



ISTA
Seed Quality Assurance

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Introducing New Technologies Equivalent to the Human Analyst for Seed Analysis

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INTRODUCTION

The Introduction to the ISTA Rules under I-1 General Information states that “Rules proposals can include the use of technologies new to the Rules, whether these are the basis of new methods or new tools within existing methods, provided they meet these requirements”. These requirements include that the methods used must be appropriate for purpose i.e., validated, for which ISTA has a Method Validation Programme [[Method Validation Programme - International Seed Testing Association](#)] and the equipment used in testing must be fit for purpose and not influence the accuracy or reproducibility of the results.

The ISTA Accreditation Standard (3.18) requires confirmation that staff (analysts) undertaking testing are competent to undertake the test being performed. This competence must be documented.

There are technologies that are equivalent to the human analyst as a different or additional pair of eyes. For methods in the ISTA Rules where technologies can be used that are equivalent to the human seed analysts the technology does not need to be re-validated, but it must be verified for the seed analyst that the technology (equipment) is competent to undertake the analysis. Technology includes any piece of equipment that enables the analysis to be achieved and any operating systems (algorithms, software etc.) that enable the technology to perform its function and, in some cases, may provide the final result. Interpretation of the data is still performed by a human analyst.

SCOPE

This document provides a policy framework to enable the introduction of technologies that are equivalent to the human analyst. Where the technology is not considered equivalent to the human analyst Method Validation will be required before the method can be proposed for inclusion in the ISTA Rules.

Proposers of any new technology for the ISTA Rules should discuss the proposal with the Technical Committee or Committees responsible for the test or tests to which the technology will be applied to determine if the new technology can be considered equivalent to the human analyst.

In the remainder of this document, the term “new technology” means a technology that is not currently in the ISTA Rules or that is not currently being used for the test it is proposed for.

RELATED DOCUMENTS

ISTA Rules

TCOM-P-01- ISTA Method Validation for Seed Testing

TCOM-SOP-05- ISTA Method Validation Process Administration

ISTA Accreditation Standard

REQUIREMENTS TO BE MET FOR A NEW TECHNOLOGY TO BE USED FOR THE ISSUANCE OF ISTA SEED ANALYSIS CERTIFICATES

In general, any stand-alone equipment designed for replacing the human vision/eye during analyses of seed lot and samples may be used in an ISTA accredited laboratory. The broad principles for use of new technologies in the ISTA Rules are the same as those for that analyst and / or equipment:

1. The technology must be fit for its purpose.
2. The technology must be verified as fit for purpose before it is used for seed analysis. A programme that includes checking and monitoring the performance of the technology, must be implemented to verify that the technology remains fit for its purpose.

This programme must be documented (described) within the laboratory's quality management system (QMS) through an SOP or working instruction. The documentation must include the frequency of monitoring and the extent of the competence of the technology including, for example, what species the technology is competent for and if appropriate which tests.

3. Where the technology needs to be "trained" to undertake the test, similar to a seed analyst, the training programme must be documented, to include verification that the technology is fit for purpose at the end of the training, and a documented monitoring programme implemented. Verification must be by participation in internal and external proficiency tests, including ISTA proficiency tests.
4. If the technology is used to perform a test independently, i.e., a complete automated system, the equipment must be supervised and comply with the same requirements as a "human analyst" as defined in the current version of the Accreditation Standard. This must be documented in the quality management system along with the requirements in point 2.
5. Each piece of equipment must be uniquely identifiable. All results generated by the technology, including for verification that the technology is fit for purpose or monitoring, must be traceable to the technology used, for example, the equipment undertaking the image analysis.
6. As for a seed analyst or piece of equipment, all data generated by the technology must be available for evaluation during ISTA audits.
7. If the machinery is used as a visual aid to a human analyst a separate verification of the machine may not be required unless it is making the testing result decision for the human analyst.

ALIGNMENT TO THE ISTA ACCREDITATION STANDARD

The use of new technologies and auditing of these technologies is aligned to the following sections of ISTA accreditation standard (Version 7.0):

Section 4. Staff: 4.5 and 4.6

Section 9. Documents and records: 9.2

Section 10.3. Quality control procedures: 10.3.1

Section 10.5. Proficiency testing: 10.5.2

ANNEX

none

DISTRIBUTION LIST

Website

REVISION HISTORY

Version #	Changes