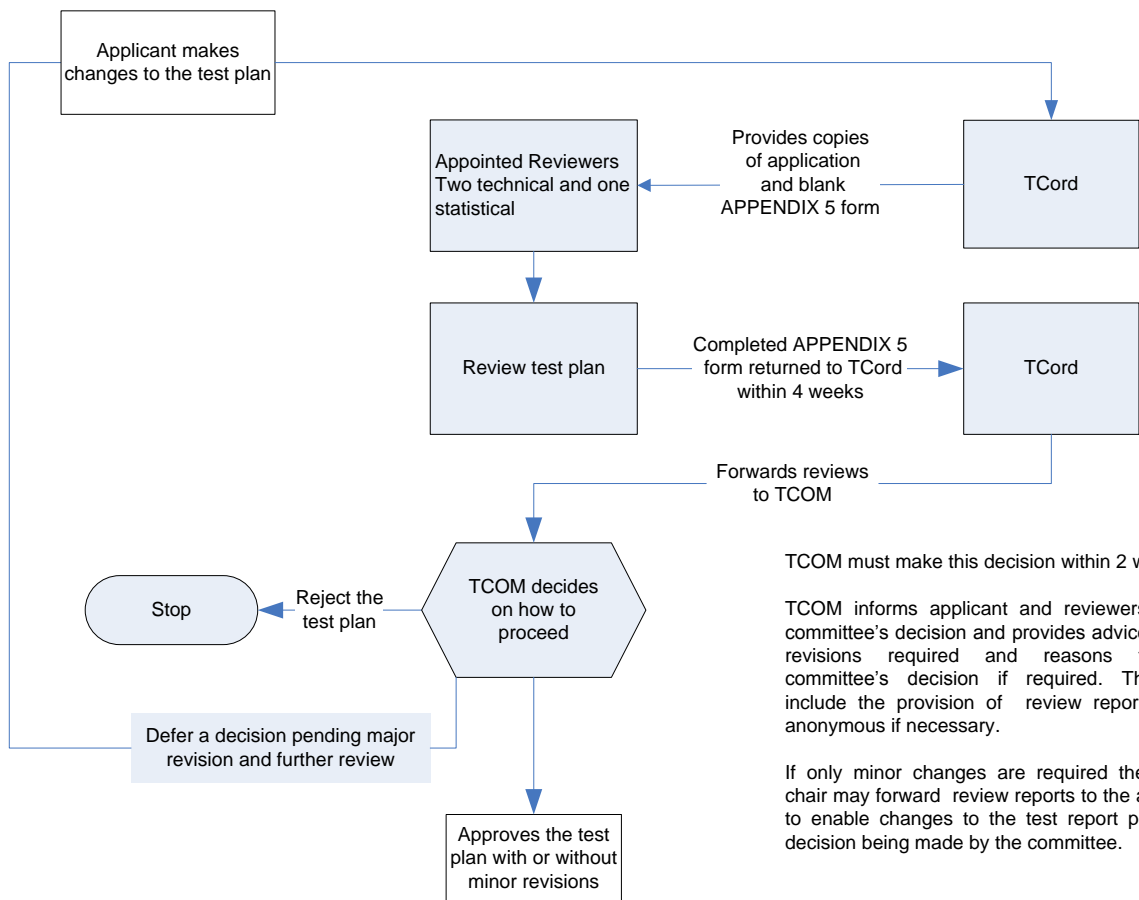
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I Process initiation and decision on whether to proceed with the validation study



II Review of Test Plan

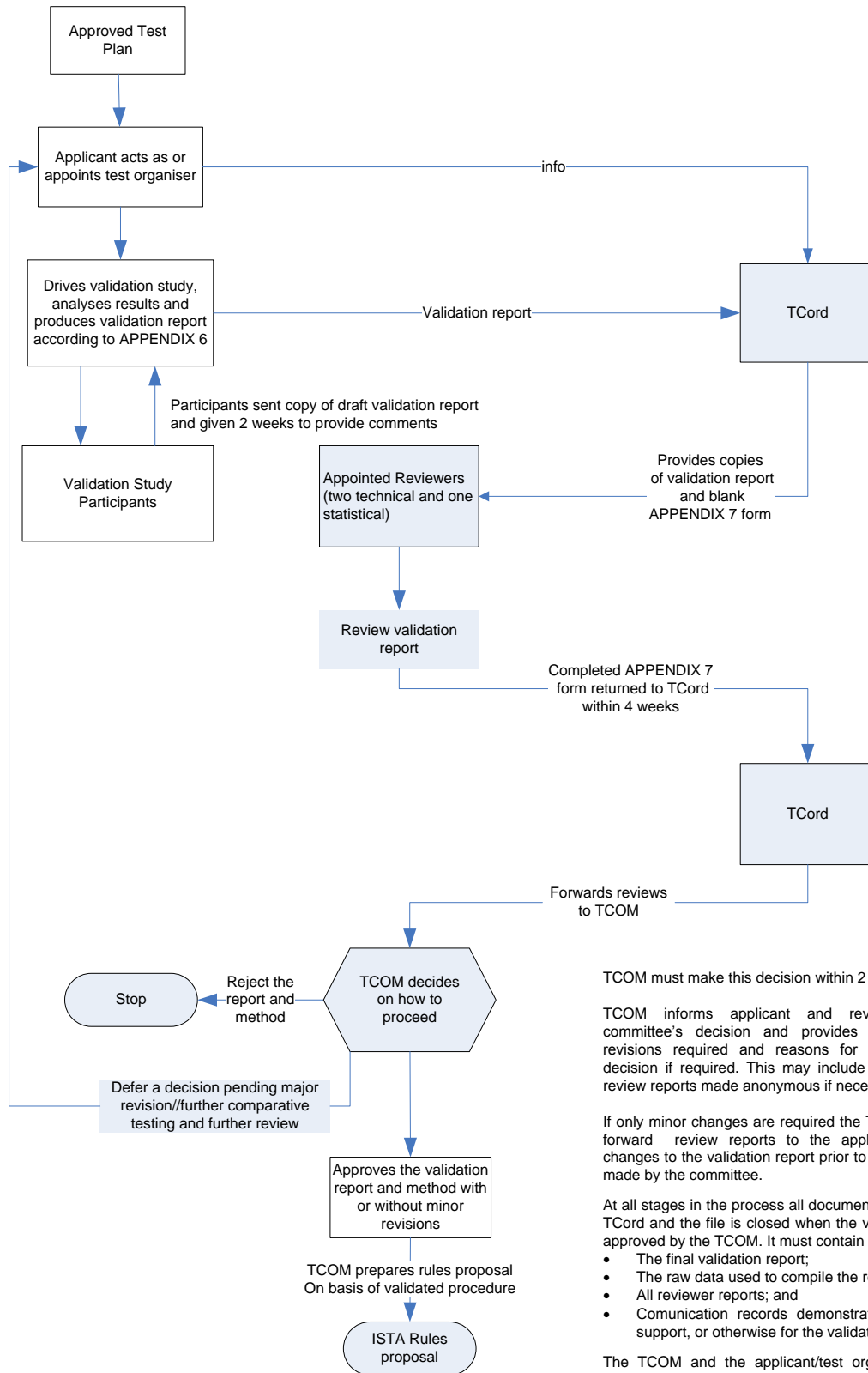


TCOM must make this decision within 2 weeks

TCOM informs applicant and reviewers of the committee's decision and provides advice on any revisions required and reasons for the committee's decision if required. This may include the provision of review reports made anonymous if necessary.

If only minor changes are required the TCOM chair may forward review reports to the applicant to enable changes to the test report prior to a decision being made by the committee.

III The Validation Study, Review of Validation Report and Preparation of Rules Proposal



TCOM must make this decision within 2 weeks

TCOM informs applicant and reviewers of the committee's decision and provides advice on any revisions required and reasons for the committee's decision if required. This may include the provision of review reports made anonymous if necessary.

If only minor changes are required the TCOM chair may forward review reports to the applicant to enable changes to the validation report prior to a decision being made by the committee.

At all stages in the process all documents are filed by the TCord and the file is closed when the validation report is approved by the TCOM. It must contain at a minimum:

- The final validation report;
- The raw data used to compile the report;
- All reviewer reports; and
- Communication records demonstrating the TCOM's support, or otherwise for the validated method

The TCOM and the applicant/test organiser have the onus for driving the validation procedure which is facilitated by the TCord.

PROCESS DESCRIPTION

Stakeholder (TCOM, third party, individual) submits method validation application to Secretariat. This application is often made after consultation with the TCOM concerned who may provide the stakeholder with assistance in the completion of the necessary forms. The application will consist of a test plan and a completed APPENDIX 4: Test Method Validation Application Form. The "ISTA Method Validation for Seed Testing" document, which can be downloaded from the ISTA website (<http://www.seedtest.org/upload/cms/user/ISTAMethodValidationforSeedTesting-V1.01.pdf>) contains guidance on the drafting of test plans and APPENDIX 4 forms can be downloaded from the website (http://www.seedtest.org/en/method_validation_programme_content---1--1254.html).

The application may also contain supporting evidence such as results of preliminary studies or published papers.

Application and related documents are forwarded to TCOM chair concerned. TCOM members are provided with copies of the application by the chair and decide whether to support the validation study. TCOM members are given 2 weeks to make this decision.

The TCOM chair informs the TCord of the committee's decision.

The TCord will inform the applicant of the committee's decision and facilitate feedback from the TCOM to the applicant should the decision be negative. If the majority of TCOM members support the study the TCOM chair will nominate 2 technical reviewers and the TCord will contact the STA with a request to appoint a statistical reviewer. (Note: The TCOM chair may suggest the name of a proposed statistical reviewer and, through the TCord, forward this name to the STA for approval).

Once the reviewers have been confirmed TCord makes sure all reviewers are aware of formal requirements and distributes the application and the APPENDIX 5 form: "Instructions for Reviewers: Draft Test Plan" to them. TCord records dates and individuals involved on the "TCM-F-2-ISTA Validation -review process checklist" and the validation database. Reviewers are expected to complete their deliberations and return the completed APPENDIX 5 form to the TCord within 4 weeks.

The TCord distributes the completed APPENDIX 5 forms to the TCOM chair who copies them to TCOM members. The TCOM members decide within 2 weeks of receiving it whether to:

- a) Approve the Test Plan without revision;
- b) Approve the Test Plan following minor revisions;
- c) Defer a decision pending major revisions and further review; or
- d) Reject the Draft Test Plan.

In cases where reviewers are willing to be identified to the applicant and only minor revisions are suggested the TCOM chair may copy the completed APPENDIX 5 forms to the applicant to enable amendments to be made before the committee makes its decision.

The TCOM chair informs the applicant of the committee's decision and provides advice on any revisions required and reasons for the committee's decision, if required.

Should the committee require any revision to the test plan the applicant must resubmit the amended plan to the TCord and the TCOM chair. The TCOM chair will copy the revised test plan to the committee who must decide within 2 weeks whether to approve the amended test plan or whether to return it to the applicant for further revision. This process is repeated until the test plan is approved or the applicant withdraws the application.

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It is the responsibility of the applicant to manage the validation study once the test plan has been approved. This can be accomplished through the services of the test organiser or the applicant could act as the test organiser. The test organiser's responsibilities are detailed in the "ISTA Method Validation for Seed Testing" document as are those of participants of the validation study.

Once the experimental work is completed, and the data checked and analysed, the test organiser will produce a draft validation report, according to the guidelines in the "ISTA Method Validation for Seed Testing" document (APPENDIX 6), which is sent to the participating laboratories for comments. Participants must send any comments back to the test organiser within one month. In light of comments received the test organiser will finalise the report and submit it to the TCord within two months of the distribution of the draft report.

The TCord copies the report to the TCOM chair and sends it to the technical and statistical reviewers, as per test plan together with a blank APPENDIX 7 form: "Instructions For Reviewers: The Validation Report" Reviewers must return their completed reports (APPENDIX 7) to the TCord within 4 weeks. The TCord monitors the review process and reminds reviewers if the reporting period is exceeded.

The TCord distributes the completed APPENDIX 7 form to the TCOM chair who copies it to TCOM members with the Validation Report. The TCOM members decide within 2 weeks of receiving it whether to:

- a) Approve the report and the method without revision;
- b) Approve the report following minor revisions;
- c) Defer a decision pending major revisions; or
- d) Reject the method.

Where technical and or statistical reviews are considered inadequate or reviewers do not agree, the Technical Committee will, at its discretion, make a final decision or seek the advice of additional reviewers. The TCOM chair informs the test organiser and reviewers of the committee's decision and provides advice on any revisions required and reasons for the committee's decision, if required. In cases where reviewers are willing to be identified to the applicant and only minor revisions are suggested the TCOM chair may copy the completed APPENDIX 7 forms to the applicant to enable amendments to be made before the committee makes its decision.

Should the committee require any revision to the validation report the applicant must resubmit the amended report to the TCord and the TCOM chair. The TCOM chair will copy the revised report to the committee who must decide within 2 weeks whether to approve the amended report and method. Should significant revisions be required the TCOM may require the report to undergo a further independent review. Completion of revisions will not guarantee approval, and a further validation round may be requested by the TCOM.

Following approval of the method by the TCOM, the method receives Validated status. The TCOM will then prepare a proposal for the ISTA Rules and submit it to the ISTA Rules Committee. The Method Validation Report and the Rules proposal will be listed on the ISTA website prior to a vote by the membership. Copies of both will be available from the ISTA Secretariat. Any interested party may submit comments and data in writing to ISTA for or against the adoption of the proposal. The TCord will forward copies of all comments to the TCOM for resolution. Methods accepted by a majority vote at the ISTA annual meeting will be published in the International Rules for Seed Testing.

At all stages in the process all documents and correspondence are filed by the TCord in the relevant folders, i.e. either of:

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test plan- in progress

test plan completed

validation study – in progress

validation study completed

In addition the data are recorded in the Access data base (TCOM WP and Membership)

Once the validation study is completed and a validation report is approved by the TCOM, the file is closed and has to contain at minimum:

- final Validation report
- the raw data used to compile the report should this not be contained within the report.
- review reports from all reviewers involved
- communication records demonstrating the committee's support (or the lack of it) for the validated method.

The onus for driving the validation process is on the TCOM involved and the applicant/test organiser. The TCord and the Secretariat support the TCOMs by keeping records of the process and providing TCOM chairs with information they require (e.g. database queries) to monitor the process.

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